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Improving healthcare decisions

Using Patient Preferences to Inform Healthcare Decision Making

Presented by the ISPOR Patient Preferences Good Practices Task Force

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- **Sebastian Heidenreich,** Associate Director, Patient Preferences, Evidera, London, England, UK
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- **Eric Low,** Independent Healthcare Consultant, Eric Low Consulting, Haddington, Scotland, UK

Question #1

How do you describe your role in the context of preferences?

1) Researcher
2) Clinician
3) Industry representative
4) Patient organization
5) Regulatory agency
6) HTA or payer agency
7) Patient, family member or caregiver of patient
8) Other

Please choose the ONE that best describes your primary role.

ISPOR Good Practices Task Force Reports on Preferences

- **Conjoint Analysis Applications in Health - A Checklist** (Bridges et al, 2011) #5 most cited article in *Value in Health*
- **Constructing Experimental Designs for Discrete-Choice Experiments** (Johnson et al, 2013) # 8 most cited article in *Value in Health*
- **Statistical Methods for the Analysis of Discrete-Choice Experiments** (Hauber et al, 2016) # 43 most cited article in *Value in Health*

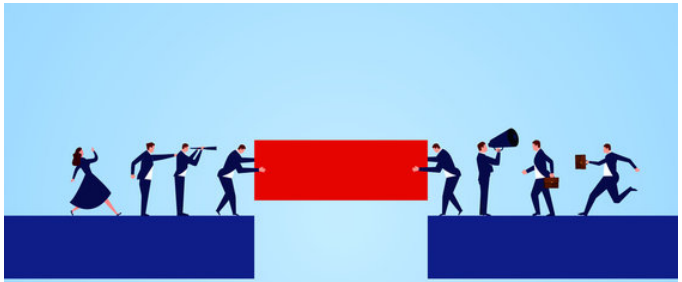
Task force currently underway in addition to this task force:

Quantitative Benefit Risk Assessment Emerging Good Practices

This Task Force Builds on….

- 3 ISPOR Good Practices Task Force Reports on preference methods
- ISPOR Special Interest Groups/Working Group activities
- Medical Device Innovation Consortium (MDIC) reports and framework
- FDA/CDRH guidance documents and case studies
- EMA reports and development of guidance
- IMI-PREFER consortium activities, publications, and case studies
- Research literature on preference methods and applied examples
- Efforts within HTAi and HTA agencies
- International Academy of Health Preference Research

Motivation and Rationale for this Good Practices Task Force



Gap: Improving Decision Making Using Preferences

- Need for a framework by which a variety of decision makers could use patient preferences
- Make patient preference studies more relevant to decision makers
- Provide guidance on the application of methods that are fit-for-purpose
- Improve decision making in healthcare

Change the conversation

Previous Preferences Task Forces:
Improving methods

This Task Force:
Using preferences in decision making

Question #2

What elements should be included in the framework?

1) The context
2) The population
3) The method
4) The data
5) The purpose
6) Additional elements not listed above
7) None of the above

Please choose ALL that apply.

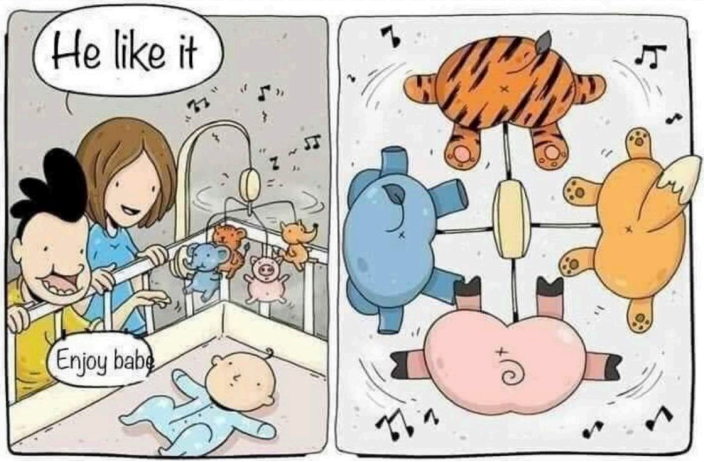
2

Eric Low
Independent Healthcare Consultant
Eric Low Consulting
Haddington, Scotland, UK

What is the problem?

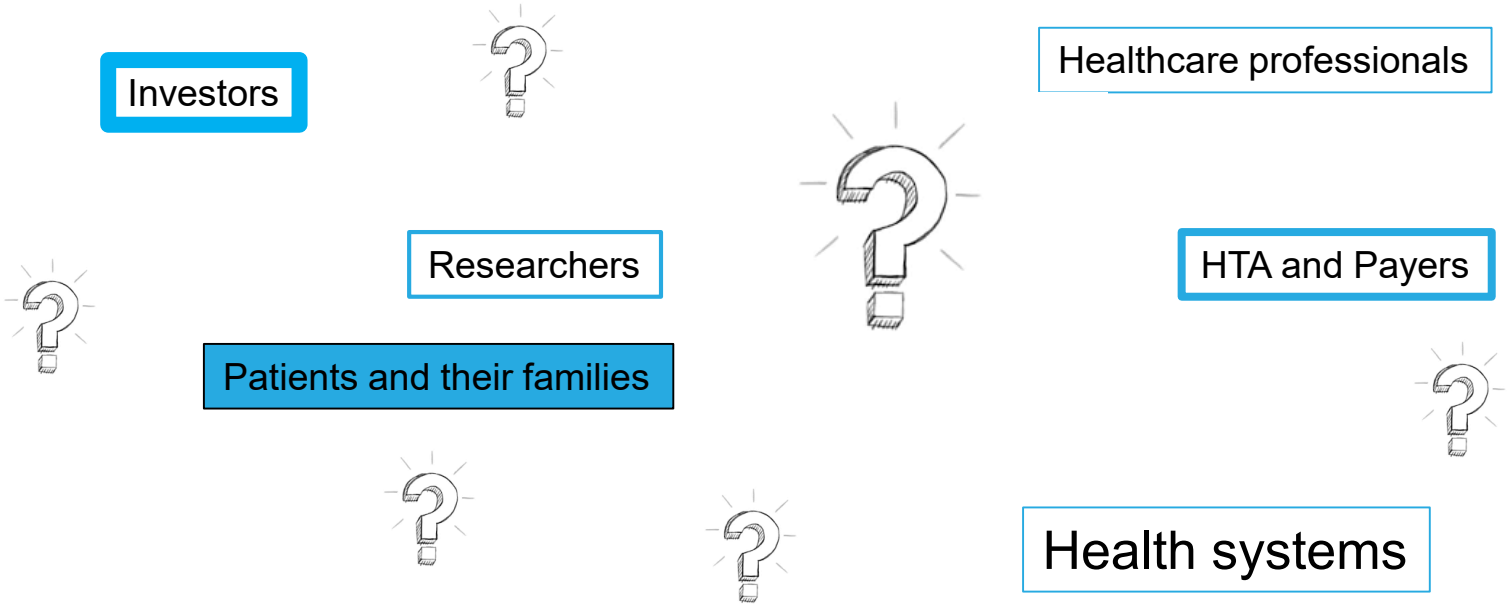
- There is no cure for most diseases. Therefore, treatments need to be viewed in terms of how long they are able to control a disease or relieve symptoms and how they affect a patient's quality of life.
- For some treatments, there is not enough clinical evidence or experience to know exactly what to expect. Furthermore, no two patients are alike. Predicting results for most treatments is a matter of probabilities – there are no guarantees.
- Many treatments have potentially serious side-effects; some treatments can lead to complications that may prove to be fatal. Patients, their families, researchers and healthcare professionals may have different perspectives and preferences about what constitutes acceptable risk. They may also have different views about what is an acceptable outcome of treatment.
- Most health systems have very scarce resources and need to allocate these to ensure the most health benefit for the population as a whole.
- R&D is almost always eye-wateringly expensive. A phase III clinical trial can often cost in excess of $300-$400m, but still most fail. For those that succeed, it's challenging to interpret results.

Therefore, it is important to ask patients about their preferences.

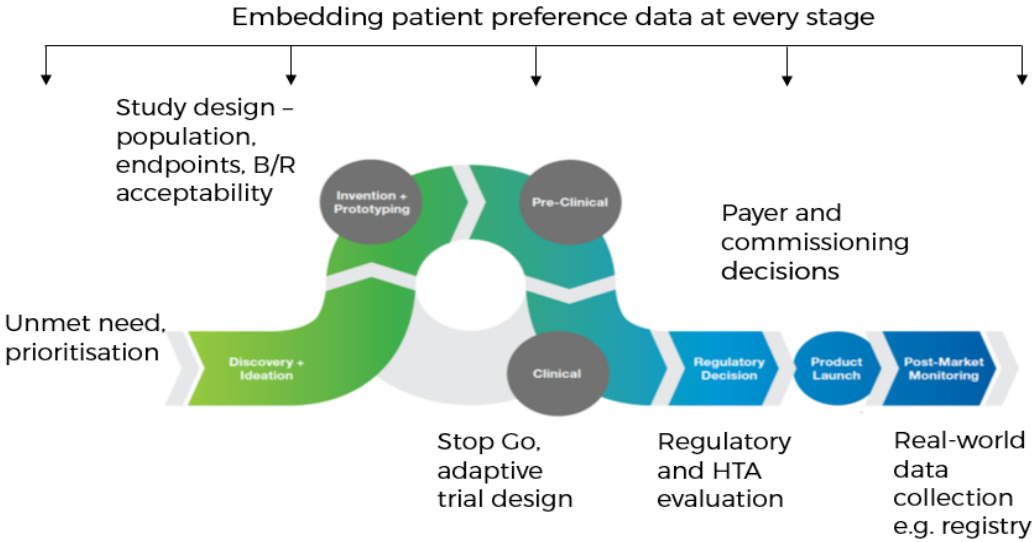


Thank you to Zac Pemberton-Whiteley CEO of Leukaemia Care for the cartoon.

Who can benefit from patient preference data?



Patient preference research should be embedded across the entire bench to bedside continuum.



If we expect patients to comment on the benefits at the evaluation phase we need to ensure that the endpoints are meaningful to them in the first place.

Patient preference data can shine a very bright torch on what matters most to patients.

Amyloidosis Research Consortium UK

Burden of disease and perspectives on treatment

Summary report from research with hereditary transthyretin amyloidosis (hATTR) patients and carers

Amyloidosis Research Consortium UK

www.arci.org

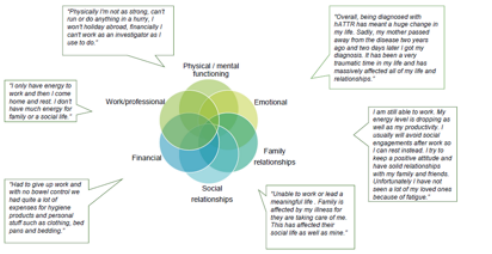
July 2018

Patients experience a high, multi-systemic symptom burden

Amyloidosis Research Consortium UK

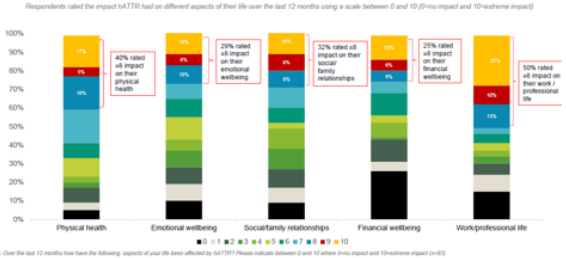
Impacts on quality of life domains are inextricably linked

Amyloidosis Research Consortium UK



Many different areas of patients' lives are affected by hATTR

Amyloidosis Research Consortium UK



Patient preference data can shine a very bright torch on what matters most to patients.

Patient Preference and Adherence
Dovepress
open access to scientific and medical research
Open Access Full Text Article
ORIGINAL RESEARCH

Myeloma Patient Value Mapping: A Discrete Choice Experiment on Myeloma Treatment Preferences in the UK

This article was published in the following Dove Press journal:
Patient Preference and Adherence

Simon Fifer[1]
Jayne Galinsky[2]
Sarah Richard[3]

[1]Community and Patient Preference Research (CaPPRe), Sydney, NSW, Australia; [2]Myeloma UK, Edinburgh, Scotland; [3]PRMA, Edinburgh, Scotland

Background: Myeloma is an incurable life-threatening hematological cancer. Recent treatment developments have seen improvements in survival; however, while patients are living longer, they are living with symptoms and treatment side effects.

Objective: To evaluate myeloma patients' preferences for treatment using a discrete choice experiment (DCE). This study set out to define the relative importance of key treatment attributes, characterize the risk-benefit trade-offs in patients' decision-making, and to analyze the predictive power of basic demographic factors.

Methods: Four hundred seventy-five myeloma patients in the UK were invited to participate by Myeloma UK. Data were collected using DCEs through an online survey. The DCEs presented patients with 10 choice scenarios, each with 2 treatment options described by 7 attributes, and a "no treatment" option. The DCE data were modelled using a latent class model (LCM). The effects of demographic characteristics were also examined.

Results: Not surprisingly, average survival was most important to all patients but there were significant contrasts between the class preferences. The LCM revealed two classes of patients. Patients in Class 1 placed greater importance on average survival and mild-to-moderate side effects, whereas patients in Class 2 focused on the mode of administration and the average out-of-pocket costs. Patients living with others and those diagnosed in the last 5 years were more likely to be in Class 1.

Conclusion: Different treatment features were not valued equally among all myeloma patients. This has important implications for healthcare policy decisions and could be used to guide decisions around the value of new myeloma medicines.

Keywords: discrete choice experiment, patient preferences, myeloma, health technology assessment, dashboards

Factors	Treatment A	Treatment B	Neither of these treatments
Average overall survival	7 years (1 year, 3 years, 5 years, **7 years**, 9 years)	3 years (1 year, **3 years**, 5 years, 7 years, 9 years)	
Average remission period	5 years 3 months (1 year, 3 years, 5 years, 7 years, 9 years)	9 months (1 year, 3 years, 5 years, 7 years, 9 years)	
Mild or Moderate side-effects	60 out of 100 (60%) risk — Lasting up to 2 mths	20 out of 100 (20%) risk — Lasting up to 2 mths	
Severe side-effects	5 out of 100 (5%) risk — Lasting longer than 2 mths	10 out of 100 (10%) risk — Lasting up to 2 mths	
How treatment is taken	Intravenous drip (Hospital / clinic) Time: 2-3 hours	Subcutaneous Injection (Hospital / clinic) Time: 15 mins	
Frequency of taking treatment	Fortnightly	Weekly	
Average out of pocket costs to you over a year	£0	£0	
I would choose	○ Treatment A	○ Treatment B	○ Neither

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Andrii Danyliv
Head HEOR Innovation, Novartis
Basel, Switzerland

Disclaimer

- Andriy Danyliv, PhD, is an **employee** of **Novartis AG.**
- These slides are based on publicly available information.
- The views and opinions expressed in this presentation are those of the presenter and do not necessarily reflect the official policy or position of Novartis or any of its officers.
- The content of this slide deck is accurate to the best of the presenter’s knowledge at the time of production.

ISPOR SIG Report: Actual use of preference data in decision-making

Themed Section: Applications of Health Preferences Research

Health Preference Research in Europe: A Review of Its Use in Marketing Authorization, Reimbursement, and Pricing Decisions—Report of the ISPOR Stated Preference Research Special Interest Group

Kevin Marsh, PhD,* Janine A. van Til, PhD, Elizabeth Molsen-David, RN, Christine Juhnke, MA, Natalia Hawken, PhD, Elisabeth M. Oehrlein, PhD, MS, Y. Christy Choi, PharmD, Alejandra Duenas, PhD, Wolfgang Greiner, PhD, Kara Haas, MD, MPH, FACS, RAC, Mickael Hiligsmann, PhD, Kimberley S. Hockley, PhD, Ilya Ivlev, MD, PhD, Frank Liu, PhD, Jan Ostermann, PhD, Thomas Poder, PhD, Jiat L. Poon, PhD, Axel Muehlbacher, PhD

VALUE HEALTH. 2020; 23(7):831–841

Examines European decision makers' consideration and use of quantitative preference data

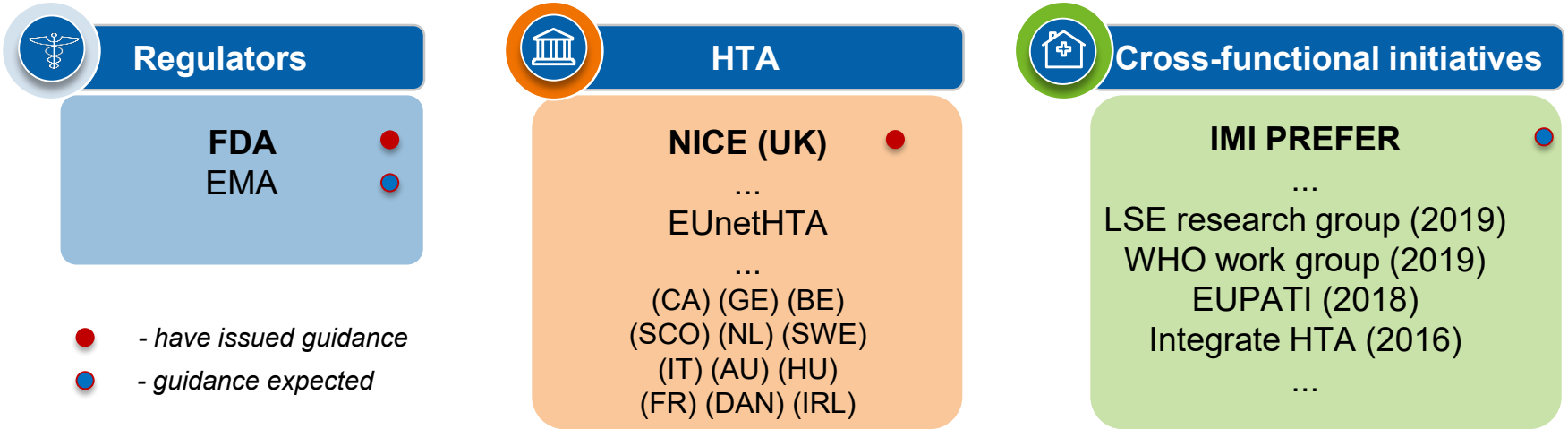
- documentary evidence identified through a literature and regulatory websites review, and via key opinion leader outreach;
- a survey of staff working for agencies that support or make healthcare technology decisions

Key findings:

- Preference data utilization was identified in 22 countries and at European level (but not for market authorization)
- The most prevalent use is to inform health-related quality of life (19 countries)
- **Other uses:**
  - Value other [than QALY] impact on patients (EN&WAL, NL, SC; GE; SE)
  - Incorporate non-health factors into reimbursement (AT, HU, IT, BE, FR)
  - Estimate opportunity cost (NL, SE)
- Pilot projects in 6 countries with the focus on MCDA and choice-based methods (BE, DK, GE, IE, NL, UK)
- Need for better alignment between decision makers

There is no single well-established guidance for the use of patient preferences in decision-making.

- Regulators, HTA bodies, as well as multi-stakeholder initiatives, expressed their views in guidance documents and/or statement papers.
- The latest multi-stakeholder initiative, **IMI PREFER**, plans to deliver recommendations in 2021.



FDA 2016 PPI guidance is a result of multi-stakeholder collaboration and informs further guidance of their use in *benefit-risk assessment.*

2012

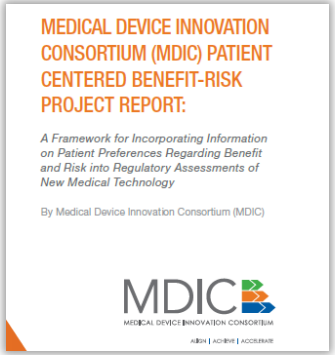
Center for Devices and Radiological Health's (CDRH) Guidance on Benefit-Risk Assessment

2013

FDA launched the "Patient Preference Initiative"

2015

CDRH and CBERs' collaboration with Medical Device and Innovation Consortium (MDIC) issued a report in 2015:


MEDICAL DEVICE INNOVATION CONSORTIUM (MDIC) PATIENT CENTERED BENEFIT-RISK PROJECT REPORT:

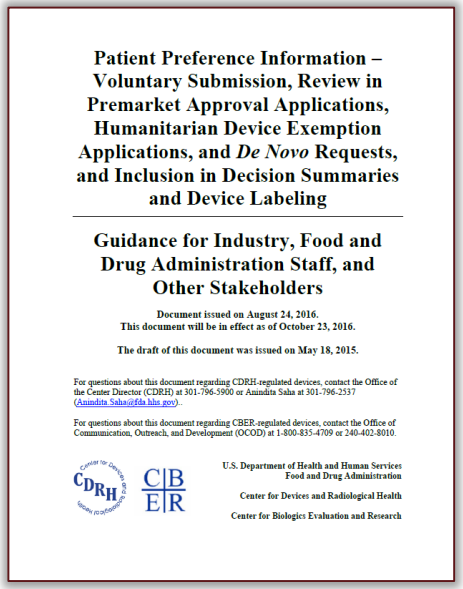
A Framework for Incorporating Information on Patient Preferences Regarding Benefit and Risk into Regulatory Assessments of New Medical Technology

By Medical Device Innovation Consortium (MDIC)

MDIC
MEDICAL DEVICE INNOVATION CONSORTIUM

2016

Patient Preference Information


Patient Preference Information – Voluntary Submission, Review in Premarket Approval Applications, Humanitarian Device Exemption Applications, and *De Novo* Requests, and Inclusion in Decision Summaries and Device Labeling

Guidance for Industry, Food and Drug Administration Staff, and Other Stakeholders

Document issued on August 24, 2016.
This document will be in effect as of October 23, 2016.

The draft of this document was issued on May 18, 2015.

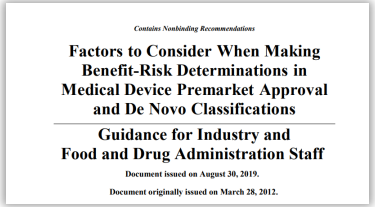
For questions about this document regarding CDRH-regulated devices, contact the Office of the Center Director (CDRH) at 301-796-5900 or Anindita Saha at 301-796-2537 (Anindita.Saha@fda.hhs.gov).

For questions about this document regarding CBER-regulated devices, contact the Office of Communication, Outreach, and Development (OCOD) at 1-800-855-4709 or 240-402-8010.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Center for Biologics Evaluation and Research

2017 - 2019

CDRH


Contains Nonbinding Recommendations

Factors to Consider When Making Benefit-Risk Determinations in Medical Device Premarket Approval and De Novo Classifications

Guidance for Industry and Food and Drug Administration Staff

Document issued on August 30, 2019.

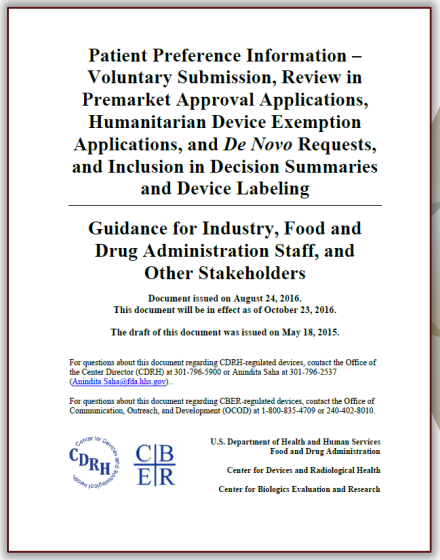
Document originally issued on March 28, 2012.

MDIC

Patient Centered Benefit-Risk (PCBR) Framework
by MDIC

FDA

PPI guidance recommends: voluntary submissions of PPI, both qualitative and quantitative, may be useful with benefit-risk assessment



Patient Preference Information – Voluntary Submission, Review in Premarket Approval Applications, Humanitarian Device Exemption Applications, and *De Novo* Requests, and Inclusion in Decision Summaries and Device Labeling

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U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Center for Biologics Evaluation and Research

2016

- **Purpose & uses:**
  - Identify the most important benefits & risks
  - Relative importance of the attributes (incl. MCI effect size)
  - Help understand heterogeneity (subgroups)
- **PPI may be useful** when patient decisions are **preference sensitive** while:
  - multiple options exist, none is clearly superior;
  - evidence is considerably uncertain or variable;
  - patients' views are heterogeneous or differ from HCPs
- The guidance outlines recommended qualities of patient preference studies (PPS) to be included as valid scientific evidence.
- Differentiates PPI from PRO and drafts accepted methods for PPI.
- The guidance helps to understand *"how PPI may inform decision making via several examples".*

EMA, thus far, has viewed *'preferences'* in the context of *decision theory* exploring several preference elicitation methods...

Swing weighting or **MACBETH** in MCDA context (Benefit-Risk Methodology project 2009-2014).
Conjoint analysis was deemed as (moderately) useful to explicate trade-offs among effects, especially for eliciting patient preferences.

More recently, EMA has been exploring the use of **stated preferences** in multiple myeloma patients (swing weighting).

2025

2008

European Medicines Agency
London, 19 March 2008
Doc. Ref. EMEA/CHMP/15404/2007
COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE (CHMP)

Recommendations:
... explore further methodologies for benefit/risk analysis (BRA), including a wide range of quantitative and semi-quantitative tools, and involving experts and assessors.

2009 - 2014

The European Medicines Agency
Pre-authorisation Evaluation of Medicines for Human Use
London, 12 March 2009
Doc. Ref. EMEA/108979/2009

Benefit-Risk Methodology Project

Development and testing of tools and processes for balancing multiple benefits and risks as an aid to informed regulatory decisions about medicinal products

WP1: Current practice of BRA
WP2: Review of current tools/methods
WP3: Field tests
WP4: BRA tool development
WP5: Training package

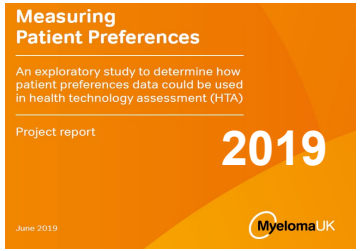
2018

The Oncologist
Health Outcomes and Economics of Cancer Care
Individual Trade-Offs Between Possible Benefits and Risks of Cancer Treatments: Results from a Stated Preference Study with Patients with Multiple Myeloma

"Although the usefulness of stated preference studies in drug regulation is still not well established, such studies, along with other methods such as focus groups and expert opinions, have the potential to become an important tool for gathering patient views in a systematic way to inform regulatory and treatment decisions"

- To develop guidance on the **roles of patient preferences** in regulatory decisions
- To consider and build on existing good practice guidance (such as that issued by **ISPOR**), guidance provided by the **FDA**, and the results of **IMI PREFER**

NICE's view on PPI in HTA has evolved to a clear vision in 2020.



The aim of this project was to undertake research to explore how quantitative methodology for eliciting patient preferences might be used in HTA.

Key Points

- Review of the PP literature and engagement with the stakeholders, primarily in myeloma.
- PPI is mostly anecdotal, and it is not always obvious how it impacts decision making.
- There is a growing interest in quantitative techniques to improve transparency.
- There is no 'one-size-fits-all' solution for generating PP data.
- DCE stands out as the most robust approach to elicit patient preferences for different treatment options, but it may not always be appropriate.
- Selection of the most appropriate method may depend on the specific research question.
- Not every recommendation will benefit to the same degree from PPI.

Use of Patient Preference Studies in HTA Decision Making: A NICE Perspective

Jacoline C. Bouvy[1] · Luke Cowie[2] · Rosemary Lovett[1] · Deborah Morrison[3] · Heidi Livingstone[4] · Nick Crabb[1,3]

2020: The Patient - Patient-Centered Outcomes Research
https://doi.org/10.1007/s40271-019-00408-4

Key Points

- Methods that allow the measuring of patient preferences in a quantitative manner might offer **valuable insights** to health technology assessment bodies, especially when patient preference studies are **representative of the wider patient population**.
- Currently, the National Institute for Health and Care Excellence **does not see a role for quantitative patient preference data** ...
- Notwithstanding, patient preference studies could be considered alongside other types of evidence, especially for appraisals that involve **distinctly different treatment options** or are **indicated for a heterogeneous population** or **for technologies that have important non-health benefits**.

IMI PREFER – Patient preferences in benefit risk assessments during the drug life cycle

prefer. PATIENT PREFERENCES

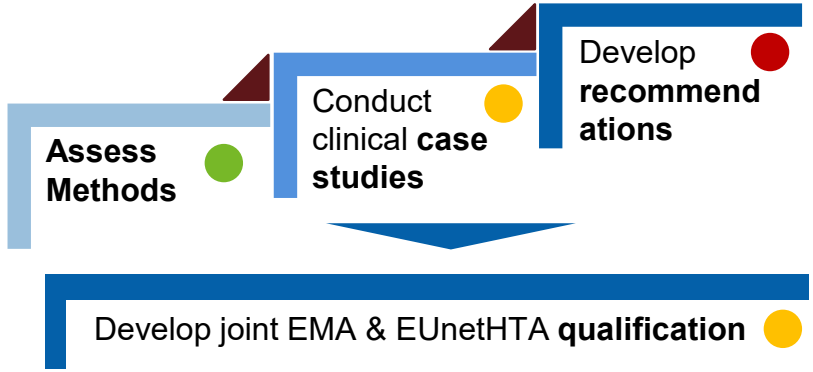
Objectives

Establish **recommendations** to **support development of guidelines** for:

- Industry
- Regulatory authorities
- HTA bodies & payers

on how and when to include patient preferences on benefits and risks of medical products.

Process



Case studies

3 Core Academic case studies
- Rheumatoid Arthritis (RA)
- Neuromuscular Disorders (NMD)
- Lung cancer

5 Academic case studies
- Glucose monitoring
- Gene therapies
- Attribute attendance in DCE
- PP for biologics
- Multiple Myeloma

3 Industry case studies
- COPD
- Antithrombotic treatments following MI
- Osteo-Arthritis and lower back pain

IMI PREFER – Key work streams and expected output

prefer. PATIENT PREFERENCES

- Finding out what stakeholders want
  - literature review,
  - interviews and focus group meetings with patient organisations, physicians, regulatory authorities, health technology assessment bodies, industry experts and academics
- Identifying methods and criteria
  - In total, **32 unique methods** were identified [a]: 10 exploration and 22 elicitation
  - IMI PREFER shall focus on **5 elicitation methods** that cover most uses: *DCE*, *BWS object case and profile case*, *threshold technique*, and *swing weighting*

- **Final Recommendations** key components:
  - Framework for patient preference studies
  - Recommendations on how to involve patients and other stakeholders
  - Preference exploration and elicitation methods

a Soekhai V et al. Methods for exploring and eliciting patient preferences in the medical product life cycle: a literature review. Drug Discovery Today 24 (7) 2019: 1324 – 1331

4

John F. P. Bridges
Professor, Departments of Biomedical Informatics, Ohio State University Columbus, OH, USA

Rationale for the Framework

- Many methods and approaches are now available to generate or synthesize **information on patient preferences.**
- There is a growing number of **methodological guidance** documents for researchers to improve studies, techniques, and publications.
- The **greatest imperative** now is to make information on patient preferences more useful to decisions makers (broadly defined) and in a variety of specific decision-making contexts.

What do we need?

- Information on patient preferences needs to be **fit-for-purpose.**
  - Relevant and useful to decision makers
  - Critical appraisal, validity and reliability, transparent
- We need tools and resources to:
  - Better communicate with decision makers and stakeholders
  - Focus of the utility of our data for decisions makers and decisions in healthcare
  - Engage all relevant stakeholders
  - To promote a **culture change** (move from getting published to getting used)

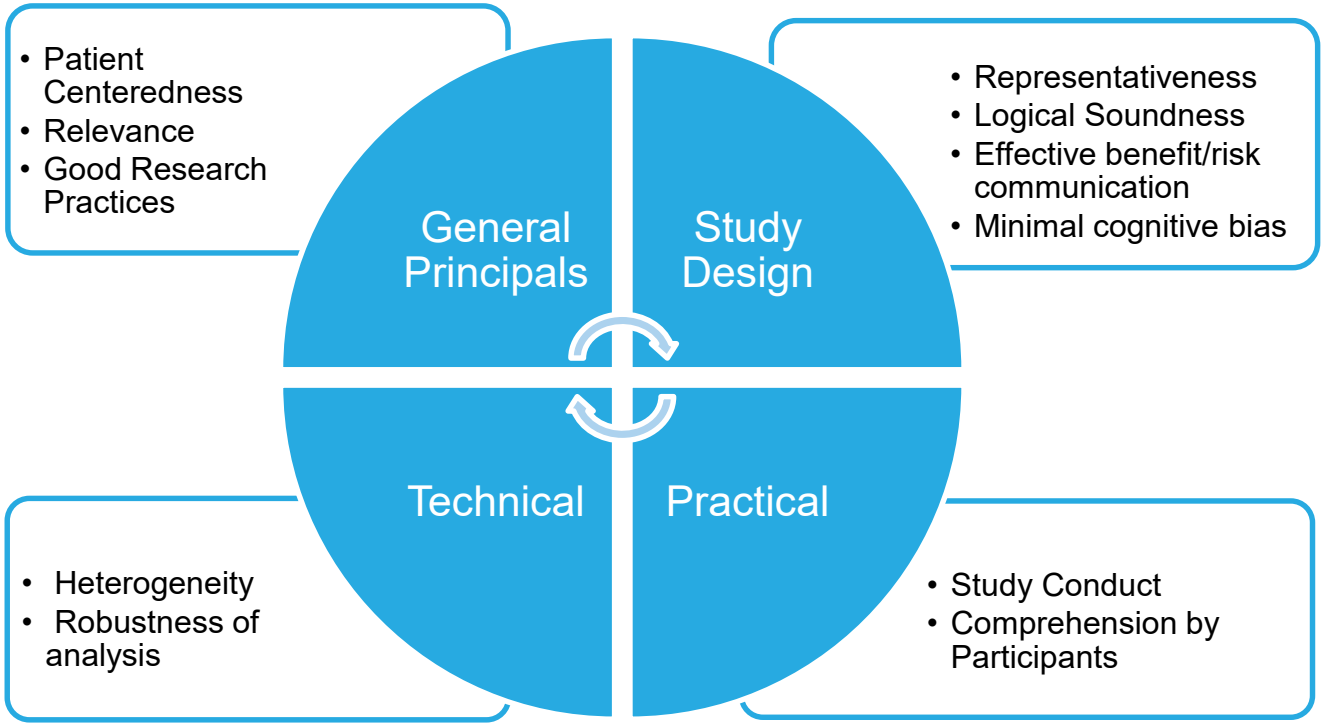
What type of Framework?

- Simple framework
  - PICOTS
  - REAIM
- Complex frameworks
  - Consolidated Framework for Implementation Research (CIFR)
  - International Patient Decision Aid Standards (IPDAS)
- Reporting of studies
  - CONSORT
  - PRISMA
  - CHEERS

REAIM

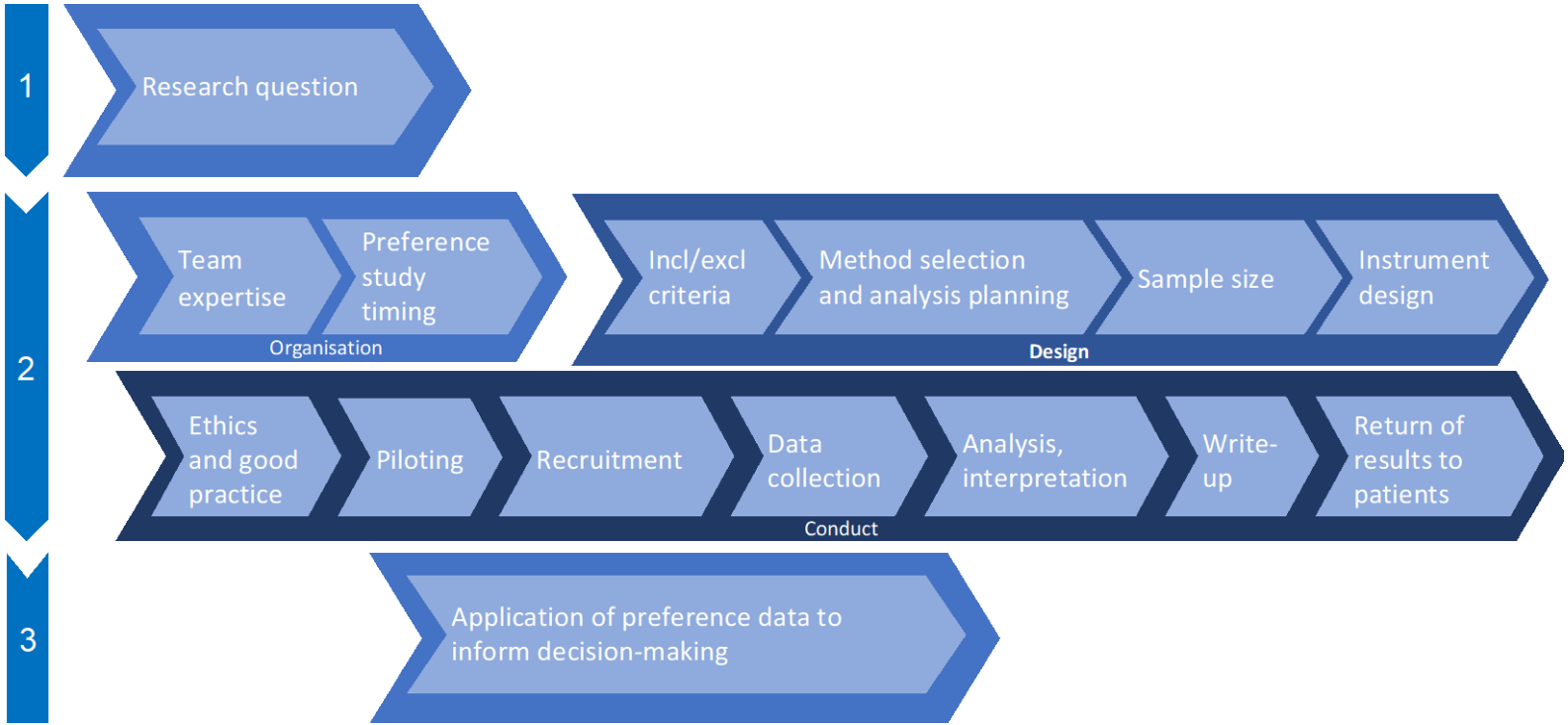
- **Reach** – How do I reach the targeted population with the intervention?
- **Effectiveness** – How do I know my intervention is effective?
- **Adoption** – How do I develop organizational support to deliver my intervention?
- **Implementation** – How do I ensure the intervention is delivered properly?
- **Maintenance** – How do I incorporate the intervention so that it is delivered over the long term?

CDRH guidance

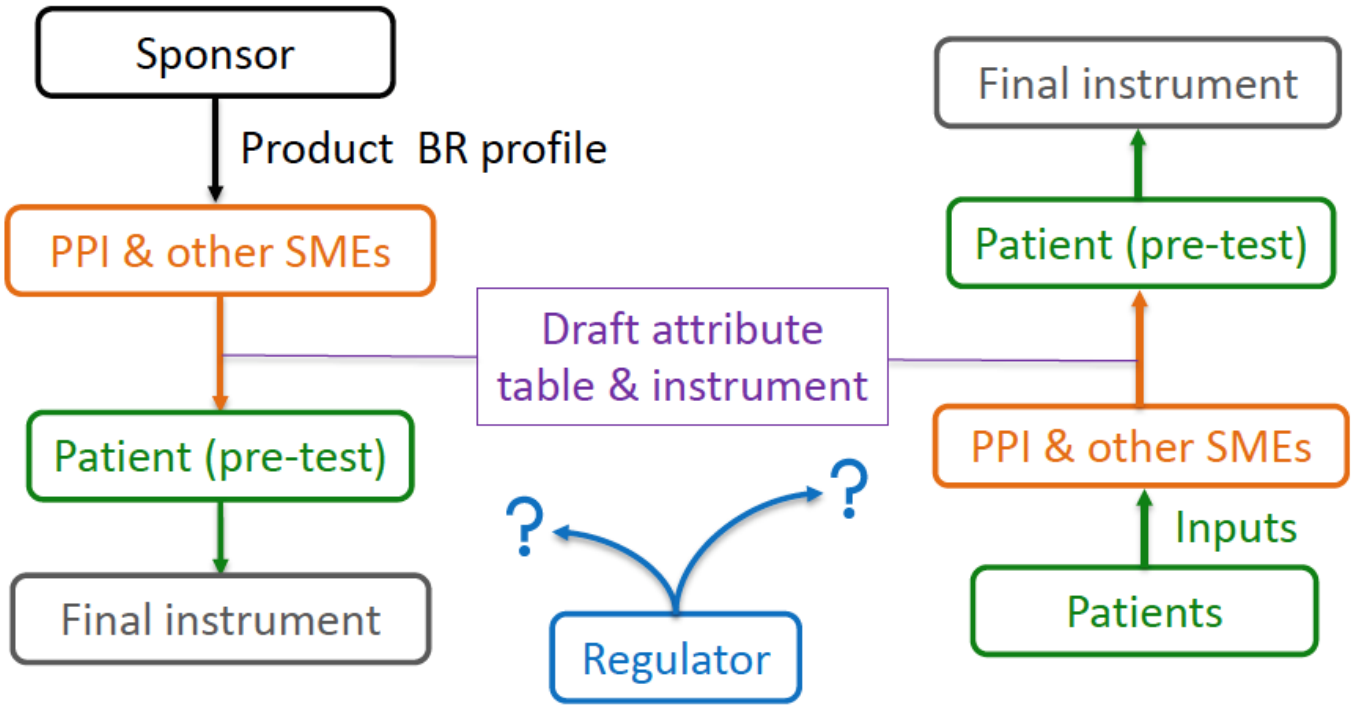


Virtual ISPOR-FDA Summit 2020: Using Patient-Preference Information in Medical Device Regulatory Decisions: Benefit-Risk and Beyond. Patient Preference Information – What It Is and What It Is Not. https://www.ispor.org/conferences-education/conferences/past-conferences/ispor-fda-summit-2020. Modified from FDA Final Patient Preference Guidance Document. August 24, 2016. https://www.fda.gov/media/92593/download

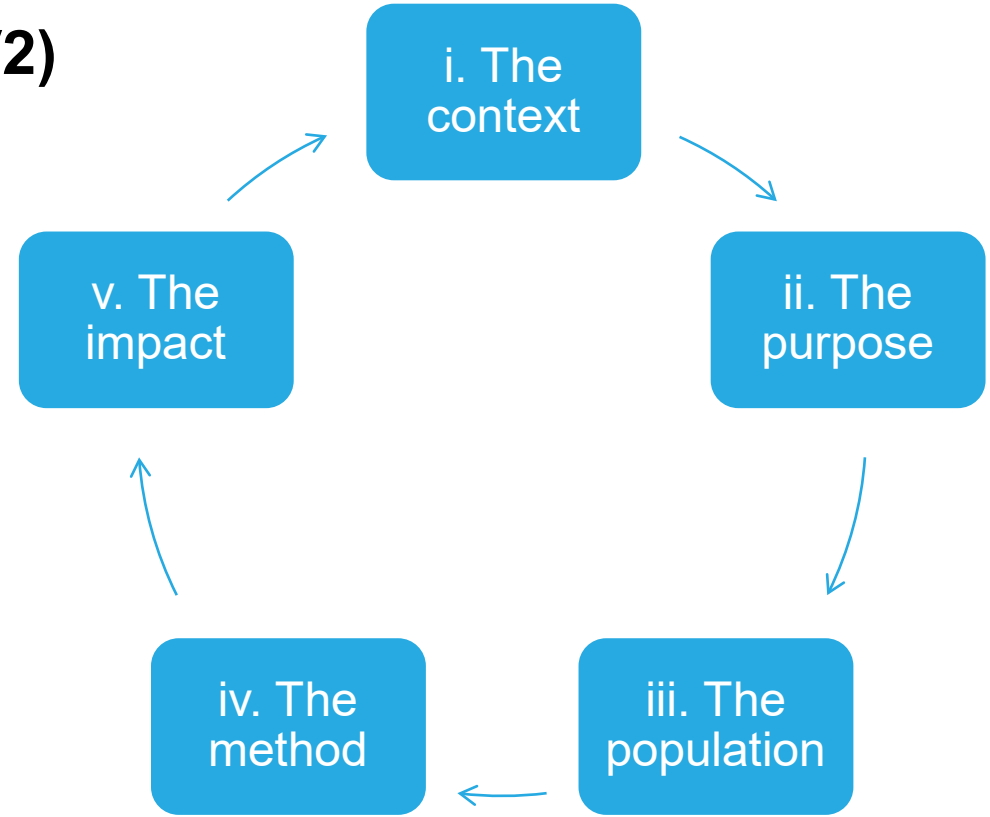
IMI-PREFER Framework (*work in progress*)



Top down or bottom up (Post MDIC)



ISPOR Framework (V2)



ISPOR Framework (V2) – Key questions

- i. **The context** – How do decision get made, what are the legal, ethical, and social constraints, and what stakeholders are involved?
- ii. **The purpose** – What role might preference information play in decision making and how/when/why is it most useful to decision makers?
- iii. **The population** – To whom does the decision apply and to which people does the decision directly and indirectly effect?
- iv. **The method** – How are decision makers and stakeholders engaged in choosing, applying, and critically evaluating the approach taken?
- v. **The impact** – Are the data presented so as to maximize the utility and value of the information for decision makers and stakeholder?

Next steps

- We want **broad input** by engaging the ISPOR membership.
- Continue to refine and **build consensus** on the Framework.
- Draft **task force report** (<5,000 words)
- Again, get **broad input** from the ISPOR membership.
- Finalize and publish the task force report in ***Value in Health***

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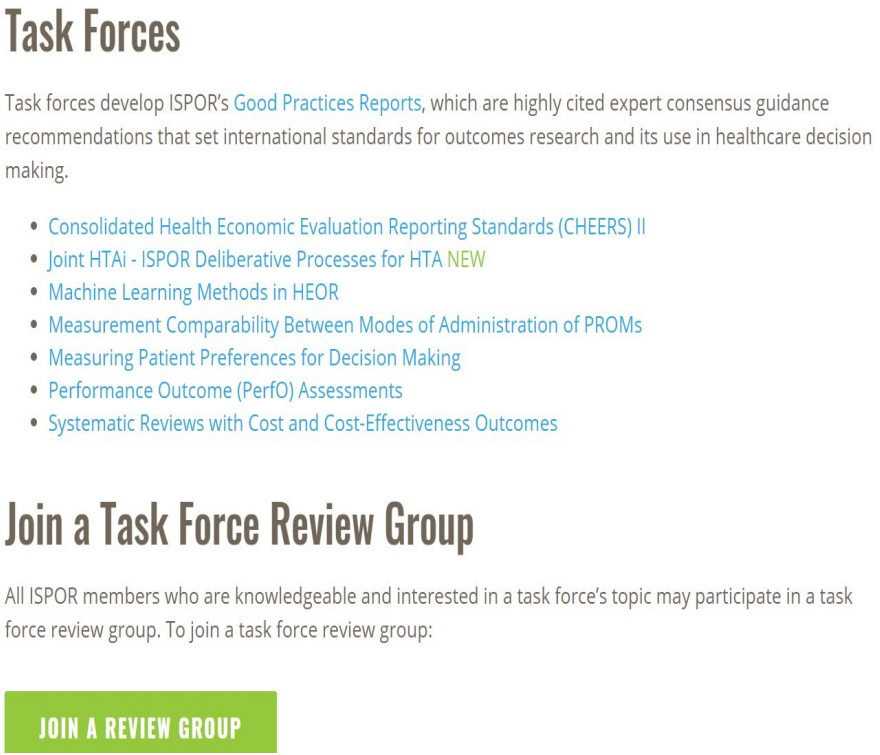

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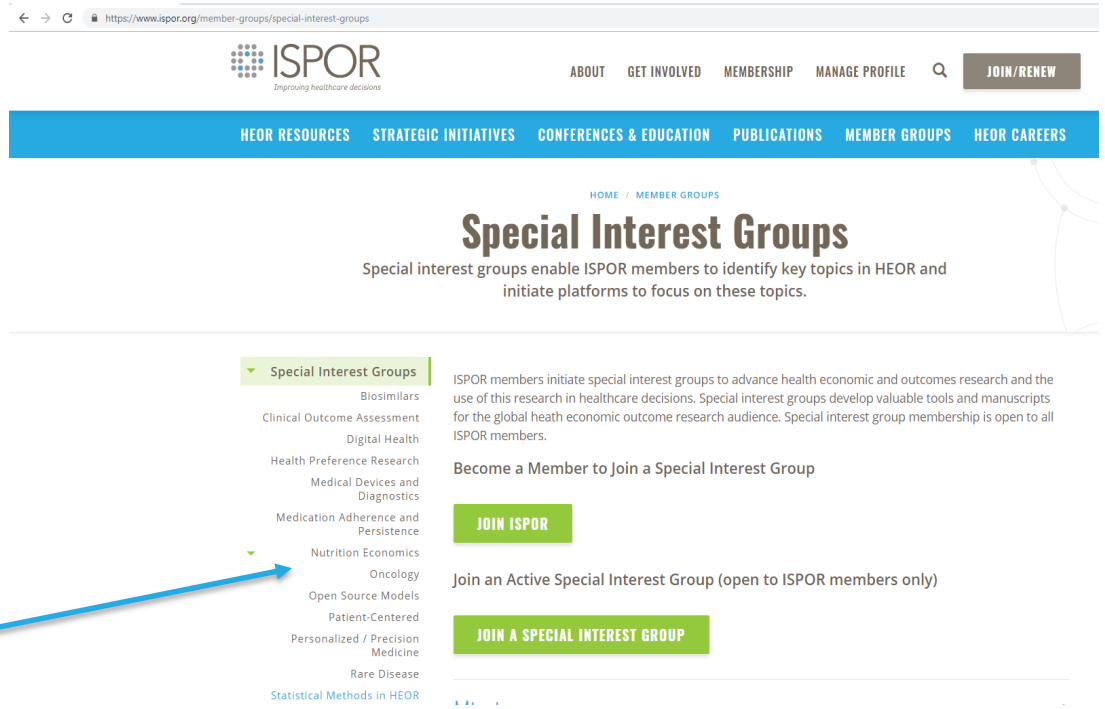

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Thank you

Please feel free to email any follow-up questions or comments on content

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