Is there room for patient-centered value assessment in Medicare negotiation and state Prescription Drug Affordability Board processes?

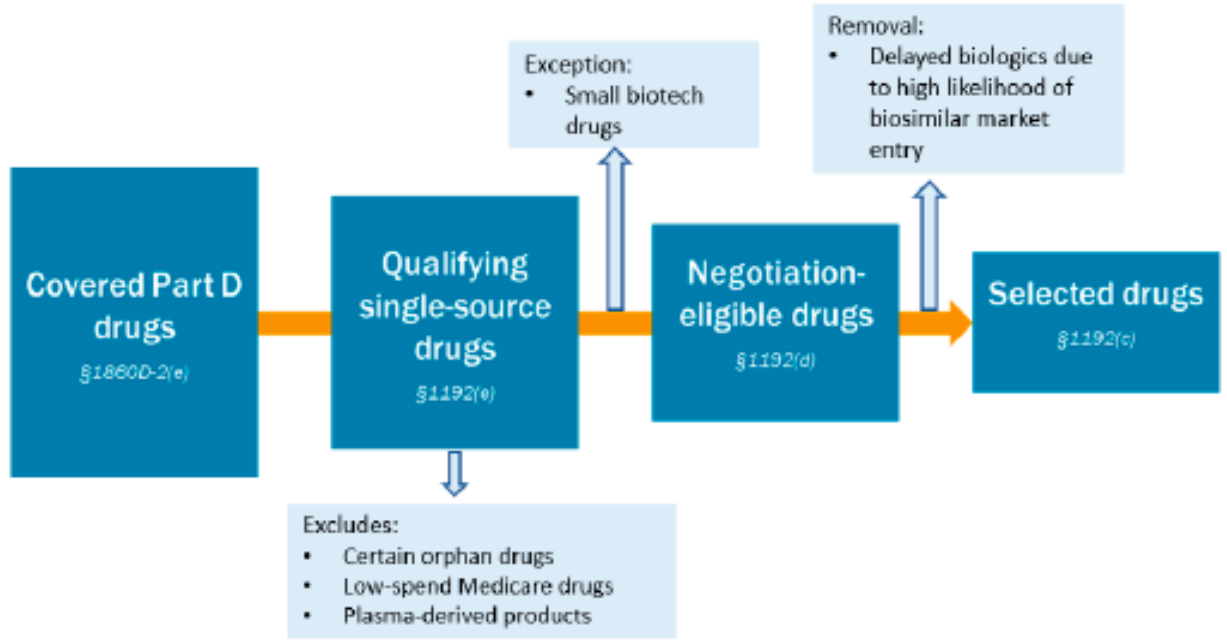
Motivation for workshop

- U.S. federal and state governments will begin assessing value and affordability to regulate drug pricing for selected drugs
- Constraints at federal and state levels may include limits on timelines and especially evidence sources
  - e.g, “…QALYs when used in association with life extension.”
  - Unclear how patient-centered research and engagement will be incorporated into decision making process
- *Goal today: provide approaches and examples that can reflect value from the patient perspective given policy constraints*

Inflation Reduction Act “Negotiation Program” timeline

- First set of drugs for negotiation fall 2023
- 3-6 month process for negotiation making new evidence generation difficult to achieve

Figure 1: Diagram of Process for Selecting Drugs for Negotiation for Initial Price Applicability Year 2026



https://www.cms.gov/files/document/medicare-drug-price-negotiation-program-initial-guidance.pdf

Methodology for determining initial offer for negotiation

- Section 60.3 includes multiple references to “outcomes of particular importance to the condition or disease being treated”
- Beyond noting the use of CMS-led literature reviews, no mention of how to inform decision making with a mix of qualitative and quantitative evidence

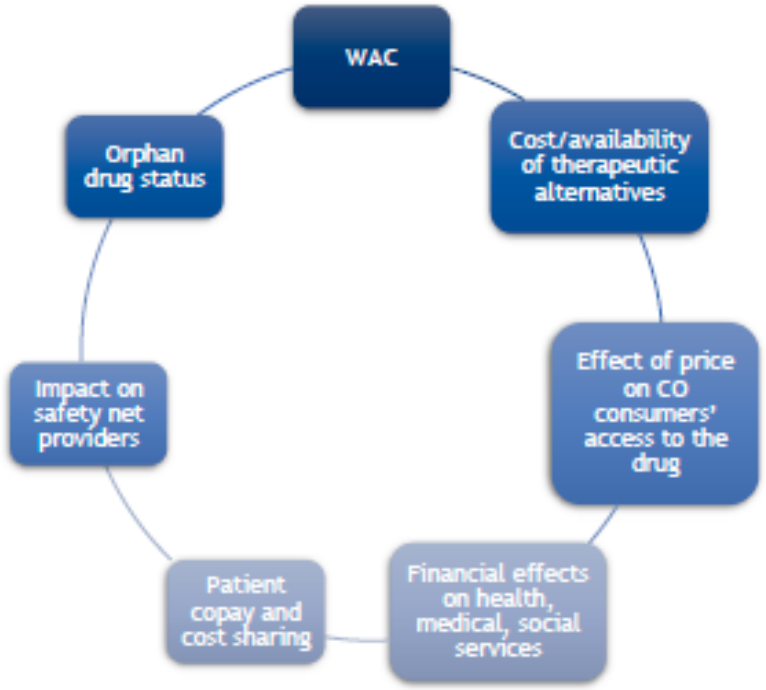
In all cases, CMS intends to consider applicable evidence and other input collectively and within the context of the course of care for the condition(s) or disease(s) that the selected drug is indicated to treat. As noted previously, this approach provides flexibility to consider multiple perspectives on the clinical benefit of the selected drug and its therapeutic alternative(s), including potential risks, harms, or side effects, and any unique scenarios or considerations related to clinical benefit, safety, and patient experience.

https://www.cms.gov/files/document/medicare-drug-price-negotiation-program-initial-guidance.pdf

Proposed Rule Part 3 - Affordability Review

E: Conduct - Overview

Per 10-16-1406(3)-(7) C.R.S., in performing an affordability review, to the extent practicable, the Board shall consider the following to determine if a drug is unaffordable:



Input from:
- Patients and caregivers
- Individuals with relevant scientific or medical training

Info voluntarily submitted from a manufacturer, carrier, PBM, or other entity

Additional factors, including:

- Rebates, Discounts, and Price Concessions
- Health Equity Factors
- Information from HCPF
- Non-adherence and utilization management info

COLORADO
Prescription Drug Affordability Board
Division of Insurance

https://doi.colorado.gov/insurance-products/health-insurance/prescription-drug-affordability-review-board

Colorado Prescription Drug Affordability Board

- Colorado PDAB requests input from patients and caregivers during an affordability review
- But uncertain how engagement will inform decision making using a similar qualitative and quantitative evidence review approach

Input from Specified Stakeholders:

i. Patients and Caregivers

(1) The Board will seek input from patients and caregivers affected by a condition or disease that is treated by the prescription drug by gathering information related to:

(a) The impact of the disease,

(b) Patient treatment preferences,

(c) Patient perspective on the benefits and disadvantages of using the prescription drug,

(d) Caregiver perspective on the benefits and disadvantages of using the prescription drug, and/or

(e) Available patient assistance in purchasing the prescription drug.

(2) In seeking additional information, the Board will attempt to gather a diversity of experience among patients from different socioeconomic backgrounds.

https://doi.colorado.gov/insurance-products/health-insurance/prescription-drug-affordability-review-board

Problem statement

- CMS and affordability boards may be faced with similar existing barriers
- Payers struggle to use additional societal, patient, and provider “perspectives” for pricing negotiations and formulary decision making
  - Absence of understanding or consensus on how perspectives can be used to inform that relate to health interventions

Gleason P, Hatton J, O’Brien JM, O’Hara B, Westrich K. AMCP Talks: incorporating value framework assessments in coverage and reimbursement decisions. Preconference session. Presented at the AMCP 2023 Annual Meeting; March 21–24, 2023; San Antonio, Texas.

Value is Context- and Perspective-Specific

Value Domains	Example Value Elements	Inclusion in Value Assessment	Perspective
Traditional, conventional, or regulatory-anchored value elements	• Survival • Quality of life (including safety impact)	• Quantitatively incorporated in CEA/CER	• Payer or societal perspective
Additional patient-centric value elements	• **Ability to reach important personal milestones** • Patient experience related to disease management • Value of hope/Balance or timing of risks and benefits	• Qualitatively incorporated through deliberations on other factors*	• Disease-specific patient perspective
Additional broader contextual value elements	• **Novel mechanism of action** • Risk protection • Rarity	• Qualitatively incorporated through deliberations on other factors*	• Plan member and/or general citizen perspective

*We acknowledge there are ongoing methods improvements in these areas but at this time infrequent inclusion in current quantitative value assessment evaluations

Industry perspective on patient engagement in government price determinations

Russ Montgomery, PhD

Gilead Sciences

Is Medicare "negotiation" truly an HTA process?

CMS proposed steps for developing an initial price offer[1]:

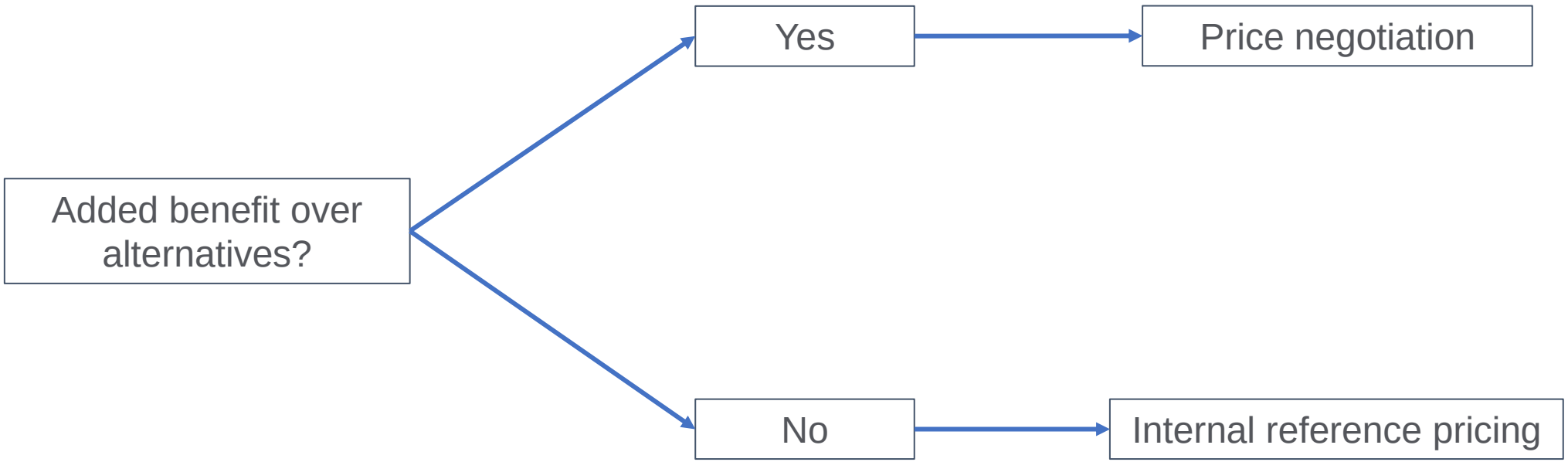
- Identify therapeutic alternatives
- Use the net prices of alternatives as a starting point
- Evaluate clinical benefit and unmet need compared to alternatives

- **ISPOR definition of HTA[2]:**
  - Health technology assessment is a multidisciplinary process that uses explicit methods to determine the value of a health technology at different points in its lifecycle. The purpose is to inform decision-making in order to promote an equitable, efficient, and high-quality health system.

- **HTAi definition of HTA[3]:**
  - HTA is the systematic evaluation of the clinical effectiveness and/or cost effectiveness and/or social and ethical impact of a health technology on the lives of patients and the health care system

1. https://www.cms.gov/files/document/fact-sheet-medicare-drug-price-negotiation-program-initial-guidance.pdf (as of 3/23)
2. https://www.ispor.org/conferences-education/education-training/learning-lab/health-technology-assessment
3. https://past.htai.org/interest-groups/pcig/resources/for-patients-and-patient-groups/faq/

German AMNOG process as an analog



https://www.oecd.org/health/health-systems/Pharmaceutical-Reimbursement-and-Pricing-in-Germany.pdf

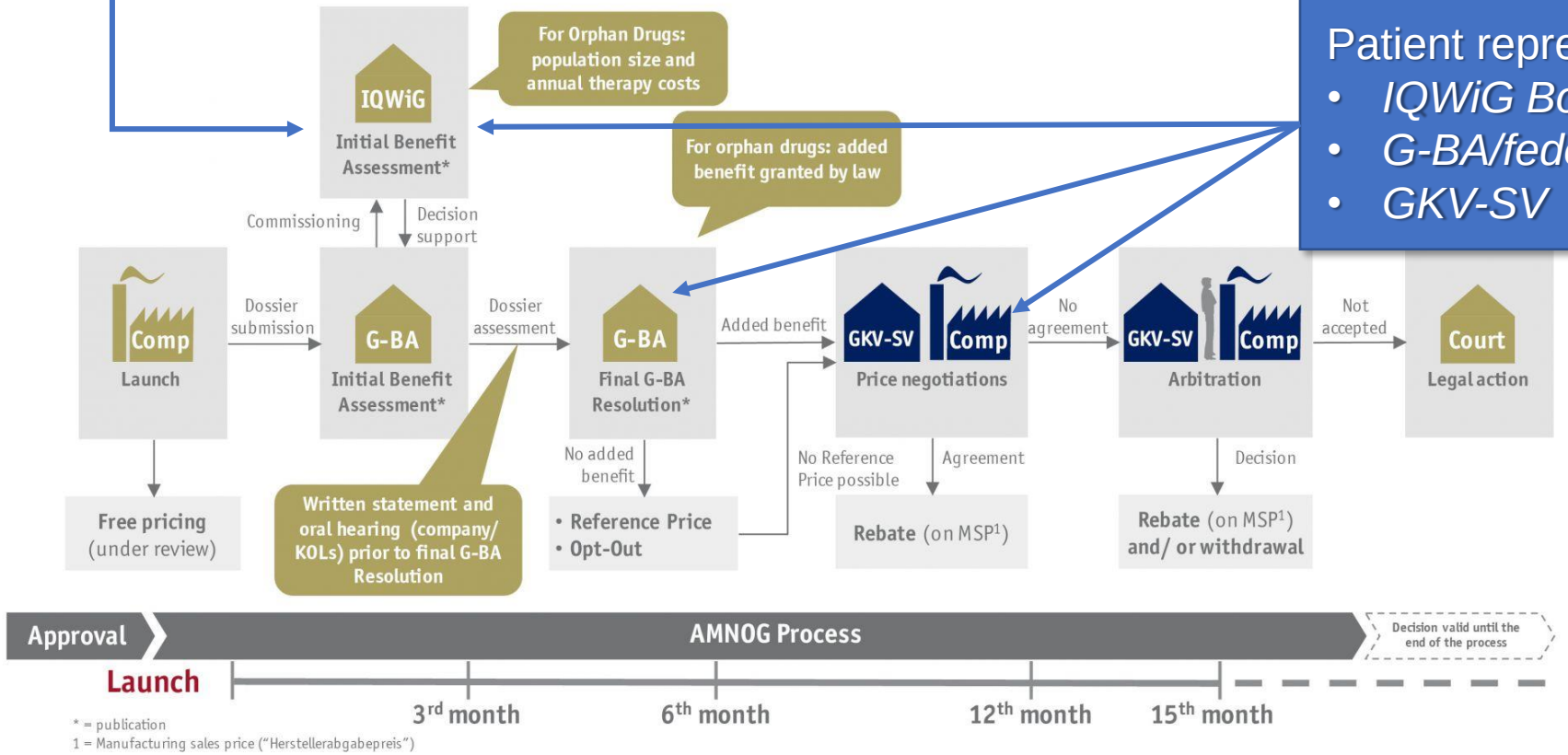
Patient engagement – AMNOG

IQWiG patient engagement procedures:

- *Topic selection*
- *Sharing patient stories*
- *Review text drafts*
- *Commenting opportunities*

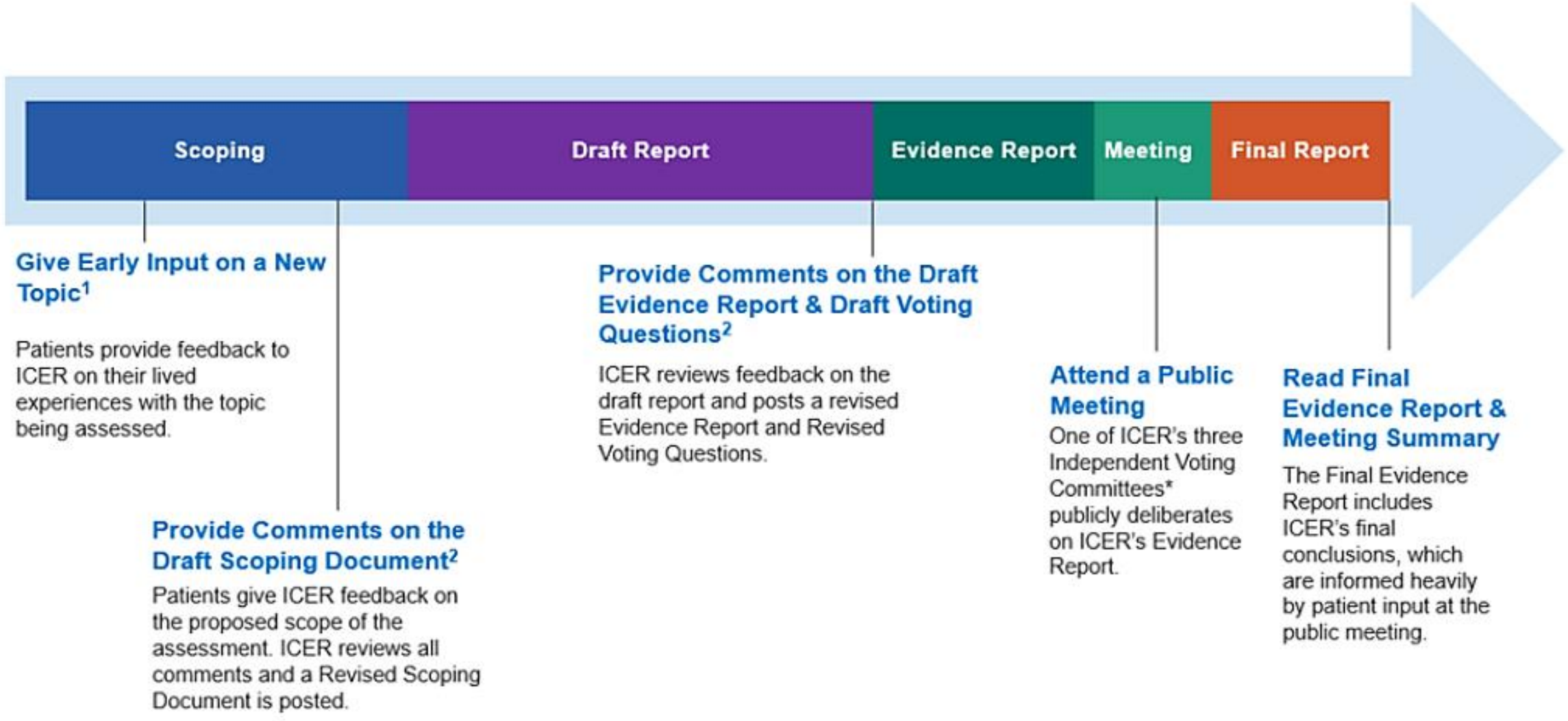
Patient representation on:

- *IQWiG Board of Trustees*
- *G-BA/federal joint committee*
- *GKV-SV*



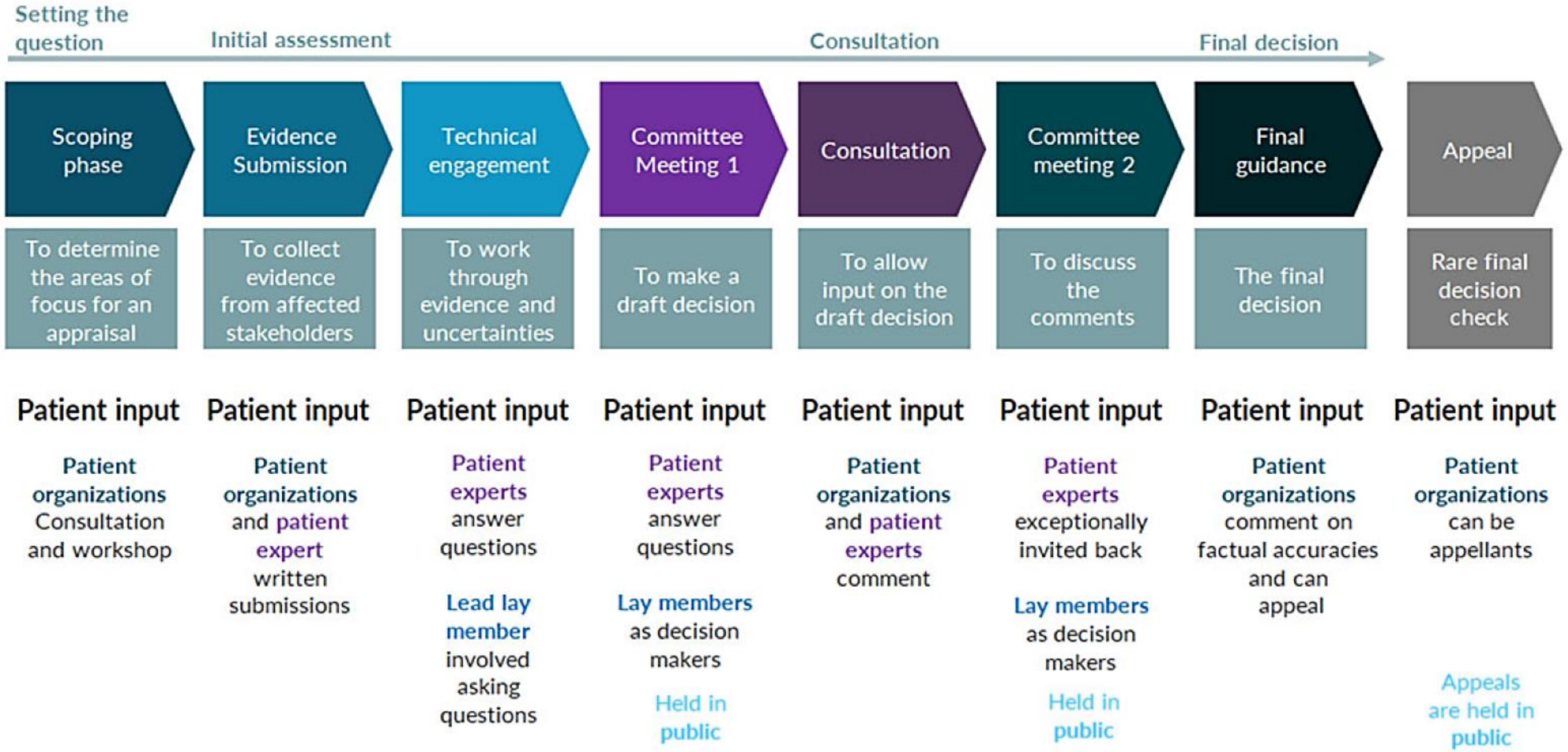
https://www.iqwig.de/methoden/general_methods_4-0.pdf
https://germanmarketaccesssimplified.com/hta-in-germany/

Patient engagement – ICER



https://icer.org/wp-content/uploads/2020/10/ICER_Patient_Engagement_Guide_102220.pdf

Patient engagement – NICE



Norburn L, Thomas L (2021). Expertise, experience, and excellence. Twenty years of patient involvement in health technology assessment at NICE: an evolving story. International Journal of Technology Assessment in Health Care 37, e15, 1–7. https://doi.org/10.1017/S0266462320000860

Patient engagement – CADTH

Governance and Advisory Roles

- Board of Directors
- Canadian Drug Expert Committee
- pCODR Expert Review Committee
- Health Technology Expert Review Panel
- Patient Community Liaison Forum

Patient Perspectives and Experiences

Patient group input:

- Common Drug Review
- pan-Canadian Oncology Drug Review
- Therapeutic Reviews

Direct interaction with patients:

- Scientific Advice

Qualitative evidence synthesis:

- Reviews of patient perspectives and experiences
- Reports on the appropriate use of multiple technologies including medical devices and clinical interventions

Opportunities for Learning

- CADTH Lecture Series
- CADTH Symposium

"If you're not involving patients in HTA, then you're not doing HTA."

Dr. Brian O'Rourke
President and CEO
CADTH

https://www.cadth.ca/sites/default/files/cdr/cdr-pdf/Patient%20Engagement%20at%20CADTH.pdf

Patient engagement – Medicare “negotiation”

- Submit evidence on comparative effectiveness and unmet need

https://www.cms.gov/regulations-and-guidance/legislation/paperworkreductionactof1995/pra-listing/cms-10847

Medicare timeline (2026 price setting)

MEDICARE DRUG PRICE NEGOTIATION PROGRAM

CENTERS FOR MEDICARE & MEDICAID SERVICES

September 1, 2023
CMS will publish a list of 10 Medicare Part D drugs selected for negotiation for 2026.

October 1, 2023
Deadline for companies of drugs selected for the Negotiation Program to sign agreements to participate in the negotiation process for 2026.

October 2, 2023
Deadline for companies of drugs selected for the Negotiation Program to submit manufacturer-specific data to CMS to consider in the negotiation of maximum fair price.

February 1, 2024
CMS sends initial offers of a maximum fair price with a justification for a selected drug to each company participating in the Negotiation Program. The negotiation period begins.

March 2, 2024
Companies have 30 days from receiving offers of a maximum fair price for a drug to accept the offer or propose a counteroffer, if desired.

August 1, 2024
The negotiation period ends.

5-month period

https://www.cms.gov/files/document/drug-price-negotiation-timeline-2026.pdf

Industry views on HTA

- We need a **uniquely American** approach
- A **single metric** that assumes uniform value across patients will never reflect the diverse experiences of the broader patient community
- **Patients and other stakeholders must be engaged at multiple steps**, and their feedback should drive the assessment – especially **selection of outcomes and comparators**
- Methodologies should be **comprehensive and capture multiple aspects of value**
  - Methodologies must capture a broad range of benefits to patients, caregivers, and societies, including adherence, disease severity, public health impact, innovation/scientific spillover, societal cost impacts
- **Multi-criteria decision analysis** (MCDA) is an example of a methodology that can meet these aims
- **Impact inventories/dashboards** can improve transparency by showing what evidence was utilized and how it impacted the assessment of value and/or determination of price

https://icer.org/wp-content/uploads/2020/10/ICER_2020_VAF_Open_Input_082119-2.pdf

Incorporating the Patient Voice in Value Assessment and Drug Pricing Policy

Joey Mattingly, PharmD, MBA, PhD

Unsure how to engage patients in the process

> Am J Public Health. 2019 Apr;109(4):559-561. doi: 10.2105/AJPH.2018.304946. Epub 2019 Feb 21.

Pharmaceutical Industry Support of US Patient Advocacy Organizations: An International Context

So-Yeon Kang [1], Ge Bai [1], Laura Karas [1], Gerard F Anderson [1]

Affiliations + expand

PMID: 30789768 PMCID: PMC6417565 DOI: 10.2105/AJPH.2018.304946

Free PMC article

HEALTH AFFAIRS FOREFRONT

RELATED TOPICS:
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Patient Influencers Paid By Pharmaceutical Companies Should Be Required To Disclose Industry Ties

Judy Butler, Adriane Fugh-Berman

JANUARY 10, 2020 10.1377/forefront.20200109.985594

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RELATED TOPICS:
QUALITY-ADJUSTED LIFE-YEARS | PHARMACEUTICAL COMPANIES | CANCER PATIENTS | QUALITY OF LIFE

Who Is Sowing Seeds Of Confusion About The QALY?

Jennifer C. Chen, Anna Kaltenboeck

JULY 24, 2020 10.1377/forefront.20200723.511880

Patient Advocacy Organizations: Institutional Conflicts of Interest, Trust, and Trustworthiness

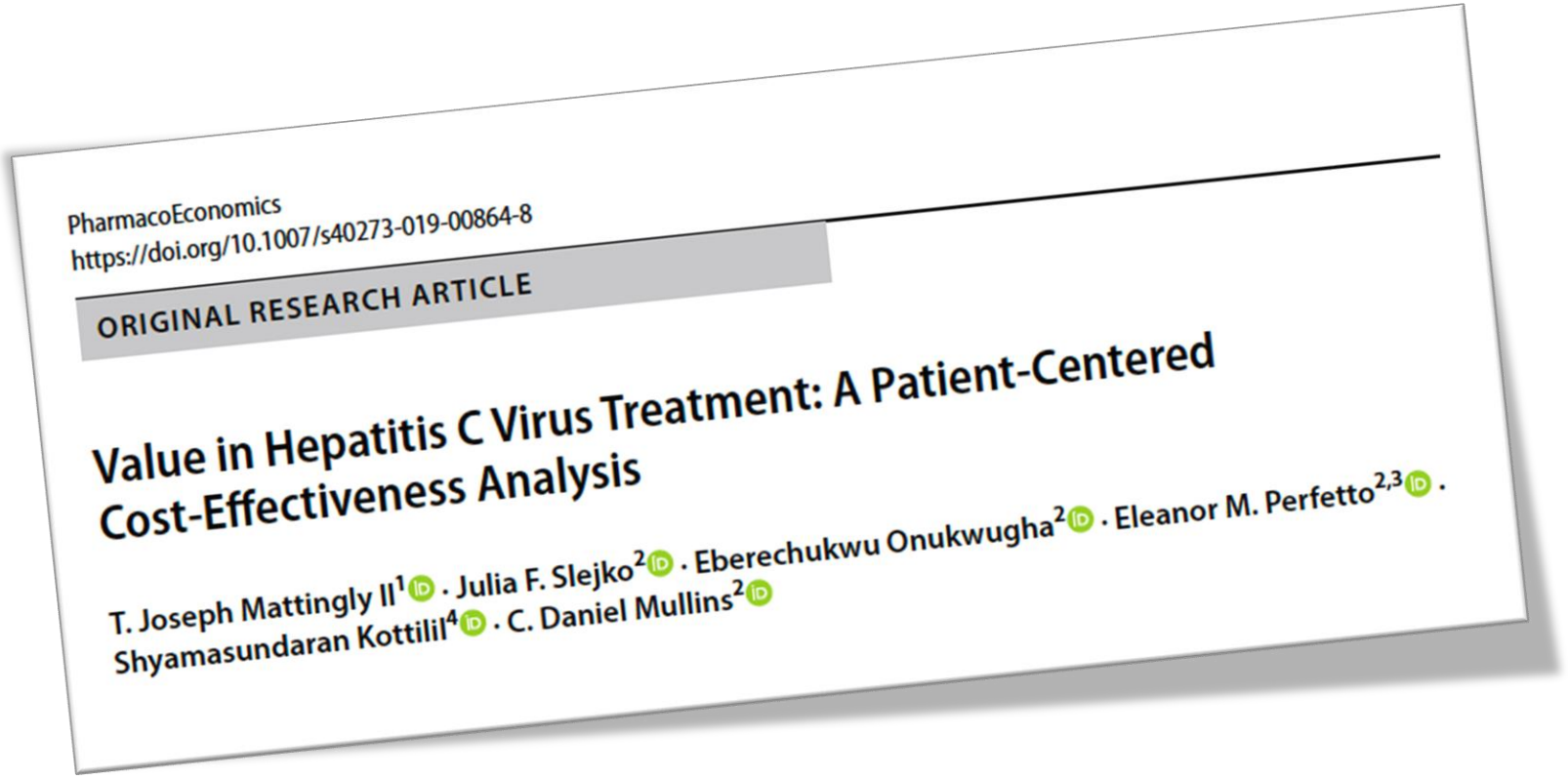
Journal of Law, Medicine and Ethics, Forthcoming

8 Pages • Posted: 20 Jul 2013 • Last revised: 7 Sep 2013

Susannah L. Rose

Cleveland Clinic, Department of Bioethics; Case Western Reserve University; Edmond J. Safra Center for Ethics at Harvard University

Date Written: July 18, 2013


PharmacoEconomics
https://doi.org/10.1007/s40273-019-00864-8

ORIGINAL RESEARCH ARTICLE

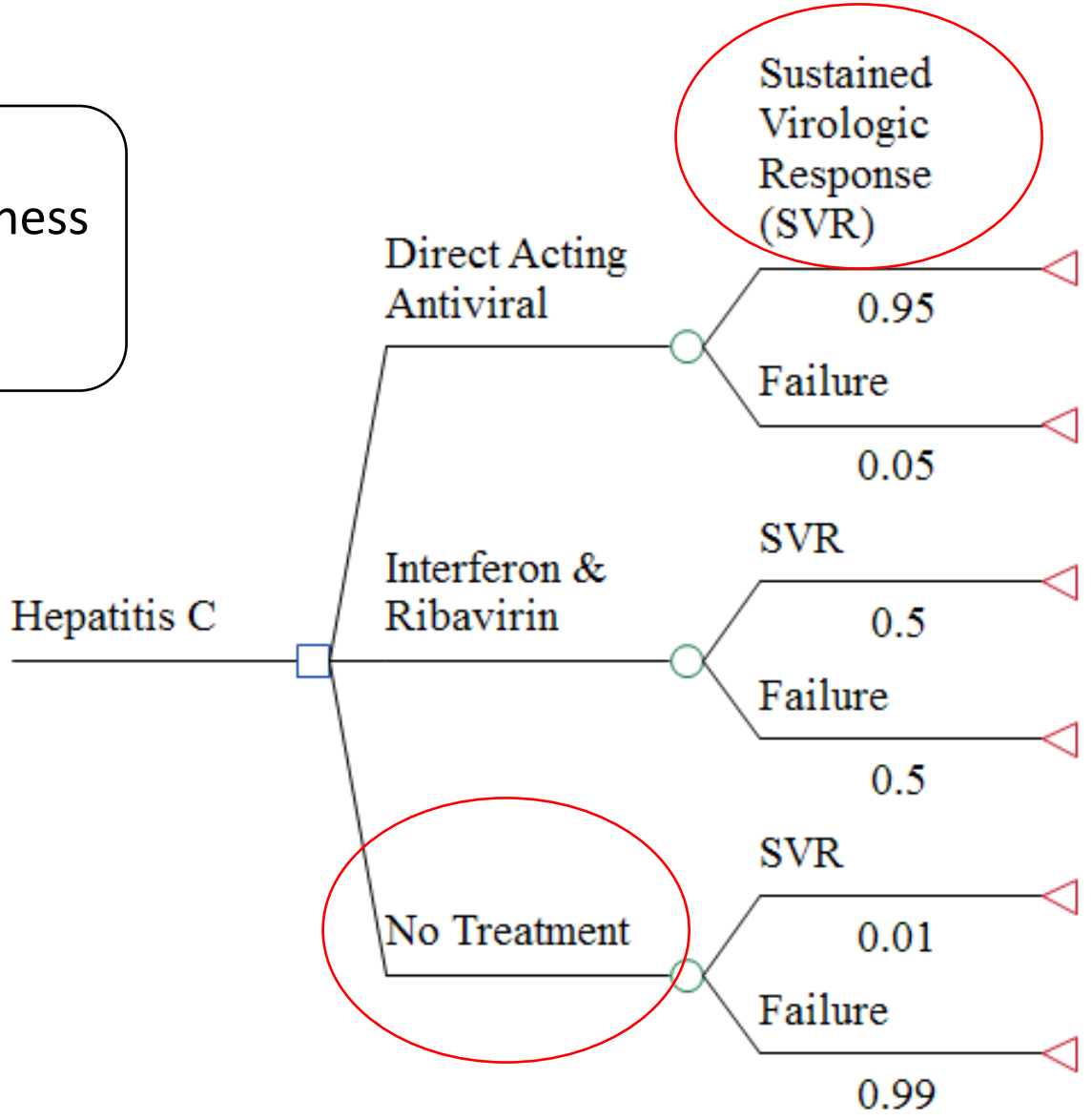
Value in Hepatitis C Virus Treatment: A Patient-Centered Cost-Effectiveness Analysis

T. Joseph Mattingly II[1] · Julia F. Slejko[2] · Eberechukwu Onukwugha[2] · Eleanor M. Perfetto[2,3] · Shyamasundaran Kottilil[4] · C. Daniel Mullins[2]

Hepatitis C Virus Treatment

A patient-centered cost-effectiveness case study

What does a typical “cost-effectiveness model” look like in HCV?



Mattingly II TJ, Slejko JF, Mullins CD. *Annals of Pharmacotherapy*. 2017;51(11):961-9. DOI: 10.1177/1060028017722007.
Mattingly II TJ, Perfetto EM, Johnson S. *Hepatology*. Epub ahead of print August 23, 2017. DOI: 10.1002/hep.29482.

How do I get started?

How do you determine the topic you study?

How do you determine your comparators and outcomes?

What analysis approach should you take?

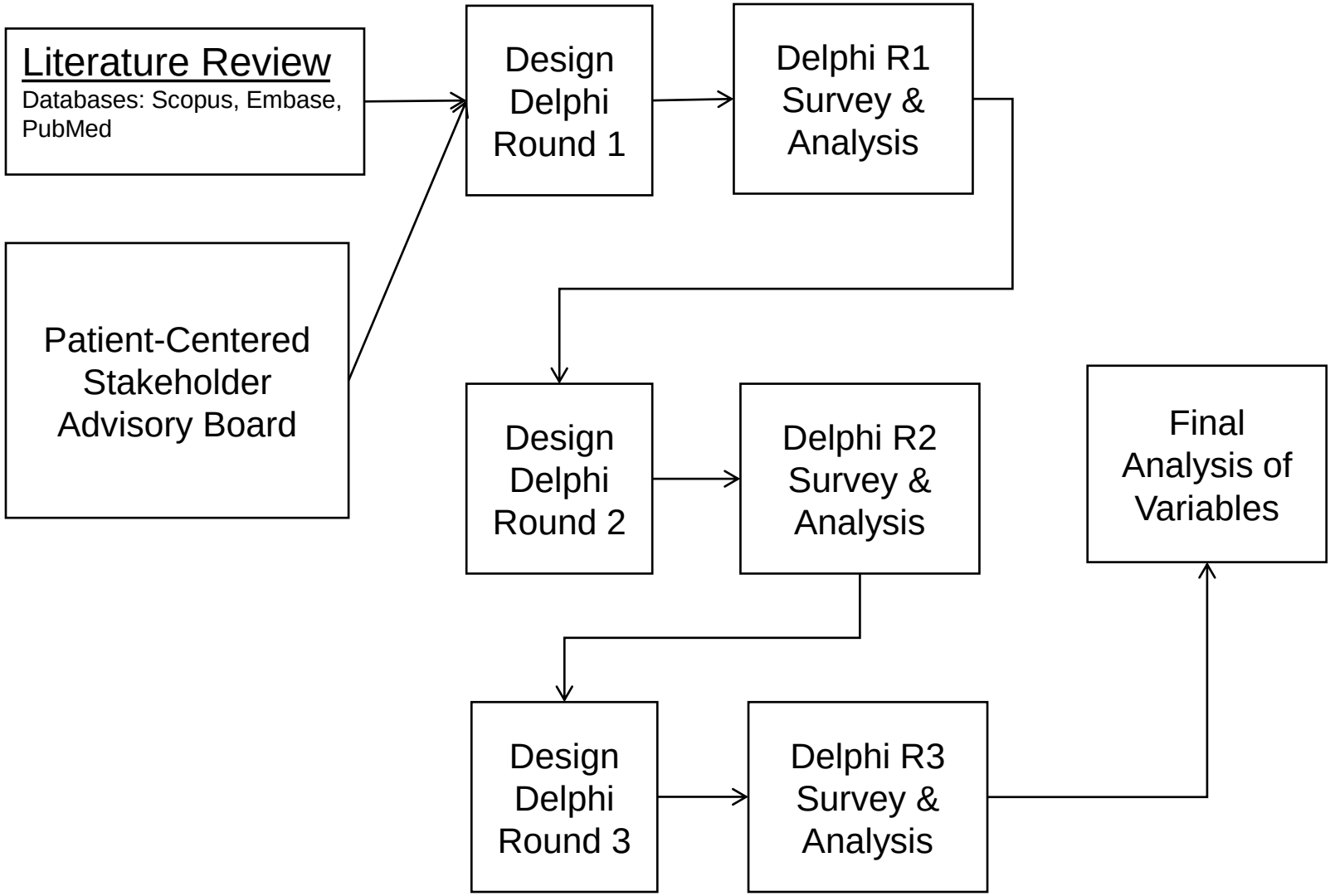
How do you ensure your results get back to the patients it impacts?

Step in CER Process	Purpose of Patient Engagement
Topic solicitation	▪ Identify topics that are important to patients, caregivers, and the community ▪ Propose topics to be investigated
Prioritization	▪ Solicit feedback on relevance and priority of topics ▪ Discuss the urgency of addressing topics
Framing the question	▪ Ascertain questions' relevance and usefulness ▪ Assess "real-world" applicability
Selection of comparators and outcomes	▪ Identify comparator treatments of interest ▪ Identify outcomes of interest ▪ Incorporate other aspects of treatment
Creation of conceptual framework	▪ Provide a "reality check" ▪ Verify logic of conceptual framework ▪ Supplement with additional factors not documented in the literature
Analysis plan	▪ Verify importance of factors and variables ▪ Ascertain whether there is a good proxy for a specific concept ▪ Inquire about potential confounding factors
Data collection	▪ Determine best approaches for data collection (eg, trial, registry, medical charts) ▪ Assist with selection of data sources
Reviewing and interpreting results	▪ Assess believability of results ▪ Suggest alternative explanations or approaches ▪ Provide input for sensitivity analysis
Translation	▪ Interpret results to be meaningful ▪ Document which results are easy or difficult to understand ▪ Indicate which results are counterintuitive
Dissemination	▪ Facilitate engagement of other patients ▪ Help other patients to understand findings

Mullins et al. *JAMA*. 2012;307(15):1587-88.

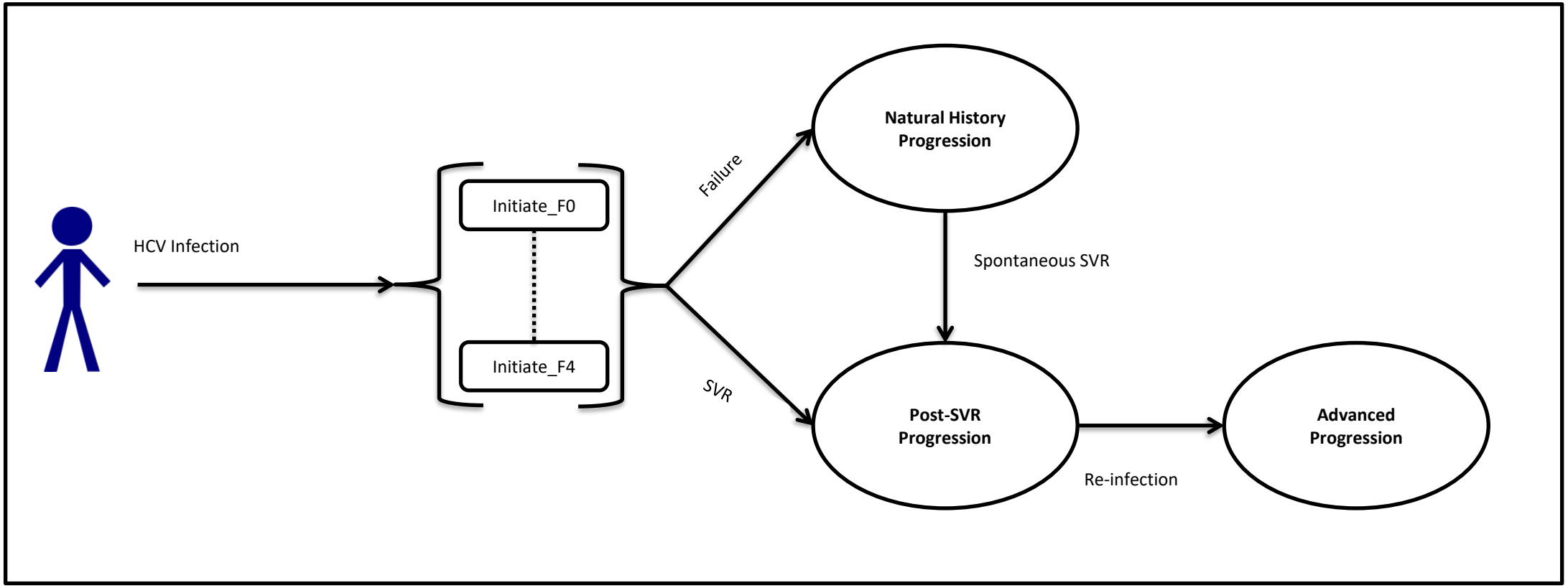
Case Example – Hepatitis C

- Stakeholder advisory board
- 30-patient Delphi Panel
- **Unique Findings:**
  - A generic "treatment" comparator vs. "no treatment" was preferred
  - "**Fear of harming others**" was more important than their own physical symptoms



Mattingly TJ, Perfetto EM, Johnson SL. *Hepatology*. 2018 Aug 23;774–81.
Mattingly et al. *The Patient*. 2019;12(6):631-8.

General Model Structure:

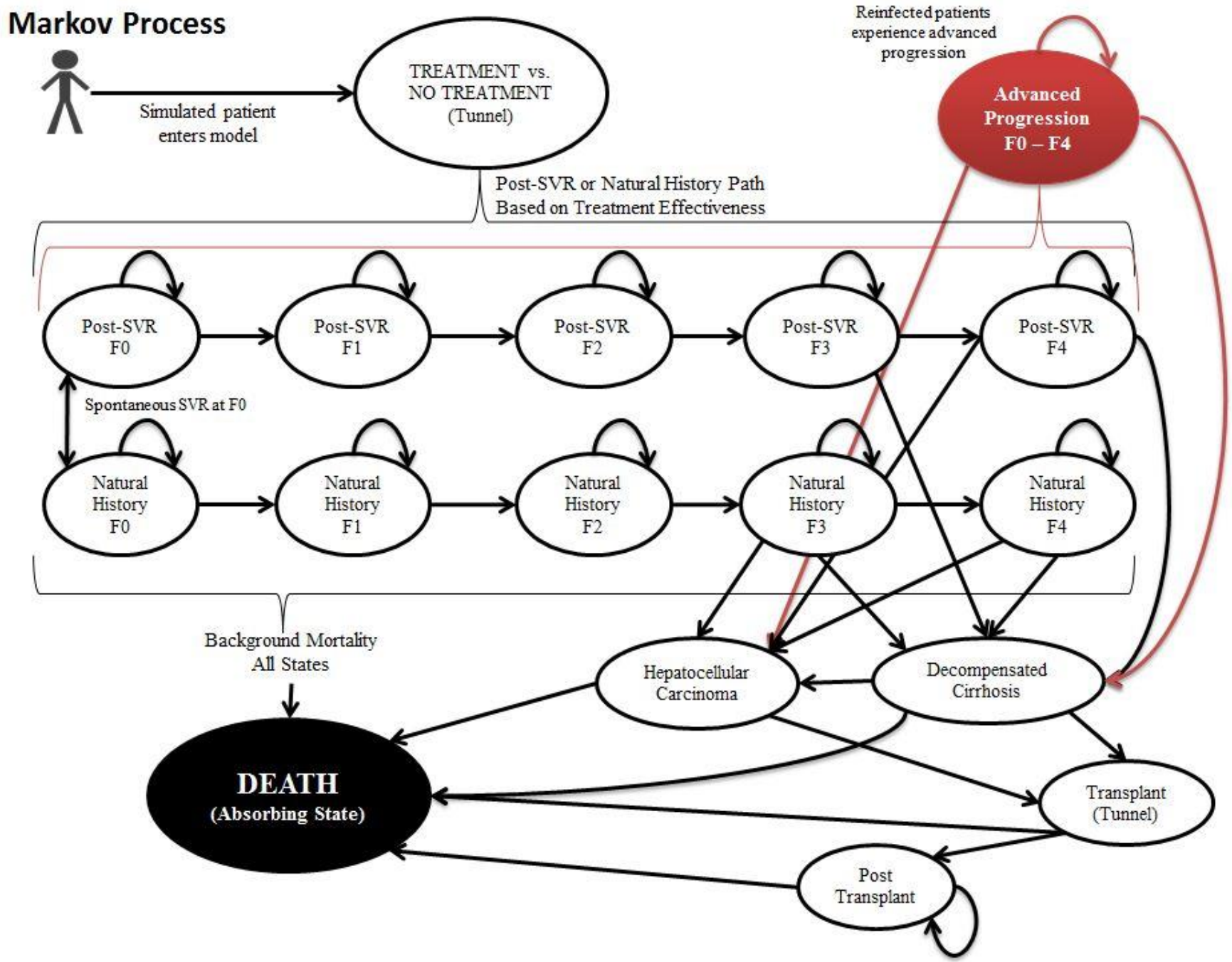


Other model features…

<u>Patient-Centered Trackers</u>

1 – Infected

2 – Absenteeism


Markov Process
Simulated patient enters model
TREATMENT vs. NO TREATMENT (Tunnel)
Reinfected patients experience advanced progression
Advanced Progression F0 – F4
Post-SVR or Natural History Path Based on Treatment Effectiveness
Post-SVR F0
Post-SVR F1
Post-SVR F2
Post-SVR F3
Post-SVR F4
Spontaneous SVR at F0
Natural History F0
Natural History F1
Natural History F2
Natural History F3
Natural History F4
Background Mortality All States
Hepatocellular Carcinoma
Decompensated Cirrhosis
DEATH (Absorbing State)
Transplant (Tunnel)
Post Transplant

Traditional vs. Patient-Centered CEA

Traditional HCV Models

- Focused on health-sector perspective
- Many published “societal” models still do not include indirect costs
- Effectiveness outcome predominantly QALY

Patient-Centered HCV Model

- Both health-sector and a limited societal perspective
- Includes indirect costs including patient/caregiver time, absenteeism, and presenteeism
- Reports cost/QALY, cost/ILY, and cost/work-days missed

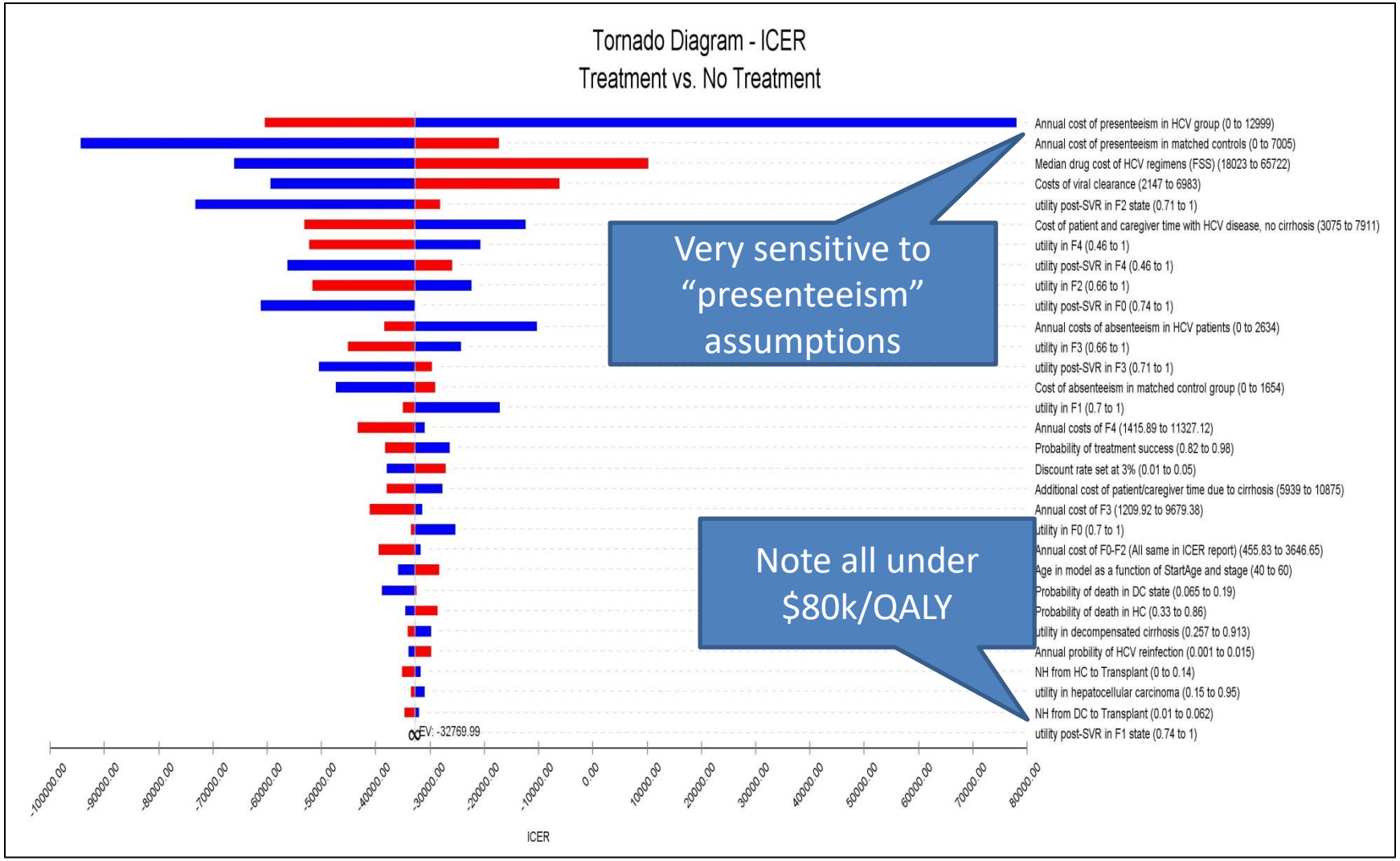
Mattingly et al. *PharmacoEconomics*. 2020;38(2):233-242.

Reference Case Results (10 year)

N = 10,000	No Treatment [95% CI]	Treatment [95% CI]	Difference[a]	Incremental Cost-Effectiveness Ratios
10 Year Model				
Cost				
Health Sector	24,096 [4,617–148,601]	49,174 [41,786–93,445]	25,078	$39,086/QALY gained $3,464/ILY avoided[b] $715/Work Days Missed avoided[b]
Societal	173,780 [62,946–301,160]	154,859 [92,724–235,354]	-18,921	Treatment Dominant[c]
Effectiveness				
QALYs	7.27 [2.43–8.48]	7.90 [3.89–8.65]	0.63	
ILYs	9.30 [3.00–10.00]	2.06 [1.00–10.00]	-7.24	
Work Days Missed	51.37 [16.58–55.25]	16.32 [5.53–55.25]	-35.05	

CI-Confidence Interval; QALYs-Quality-Adjusted Life-Years; ILYs – Infected Life-Years
a Mean values for [Treatment – No Treatment]
b [Treatment – No Treatment] x -1 to convert to cost per outcome avoidance
c Treatment Dominant refers to the treatment group being less costly and more effective than the No Treatment group

10 Year Societal Perspective



Limitations

- Using a Delphi panel approach
  - Does not force a “discrete choice”
  - No weighting of different variables
  - Defining and appropriate “agreement” level
- Societal perspective inputs
  - Very few studies to support the estimates for absenteeism and presenteeism
- ILY / Work-days missed
  - Unable to compare across diseases

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innopiphany

Why the patient perspective is important, challenges patients face navigating value processes

Deanna Darlington
Innopiphany, LLC.

May 9th, 2023

WOMAN OWNED | SBA HUBZONE CERTIFIED

Challenges of value assessments for the patient community

Not Patient-centered

- Most value assessments are focused on payer concerns about cost-reduction
- The patient perspective is rarely prioritized leading to a skewed view on value

Restrictive Methodologies

- The QALY can discriminate against vulnerable and historically marginalized populations
- Traditional scope of elements contributing to "value" has been limited
- Assessments fail to capture the entirety of the patient experience (*e.g.,* caregiver burden, stigma)

Engagement Challenges

- Interpreting long and technically complex reports and quickly composing an effective response is burdensome for advocates with limited resources
- Patients can typically only engage during select parts of an assessment

Access Barriers

- Typically not from the patient perspective: value assessments can undervalue new technologies & recommend restrictive payer policies

Coordination across patient groups essential

Evolution of Patient Voice in Value Assessment

	Un-named chronic disease	Multiple myeloma	Migraine
Coordination	Uncoordinated	Semi-coordinated	Coordinated
Resources	Lacking tools & resources and coordinated messages	Resourced and equipped with tools & education	Resourced and equipped with tools & education
Impact on Patient Access	ICER review does not recommend patient access	ICER review recommends patient access	ICER review recommends patient access
Overall patient engagement value			

Examples of patient-important value considerations

Disease transmission
Viral diseases have unique implications for public health and among families/partners

Healthy aging
Through innovative therapies, individuals want to be able to retain their quality of life as they get older

Health equity
Health equity considerations are essential but rarely prioritized and current value assessment metrics may be considered inequitable

Value of innovation
Current value assessment approaches deter rather than reward innovation

Patient choice
Patients want open access and to have the ability to use their choice of therapies

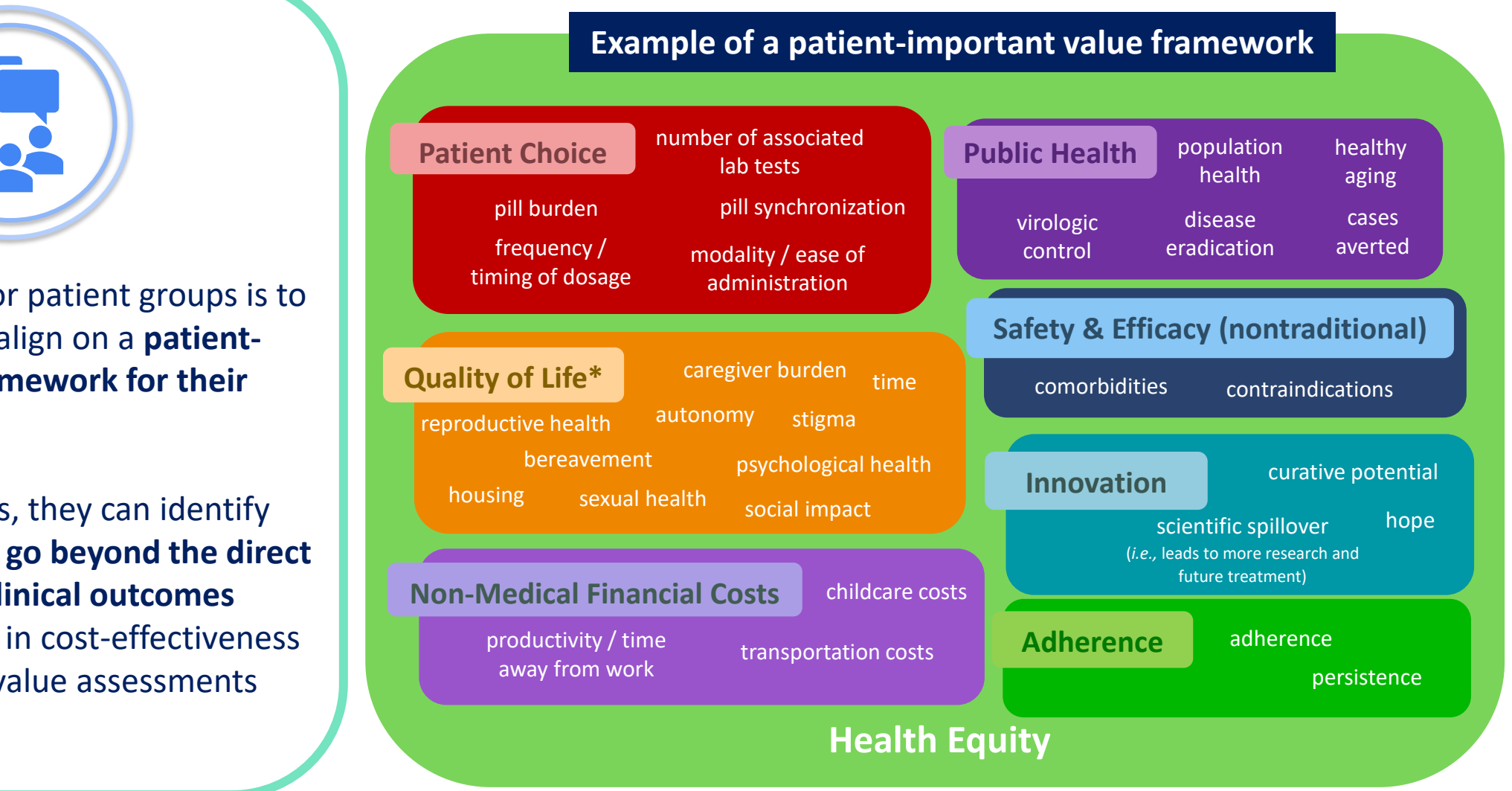
Historical access barriers
Patients living with some diseases have faced discrimination & stigma: maximizing access is needed to close such gaps

Developing patient-centered, disease specific frameworks

Patient-centeredness & innovative methods to expand the definition of value beyond the payer

A key opportunity for patient groups is to come together and align on a **patient-important value framework for their disease area**.

Through this process, they can identify value elements that **go beyond the direct medical costs and clinical outcomes** typically considered in cost-effectiveness analyses (CEA) and value assessments



Skaggs School of Pharmacy and Pharmaceutical Sciences

UNIVERSITY OF COLORADO
ANSCHUTZ MEDICAL CAMPUS

Multi-criteria decision analysis for understanding what's most important to patients

R. Brett McQueen, PhD, Assistant Professor and PDAAC member

pValue
Evidence for Decisions

Acknowledgements and disclosures

Acknowledgements for recent work on multi-criteria decision analysis

- Past investigators: Jonathan D. Campbell, PhD; Melanie D. Whittington, PhD
- Other pValue team members: R. Brett McQueen, PhD; Kavita V. Nair, PhD; Jeffrey Bennett, MD, PhD; Nick Mendola, MPH; Julie Parsons, MD
- pValue collaborators from Syreon Research Institute:
  - Zoltán Kaló, PhD; András Inotai, PhD; Ivett Jakab, MSc; Tamás Zelei, MD, PhD; Baher Elezbawy, PhD; Bertalan Németh, PhD, Antal Zemplényi, PhD

Disclosures:

- Institutional support from PhRMA Foundation, University of Colorado Data Science to Patient Value
- No funding from CMS or the Colorado Prescription Drug Affordability board, however, I am an advisory council member to CO PDAB
  - This presentation uses publicly available materials and I do not speak on behalf of the State of Colorado

pValue
Evidence for Decisions

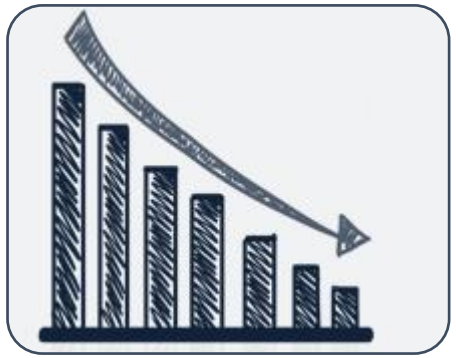
Hypothesis

- Supplemental decision aids that prioritize value elements will advance the application of health technology assessment
- Target audience: population-level, value assessment/coverage and reimbursement entities
- Stratification by perspective:
  - **Patient-centric: patient with condition and indicated for the treatment perspective**
  - Broader contextual value elements: plan member or general citizen perspective

Pharmaceutical Value (pValue) workshops

- *Aim: prioritize additional value elements from patient and plan member perspectives*
  - Step 1: Synthesize current value elements cited in value assessments and peer-reviewed literature
  - Step 2: Refine definitions with participants and discuss examples to address gaps in the literature
  - Step 3: Prioritize value elements in hybrid format
- Patient experience workshops in rare neurologic conditions
- Broader contextual value workshop among multi-stakeholder panel of experts from value assessment, pharmaceutical companies, patient advocates, and researchers

Two steps to prioritization

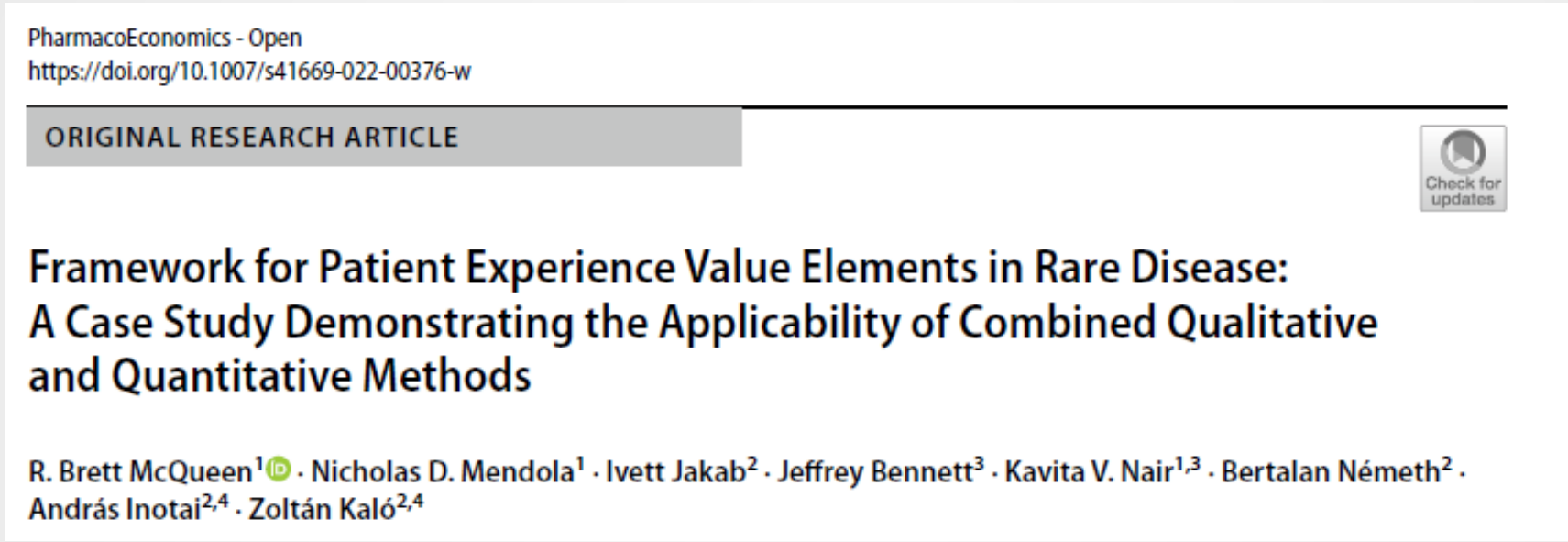


1. Ranking the value elements

2. Assigning weights

Edwards W, Barron FH. SMARTS and SMARTER: Improved simple methods for multiattribute utility measurement. Organ Behav Hum Decis Process. 1994; 60: 306-25.

Patient experience (PEx) perceptions and prioritization



PharmacoEconomics - Open
https://doi.org/10.1007/s41669-022-00376-w

ORIGINAL RESEARCH ARTICLE

Check for updates

Framework for Patient Experience Value Elements in Rare Disease: A Case Study Demonstrating the Applicability of Combined Qualitative and Quantitative Methods

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- Mixed methods grounded in multi-criteria decision analysis can efficiently help us understand what's important to patients and their experience with treatment

McQueen RB, Mendola ND, Jakab I, Bennett J, Nair KV, Németh B, Inotai A, Kaló Z. Framework for Patient Experience Value Elements in Rare Disease: A Case Study Demonstrating the Applicability of Combined Qualitative and Quantitative Methods. PharmacoEconomics – Open 2022.

Select results from neuromyelitis optica spectrum disorder (NMOSD)

Rank	Weight	Value Element	*Qualitative Response Example*
1	25%	Uncertainty about long-term benefits and safety of the treatment	*"The long term safety of treatment concerns me. I often wonder if the drugs to treat the illness will do more irreparable damage to my body than the illness might do."*
2	19%	Patient experience related to treatment regimen	*"…Reducing the number infusions is always a bonus when discussing treatments…I will deal with a little pain from infusion sites or any inconvenience…if the end result is preventing future attacks."*
3	14%	Patient's financial burden	*"…Out of pocket expenses being as high as they are, absolutely the cost is important. As well as the impact of treatment i.e. a whole day lost at work, etc."*

Colorado Multiple Institutional Review Board #21-3409

Preliminary findings comparing across disease

	NMOSD (N=8)	SMA (N=8)
1st most important PEx element	Uncertainty about long-term benefits and safety of the treatment	Ability to reach important personal milestones
2nd most important PEx element	Patient experience related to treatment regimen	Patient's financial burden
3rd most important PEx element	Patient's financial burden	Value of hope / Balance or Timing of Risks and Benefits

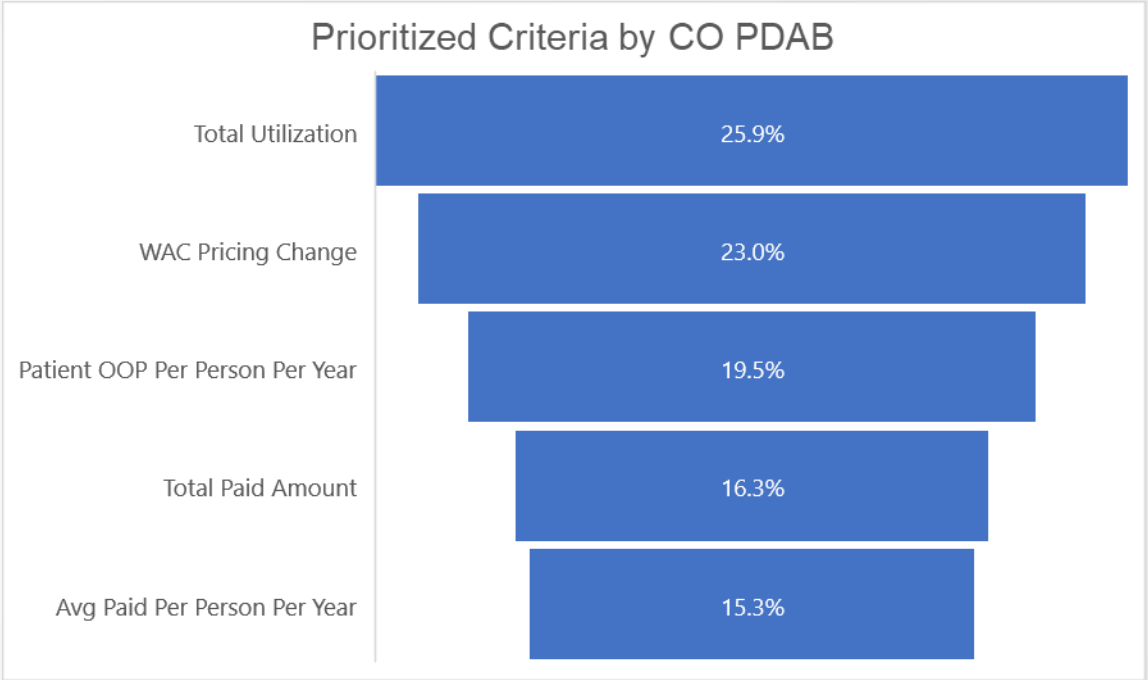
- Order and relative importance of PEx elements from a patient perspective seems to be disease-specific and **therefore is not transferable among disease areas**

Key takeaways from patient workshops

- Mix of qualitative and quantitative exercises facilitates deliberation on the most important value concepts
- Efficient and reproducible multi-stakeholder process allows for updating preferences over time
  - Through efficiency updates, the entire process can be done in less than 4 hours
- The framework is useful for multiple decision contexts

Priority setting for CO PDAB

- MCDA helpful for priority setting by board on March 31, 2023
  - Evidence generation and “sorting” the list of eligible drugs by weights
- Additional contextual factors will be included in public discussions with patients, providers, and other stakeholders



Summary and next steps

- Mixed methods grounded in multi-criteria decision analysis can facilitate structured deliberation and set priorities for qualitative and quantitative evidence
- Future research from pValue
  - Scoring functions with potential applications as modifiers, e.g., “patient-experience index”
  - Continue to test and refine framework in simulated assessments

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- https://pharmacy.cuanschutz.edu/research/research-centers/pvalue