

Treating the Family and Not the Individual: How Can We Capture Burden and Quality of Life for Familial Carers of Those with Life-Limiting Illness?

ISPOR Vienna Issues Panel: Tuesday 8 November 2022, 16.30–17.30

Moderated by:

[Ron Akehurst](#) Lumanity



Speakers

- Ron Akehurst – Chair of Lumanity HEOR and Prof Emeritus, University of Sheffield; member of NICE, England, Highly Specialised Technologies Committee
 - Will introduce the topic
- Fleur Chandler – Health Economist, Head of Market Access UK and Ireland at Sanofi; Chair of Project Hercules at Duchenne UK; Mother and Carer of a Son with DMD
 - Will discuss how, when it is incorporated at all, HTA incorporates carer burden in appraisals and the degree of meaningful reflection of the experience of being a carer
- Jill Carlton – Research Fellow at University of Sheffield working in Outcome Measurement; has been part of team working on a general instrument that includes elements that capture carer burden, and has been reviewing the instruments that have been used to capture carer QoL specifically in DMD
 - Will discuss the practical challenges of developing carer burden instruments to use in HTA
- Peter Neumann – Health Economist, Prof and Director at Tufts Medical Center, Boston MA; extensive research on concepts of value and part of the ISPOR Working Group responsible for the ‘Value Flower’
 - Will discuss if and how carer burden is reflected in funding decisions in a non-centralized system such as in the US and how the ISPOR working group considered this topic

Key: DMD, Duchenne muscular dystrophy; HTA, health technology assessment; NICE, National Institute for Health and Care Excellence; QoL, quality of life.

Introduction – summary

In this issues panel we shall consider, *inter alia*:

- Should carer burden matter in HTA?
- Is HRQoL or general QoL the relevant concept?
- How should we capture and measure relevant dimensions of HRQoL or QoL?
- How different should approaches be depending on the health system in which they are applied?

Key: HTA, health technology assessment; HRQoL, health-related quality of life; QoL, quality of life.

Introduction 1 – why and how?

Ron Akehurst

- Much care to the chronically ill is provided by family and not covered by state or private insurance
- When we treat someone effectively for a chronic condition, we not only improve things for them but, self evidently, may also improve things for their carer(s); in principle it would be perverse not to consider this
- Important questions are whether and how we should reflect reduction in carer burden in HTA and reimbursement decisions, particularly, should we look at HRQoL only or at a broader concept of QoL; how should we include cost changes?
- Very few HTA agencies formally incorporate carer burden in their assessments (although whether it figures widely informally is unknown). NICE, in England, is an exception. (On HST, on which I sit, virtually every appraisal includes estimates of reduction in carer burden from treatment)

Key: HTA, health technology assessment; HRQoL, health-related quality of life; HST, Highly Specialised Technologies; NICE, National Institute for Health and Care Excellence; QoL, quality of life.

Introduction 2 – NICE’s approach

- The focus of NICE is firmly on HRQoL and costs of caring that fall on the health service because Parliament votes money to the Department of Health for health care and not for general promotion of QoL
- In Committee we see many approaches taken by companies (using vignettes with population gathered preference weights, for example) but NICE usually defaults to EQ5D if it can, and usually the utility gains that are attributed to carers are much more modest than companies claim
- Interestingly, I have seen divergencies between company claims and those of patient groups and some of the best presentations I have seen at NICE have come from the latter

Key: HRQoL, health-related quality of life; NICE, National Institute for Health and Care Excellence; QoL, quality of life.

Introduction 3 – criticisms of NICE’s approach

The NICE approach has a logic to it, but it has not been without its critics.

Example One:

- In the UK, if the state pays for care and a treatment saves on that care, there would be a cost offset to the treatment included in a NICE assessment
- If the patient’s family paid for the care, either by buying in services or by a family member giving up work, that private cost saving would not be included in any cost-effectiveness calculation
- In the latter case, what could be included would be the impact of the financial strain on the health of the carer. Allowing both cost offsets and impact on HRQoL has been resisted as double counting benefits
- Whether the two approaches are comparable and if there is fairness or arbitrariness in the way different groups are treated is unknown

Example Two:

- Carers may face a heavy burden when they have a very dependent relative and the requirement to be constantly on duty, toileting, changing bedclothes, etc. can disappear overnight if the patient dies
- Thus, in a cost-effectiveness calculation there is a benefit from the death
- Some critics have argued that the QoL loss from bereavement never ends and should be included until the carer dies, offsetting the other aspects of carer burden reduction
- NICE might argue that the loss from the death is reflected in the loss of weighted life years and that to include bereavement would partially stray into general rather than HRQoL issues
- To the extent that the effects were on HRQoL, there would be a risk of double counting

Key: HRQoL, health-related quality of life; NICE, National Institute for Health and Care Excellence; QoL, quality of life.

Introduction 4 – jurisdiction variation

- It is likely that the approach we want to take in a particular jurisdiction will vary depending on the underlying philosophies of the country in question and the need for consistency in the valuation approach taken
- There is also a need for more careful thought on how we should measure the changes in burden consequent on treatment, whatever the philosophical position we start from
- Today's panel will provide some thoughts on the issues raised

Treating the family and not the individual - How can we capture burden and quality of life for familial carers of those living with life limiting illness?

Fleur Chandler

Head of Market Access Sanofi

Parent Advisory Board Duchenne UK

Chair Project HERCULES

Rare disease parent carer

Paediatric clinical trial parent

sanofi

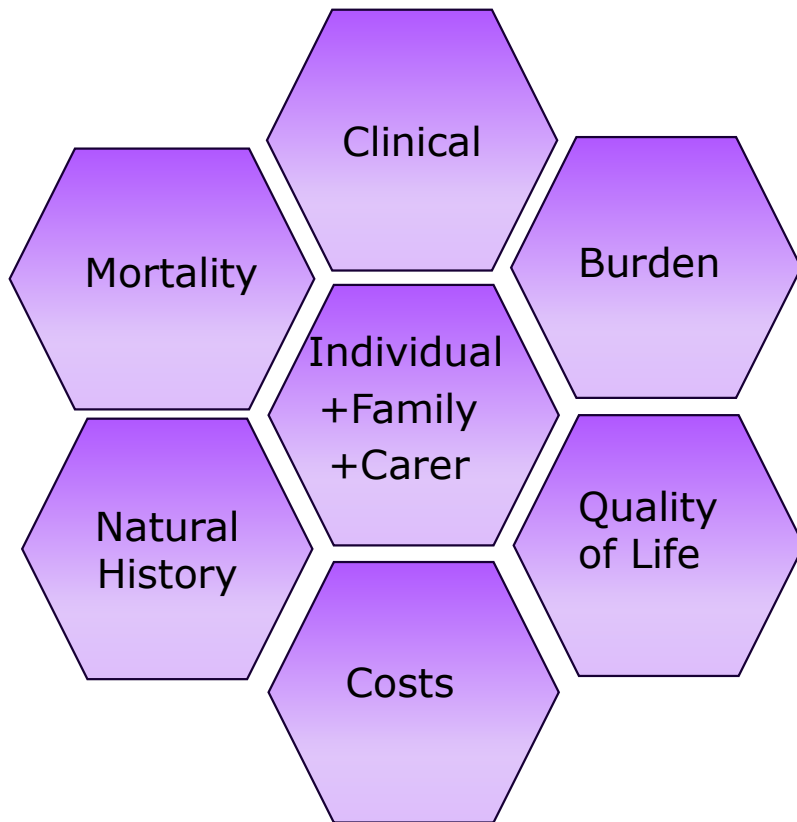


Disclosures

- Head of Market Access Sanofi UK & Ireland
- Parent Advisory Board Duchenne UK
- Chair Project HERCULES
- Rare disease parent carer
- Paediatric clinical trial parent
- Employee and Stock Holder of Sanofi
- Stock holder GlaxoSmithKline

Industry perspective

HTA describes the impact of the treatment on health

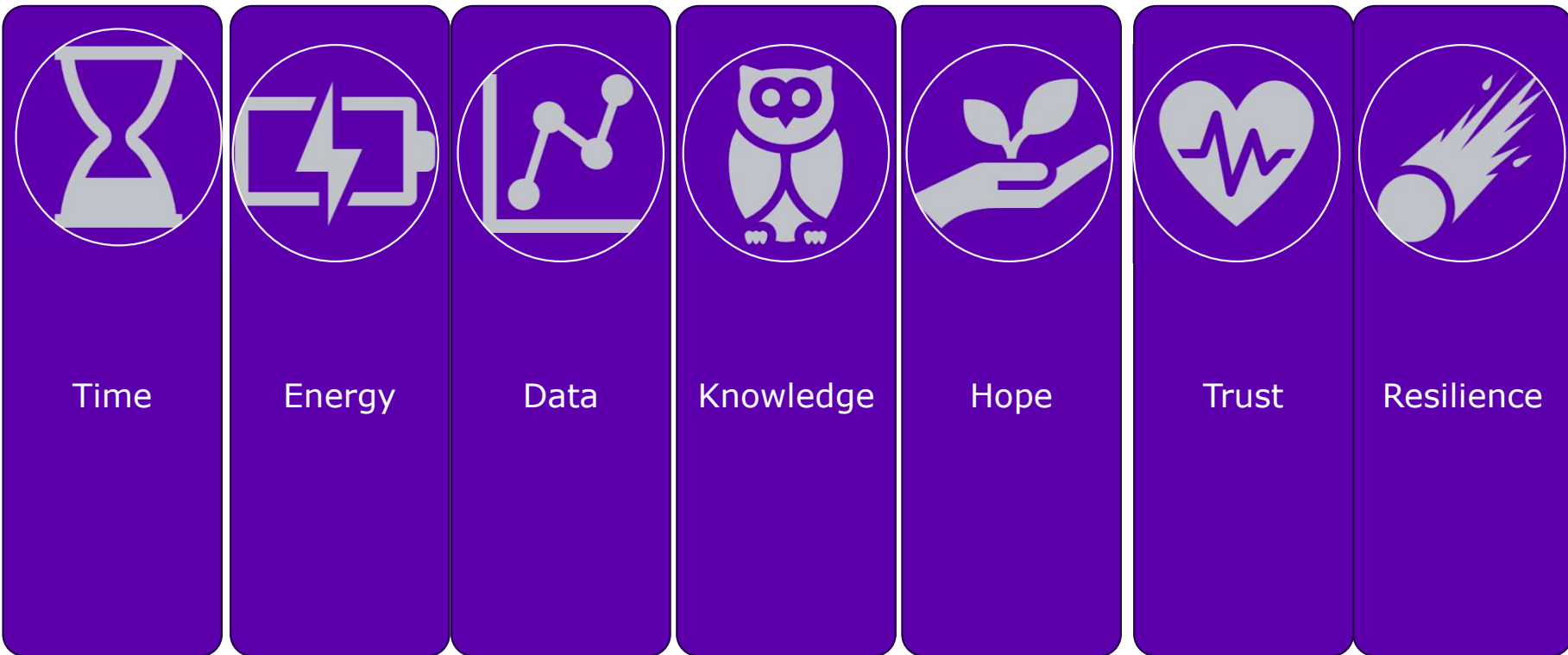


Aspects of living with life limiting conditions impact beyond the individual – this needs to be represented

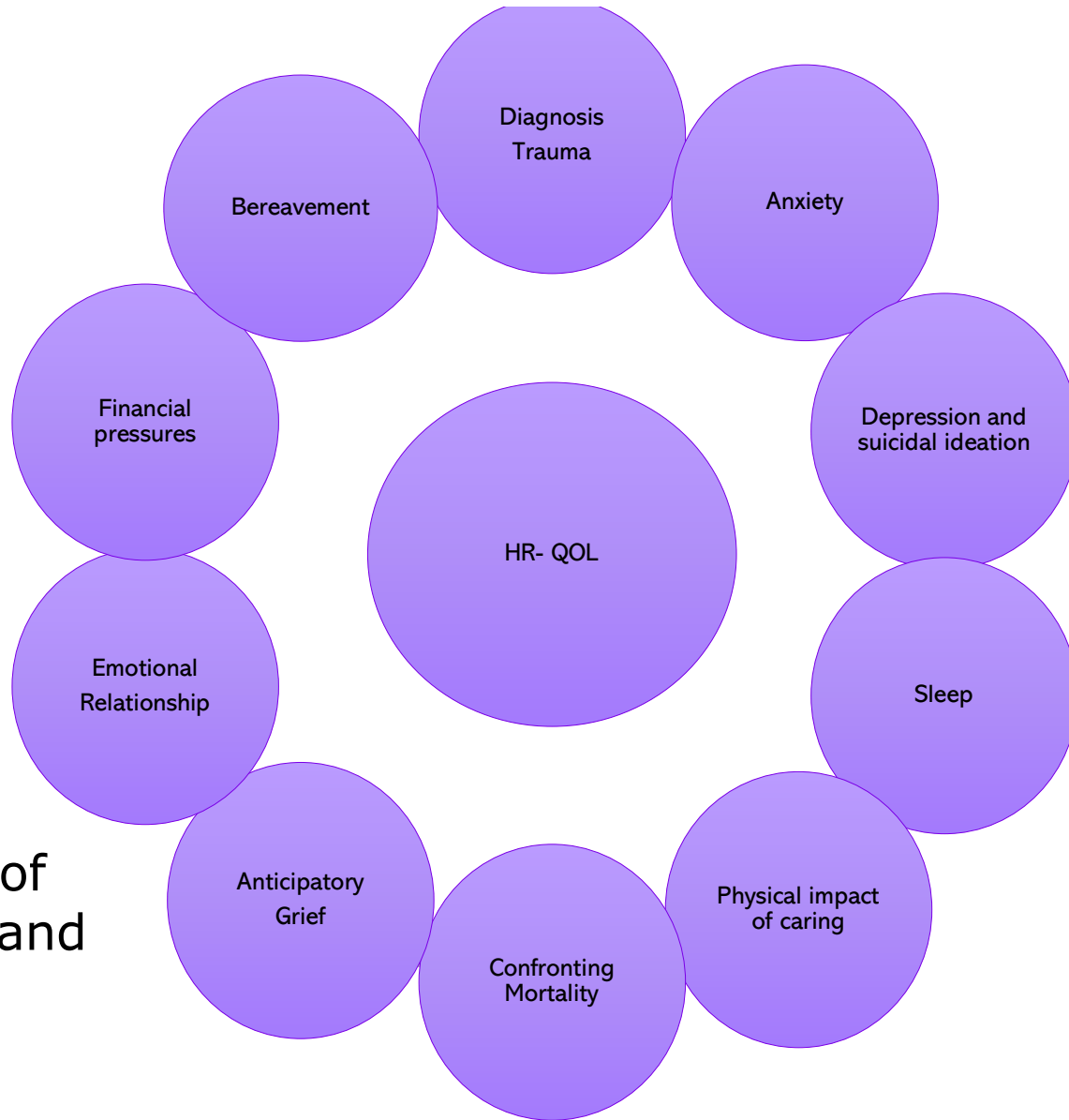
- Is it measured?
- Can it be measured?
- How should it be measured?
- When should it be measured?
- Who should we measure it in?
- How can we do this - being mindful and respectful?

Familial Carer Resources

These resources are scarce and precious
They must be treated with respect by industry, regulatory and HTA agencies



HR-QOL in the familial carer



Timing and level of
impact non-linear and
unpredictable

Conclusion

- As an industry – we need to be able to articulate the impact of treating a disease or condition on the health care system – which means impact beyond the individual
- In life-limiting illnesses which have a familial carer element – that needs to be included, and HR-QOL is relevant
- This could be quantitatively or qualitatively
- As a familial carer - our experience and voice on HR-QOL and burden needs to be heard, understood and represented. Respectfully.



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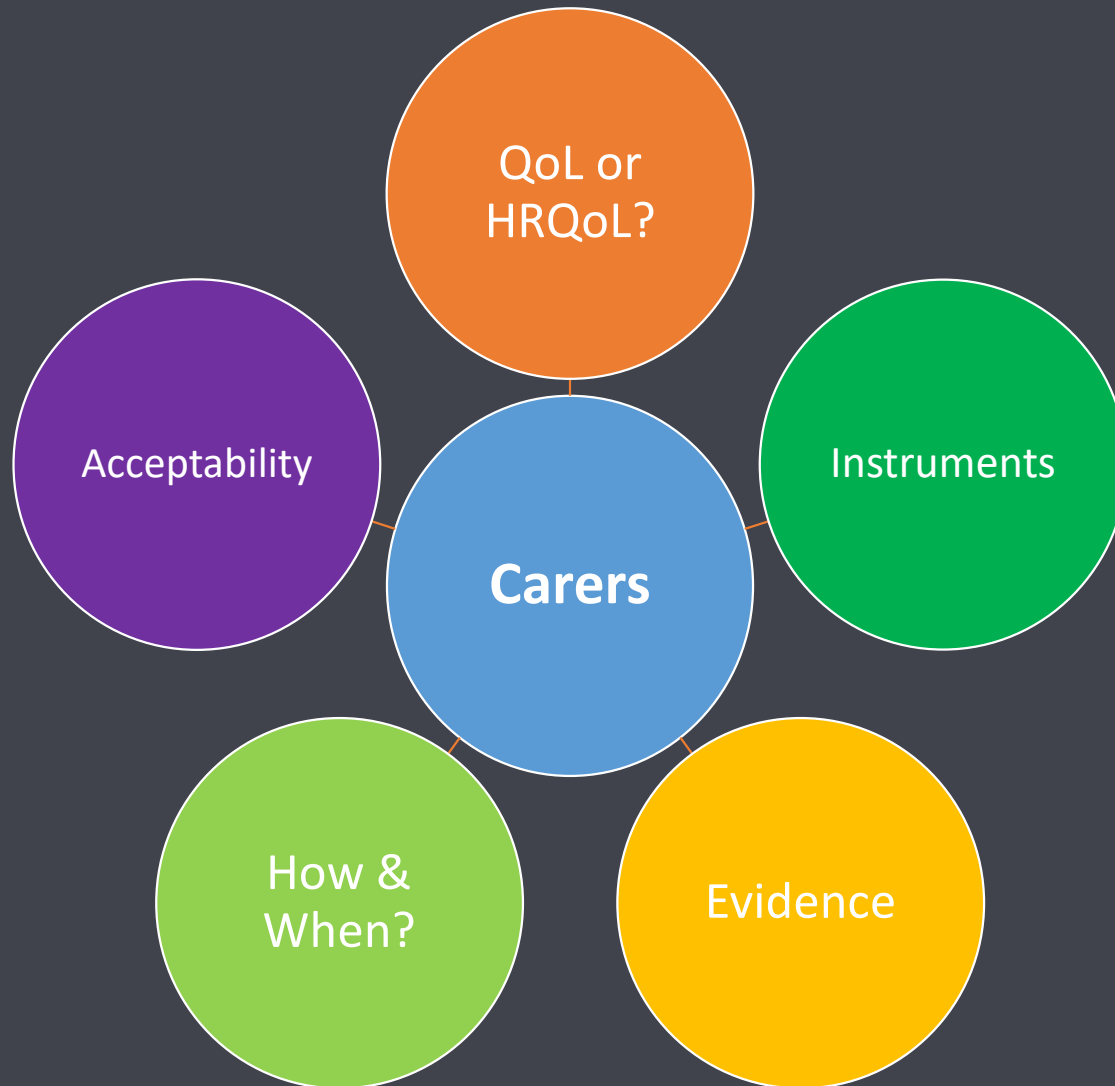
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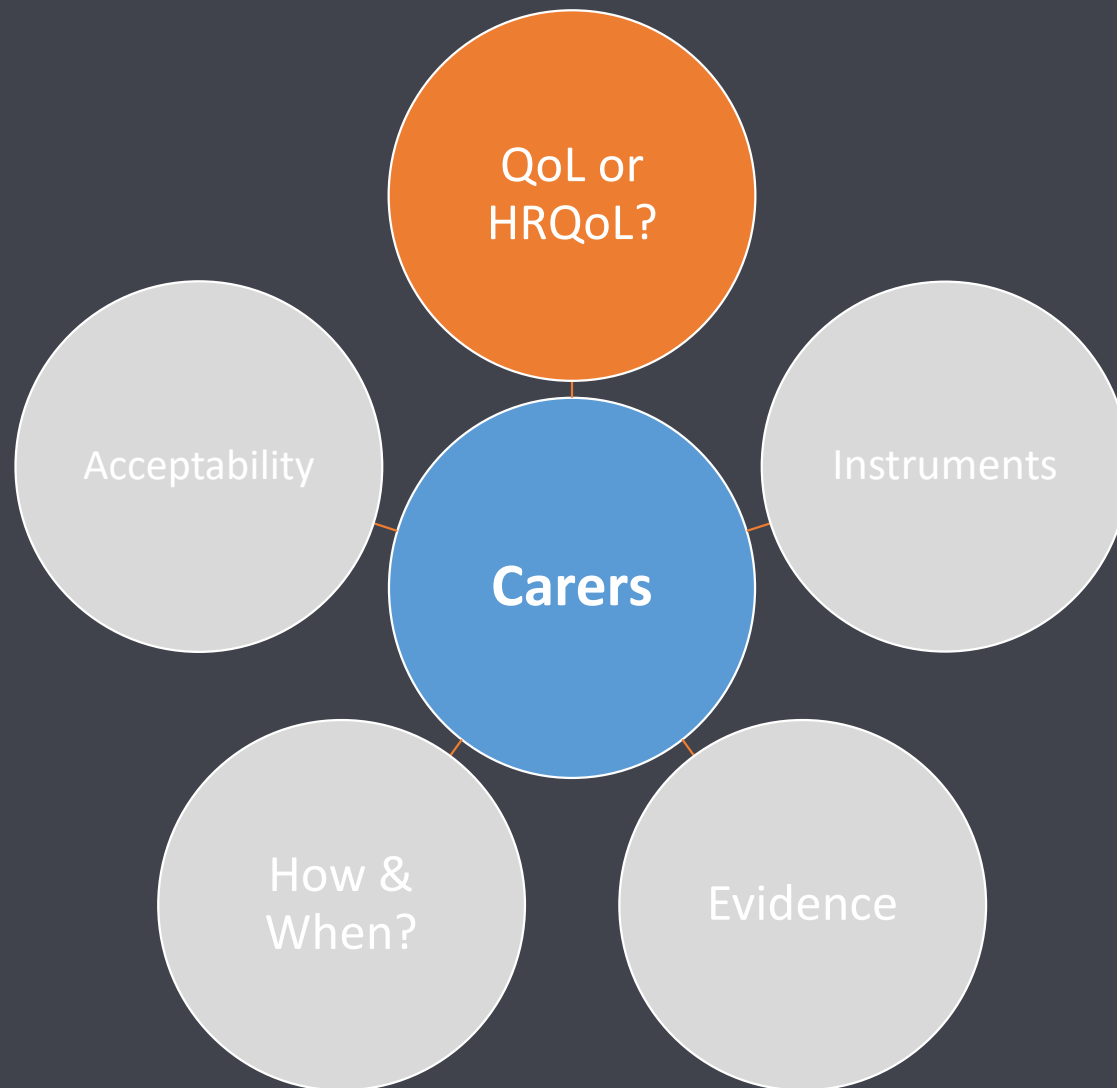


Treating the family and not the individual - How can we capture burden and quality of life for familial carers of those living with life limiting illness?

Jill Carlton

ScHARR Outcomes, University of Sheffield







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QoL or HRQoL?



Quality of life is an all-inclusive concept
incorporating all factors that impact
upon an individual's life.

Torrance GW. Utility approach to measuring health-related quality of
life. J Chronic Dis. 1987;40(6):593–600

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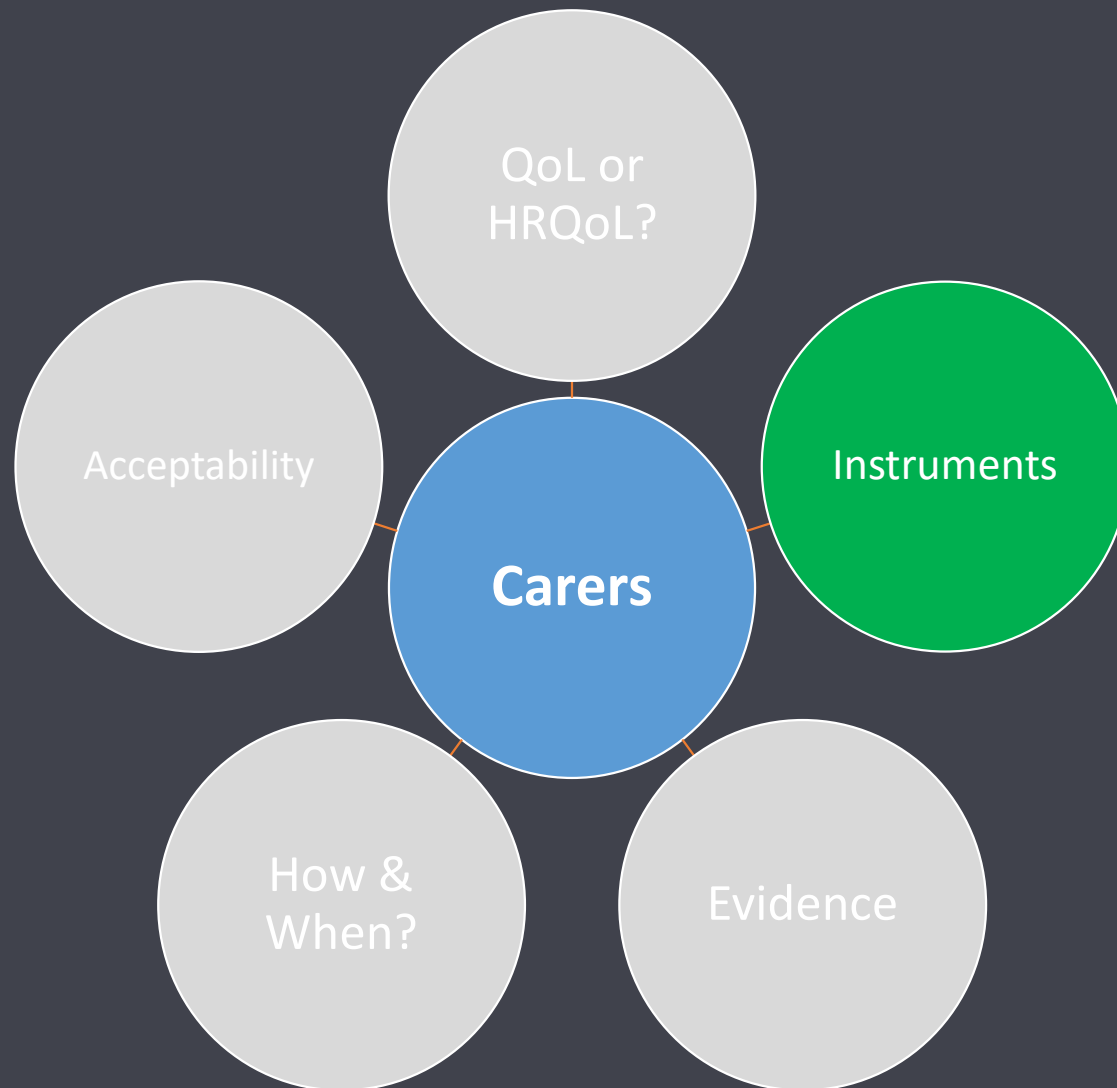
QoL or HRQoL?



Quality of life is an all-inclusive concept incorporating all factors that impact upon an individual's life. **Health-related quality of life includes only those factors that are part of an individual's health.**

Torrance GW. Utility approach to measuring health-related quality of life. *J Chronic Dis.* 1987;40(6):593–600

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Instruments



Form A: to be completed by the caregiver

ZARIT BURDEN INTERVIEW

Indicate how often you experience the feelings listed by circling the number in the box that best corresponds to the frequency of these feelings.

	Never	Rarely	Sometimes	Quite Frequently	Nearly Always
1) Do you feel that because of the time you spend with your relative that you don't have enough time for yourself?	0	1	2	3	4
2) Do you feel stressed between caring for your relative and trying to meet other responsibilities (work/family)?	0	1	2	3	4
3) Do you feel angry when you are around the relative?	0	1	2	3	4
4) Do you feel that your relative currently affects your relationship with family member or friends in a negative way?	0	1	2	3	4
5) Do you feel strained when you are around your relative?	0	1	2	3	4
6) Do you feel that your health has suffered because of your involvement with your relative?	0	1	2	3	4
7) Do you feel that you don't have as much privacy as you would like because of your relative?	0	1	2	3	4
8) Do you feel that your social life has suffered because you are caring for your relative?	0	1	2	3	4
9) Do you feel that you have lost control of your life since your relative's illness?	0	1	2	3	4
10) Do you feel uncertain about what to do about your relative?	0	1	2	3	4
11) Do you feel you should be doing more for your relative?	0	1	2	3	4
12) Do you feel you could do a better job in caring for your relative?	0	1	2	3	4

Total for each column

Total Score

CarerQol-7D

PedsQL Family Impact Module

Zarit Burden Inventory

Caregiver Wellbeing Scale

Caregiver Strain Index

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Instruments



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2) Do you feel stressed between	0	1	2	3	4

CarerQoL-7D

QoL Family Impact Module

QoL vs. PBM?

7) Do you feel that you don't have as much privacy as you would like because of your relative?	0	1	2	3	4
8) Do you feel that your social life has suffered because you are caring for your relative?	0	1	2	3	4
9) Do you feel that you have lost control of your life since your relative's illness?	0	1	2	3	4
10) Do you feel uncertain about what to do about your relative?	0	1	2	3	4
11) Do you feel you should be doing more for your relative?	0	1	2	3	4
12) Do you feel you could do a better job in caring for your relative?	0	1	2	3	4

Total for each column

Total Score

Caregiver Wellbeing Scale

Caregiver Strain Index

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Evidence



- Measuring what matters?

- Content validity

- Relevance
- Comprehensibility
- Comprehensiveness

- Life limiting illness





QoL or
HRQoL?

Acceptability

Carers

Instruments

Evidence

How &
When?



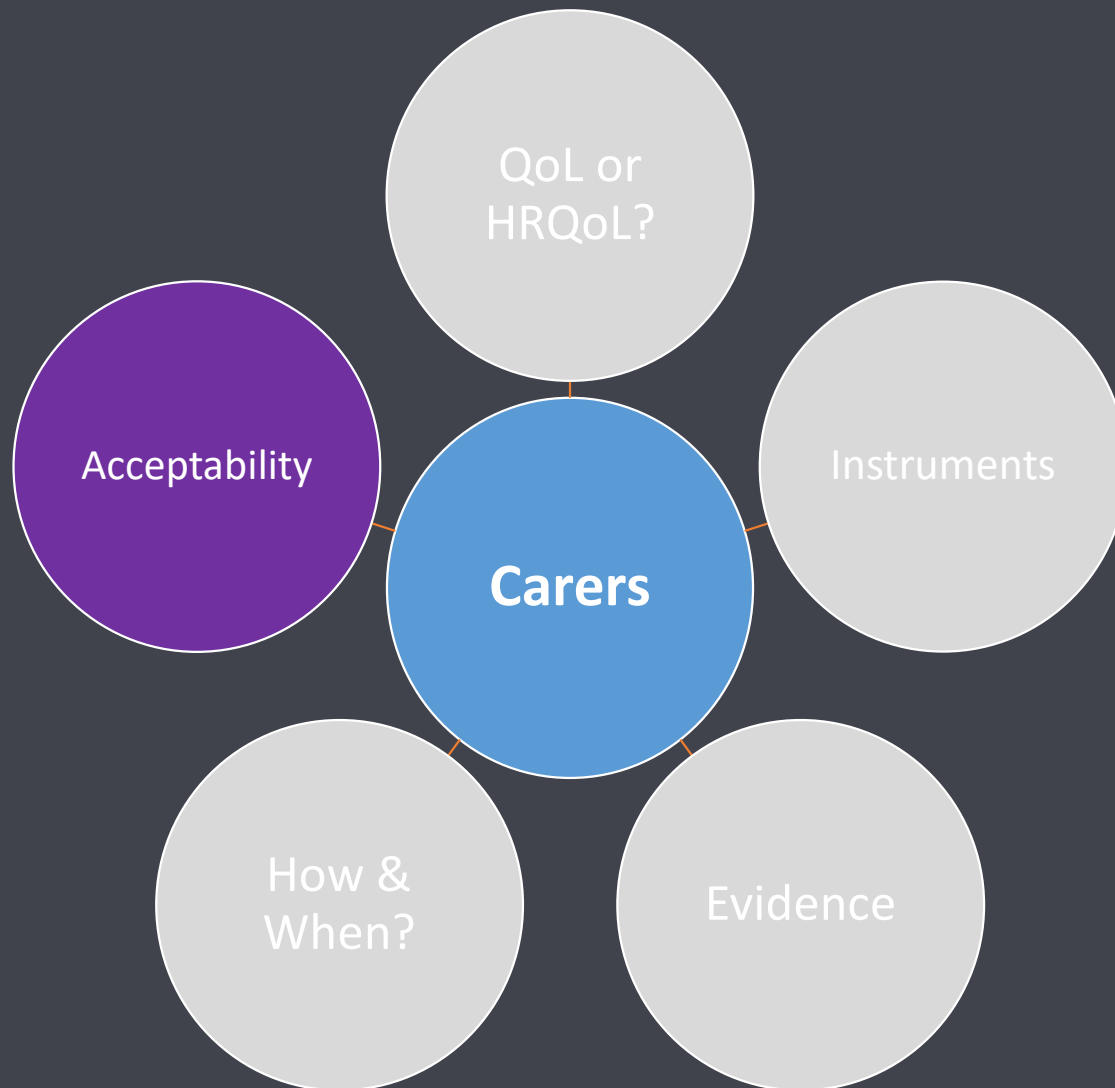
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How and When?



- Time of diagnosis
 - Retrospectively?
 - Recall bias
- Key stages of condition progression
 - Number of clinical stages may differ between conditions
- Who's perspective?
 - Primary caregiver
 - What if this is shared equally?
 - Siblings
 - Can and should this be included?
- Method of administration
 - Online or face-to-face
 - Experiential sampling (multiple sampling) or single time point





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Acceptability



Physical
functioning

Daily activities

Sleep



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Acceptability



Physical
functioning

Daily activities

Sleep

Self
care

Work

Eating

Hobbies

Fatigue

Socialising

Cognition



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Acceptability



Relationship with
partner

Emotional health

Financial problems



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Acceptability



Depressed

Guilty

Lonely

Anxious

Lonely

Hopeless

Worried

Sad

Scared

Relationship with
partner

Emotional health

Financial problems

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Acceptability



Physical
functioning

Daily activities

Sleep

Relationship with
partner

Emotional health

Financial problems



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Acceptability



Physical
functioning

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Relationship with
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Conclusion



- Methodological challenges
 - What we are measuring
 - When we are measuring it
 - Whether what we measured is 'valued' (i.e. utility based instruments)
 - Who's values should we use?
- Generic vs. carer-specific vs. condition-specific carer
 - Life limiting
- Ethicality
 - Instrument development
 - When collecting data

ISPOR Issues Panel

*Treating the family and not the individual:
How can we capture burden and quality of life for familial carers of
those with life limiting illness?*

Peter Neumann, ScD

November 8, 2022



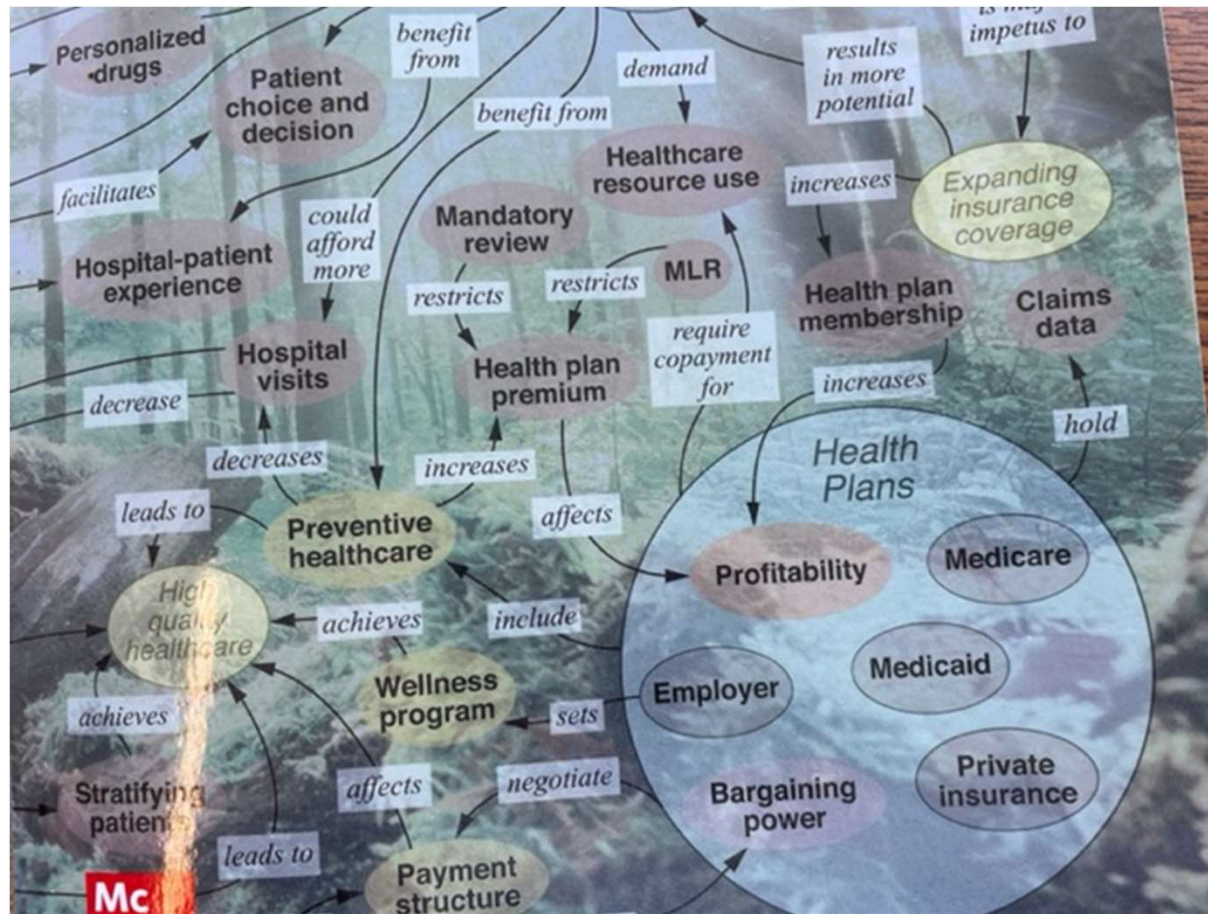
Overview

- The view from the US
- Recent experiences in value assessment
- Where things may be going

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- Recent experiences in value assessment
- Where things may be going

The US Health Care System



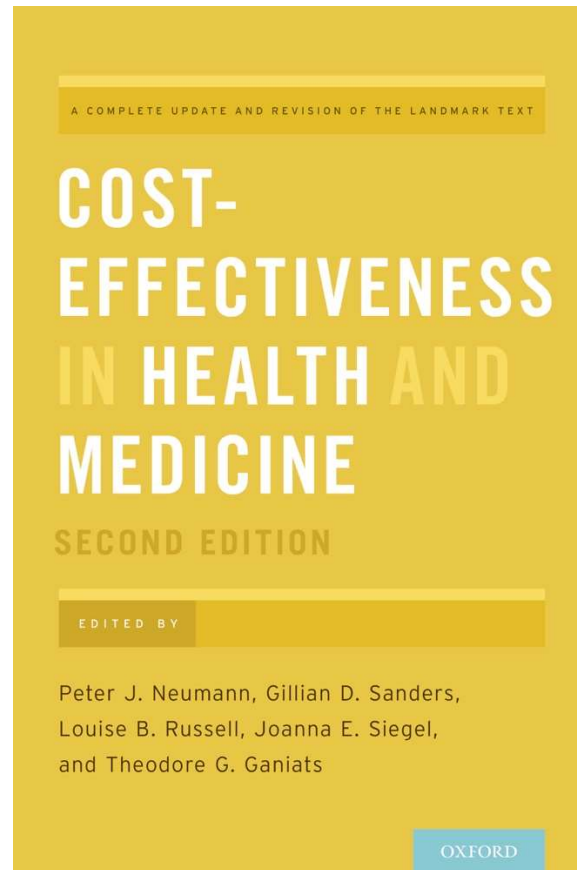
Burns, The US Health Care Ecosystem, 2021

Overview

- The view from the US
- Recent experiences in value assessment
- Where things may be going

The “Second Panel”

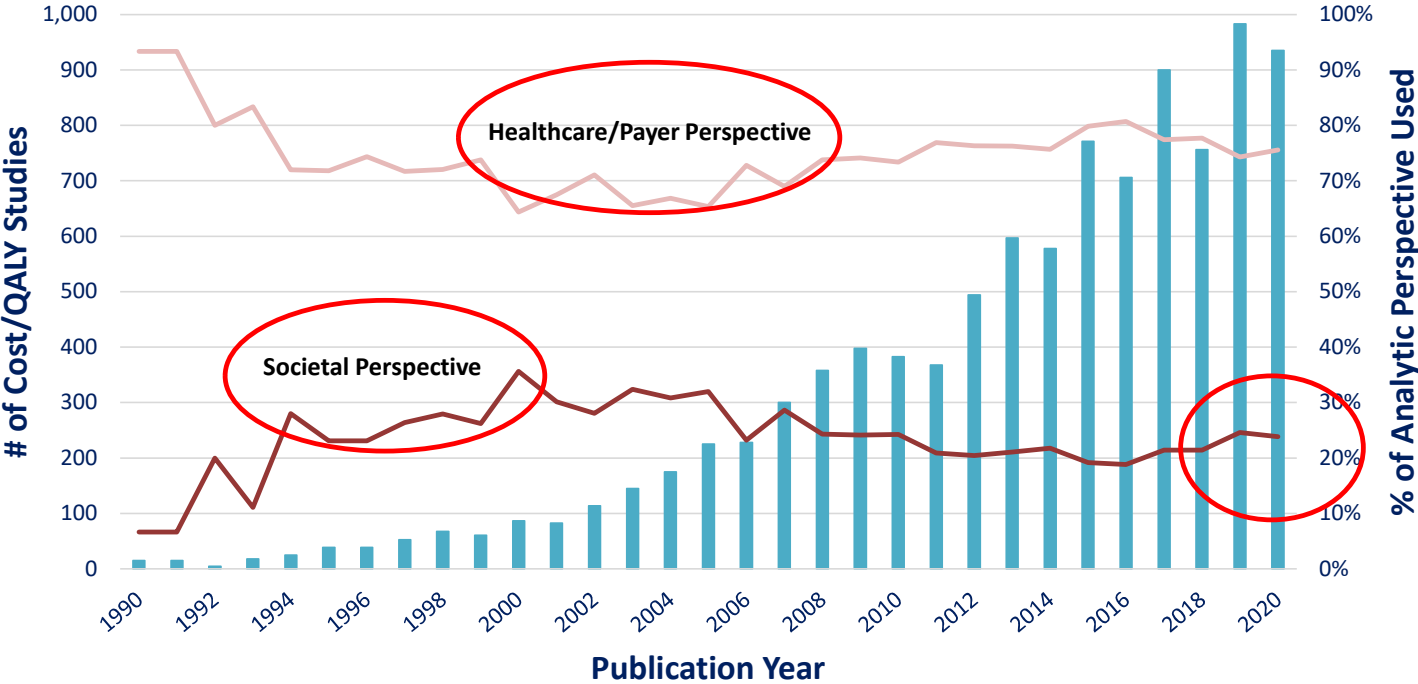
2017



2nd Panel Recommendations

- *Two* Reference Cases (Health care & Societal)
- Impact inventory

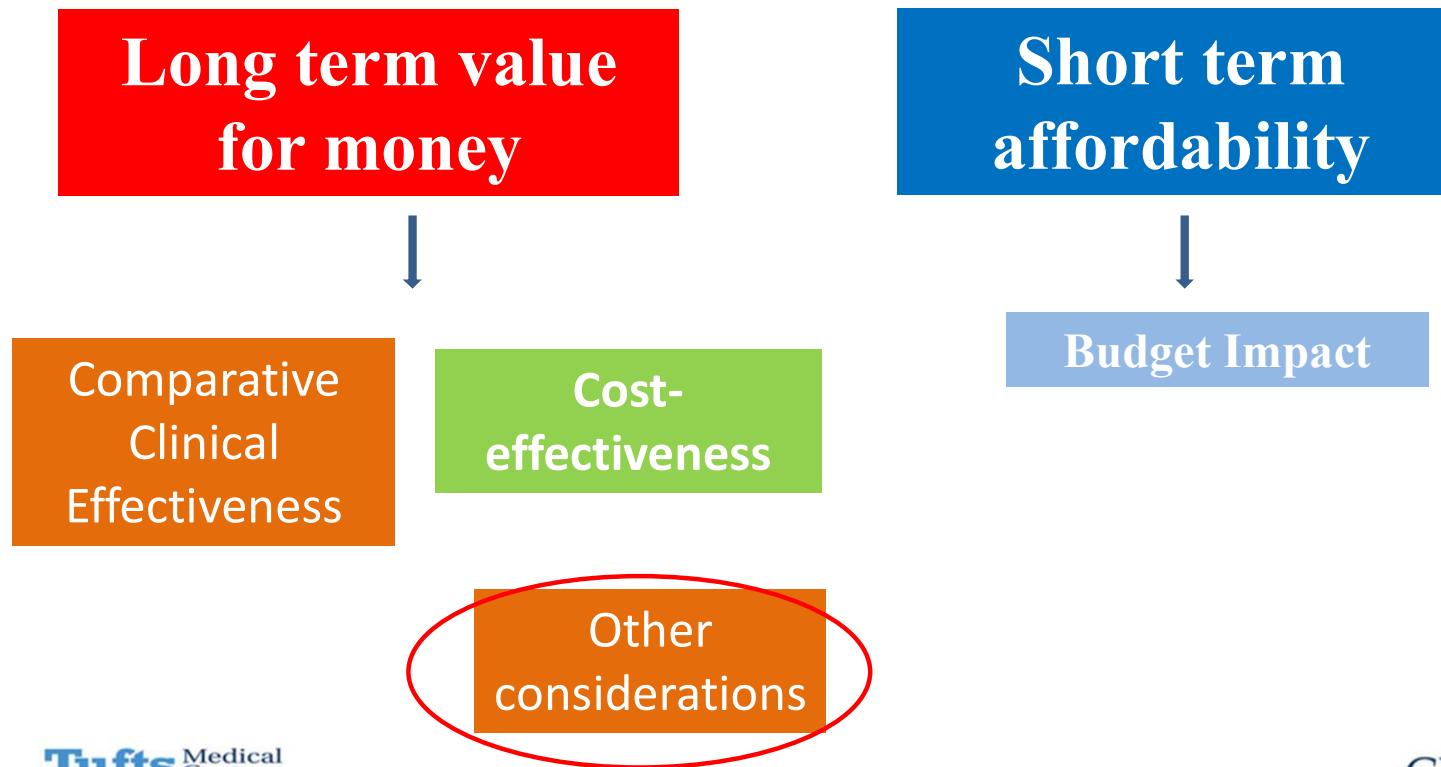
Perspectives used in published CEAs



Source: Kim et al., 2020



ICER's value framework



Why the omission of family spillovers?

- Measurement challenges
- Payers have weak incentives to consider non-health effects and spillovers

Overview

- The view from the US
- Recent experiences in value assessment
- Where things may be going



Original Investigation | Geriatrics

Evaluation of the Cost-effectiveness of Drug Treatment for Alzheimer Disease in a Simulation Model That Includes Caregiver and Societal Factors

Kouta Ito, MD, MS; Rick Chapman, PhD; Steven D. Pearson, MD, MSc; Ali Tafazzoli, PhD; Kristine Yaffe, MD; Jerry H. Gurwitz, MD

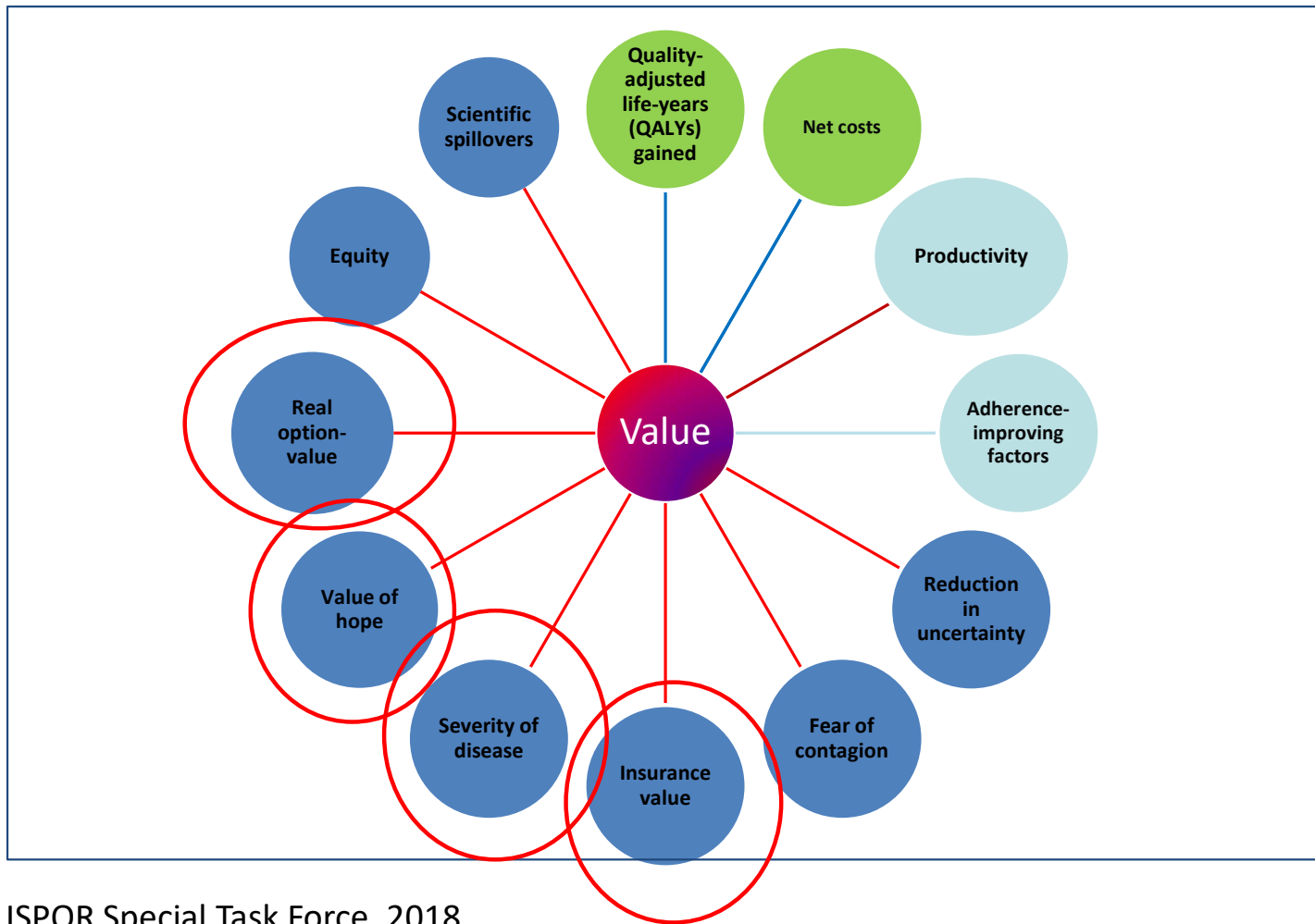
Abstract

IMPORTANCE The possibility of widespread use of a novel effective therapy for Alzheimer disease

Key Points

Question How does including caregiver and societal costs affect cost

The ISPOR “Value Flower”





2022



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Brief Report

The History and Future of the “ISPOR Value Flower”: Addressing Limitations of Conventional Cost-Effectiveness Analysis

Peter J. Neumann, ScD, Louis P. Garrison, PhD, Richard J. Willke, PhD

ABSTRACT

Objectives: Since its publication as part of the 2018 ISPOR Special Task Force (STF) on US Value Assessments, the “ISPOR value flower,” with its petals highlighting elements that may be overlooked or underappreciated in conventional drug value assessments, has been discussed and debated. We review the history of the value flower, describe recent developments, and

THE RIGHT PRICE

A Value-Based Prescription
for Drug Costs



Peter J. Neumann | Joshua T. Cohen | Daniel A. Ollendorf

Thank you!

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