HTA from a Patient Perspective

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#background

some basics on the evaluation frameworks

Evaluation criteria

Framework review

- The evaluation of drugs has been a common theme in HTA (Health Technology Assessment).
  - Metrics for the evaluation of drugs are variable, but they mostly include efficacy/effectiveness (and safety), cost (and cost-effectiveness)
  - Unmet Need is the most frequent element used in Drug evaluations

- **However**
  - **QoL is not universally used nor accepted**
  - **Patient's perspective is not a must**

HTA Criteria adopted in selected countries according th Healthcar System model

NHS (Beveridge) (n = 9 countries)	NHI (n = 3 countries)	SHI (Bismarck) (n = 7 countries)
unmet need (n = 7)	unmet need (n = 3)	unmet need (n = 5)
conditional approval (n = 4)	conditional economic analyses (n = 2)	conditional economic analyses (n = 4)
disease nature (n = 4)	disease nature (n = 2)	disease nature (n = 4)
impact on organizational aspects (n = 4)	patient participation (n = 2)	expedited process (n = 4)
innovation (n = 4)	conditional ICER threshold (n = 1)	flexible evidence requirement (n = 4)
real-world data collection (n = 4)	flexible evidence requirement (n = 1)	budget impact (n = 3)
additional benefit (n = 3)	price negotiation (n = 1)	conditional approval (n = 3)
conditional ICER thresholds (n = 3)	real-world data collection (n = 1)	conditional ICER threshold (n = 3)
flexible evidence requirement (n = 3)	risk sharing (n = 1)	additional benefit (n = 2)
impact on caregivers' quality of life (n = 3)		drug program (n = 2)
patient participation (n = 3)		patient participation (n = 2)
conditional economic analyses (n = 2)		price negotiation (n = 2)
life-extending and end-of-life qualities (n = 2)		real-world data collection (n = 2)
price negotiation (n = 2)		impact on organizational aspects (n = 1)
quality of life improvement (n = 2)		innovation (n = 1)
risk sharing (n = 2)		quality of life improvement (n = 1)
weighted QALY (n = 2)		
budget impact (n = 1)		
expedited process (n = 1)		

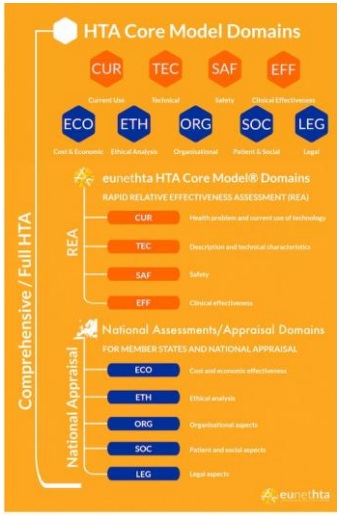
ICER, incremental cost-effectiveness ratio; QALY, quality-adjusted life-year

https://www.binasss.sa.cr/bibliotecas/bhm/jun24/28.pdf

Two main frameworks

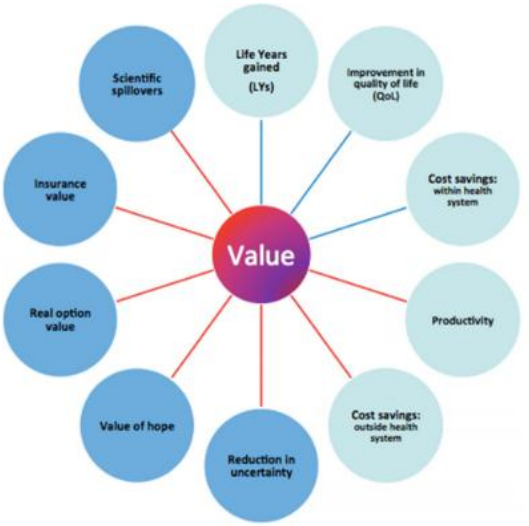
The EuNetHTA (2006-18) collaboration (EU HTA bodies) suggested an evaluation based mainly on clinical aspects

- **Core clinical evaluation**: Magnitude of clinical problem, Technical features of the technology, Relative safety, Relative clinical effectveness
- **Non core non-clinical** domains: cost and economic evaluation, ethical, organizational, social and legal aspects



The Value Flower proposal (US academic focus) suggested an evaluation including other elements of value

- New elements included Reduction in uncertainty, Insurance value, value of hope, Real option value and Scientific spillovers



Evaluation criteria

Framework review

- A Study in 2013 looked at the dimensions used to evaluate decision-making
- The criteria could be organized in several sub-categories
- They analyzed what should and was considered

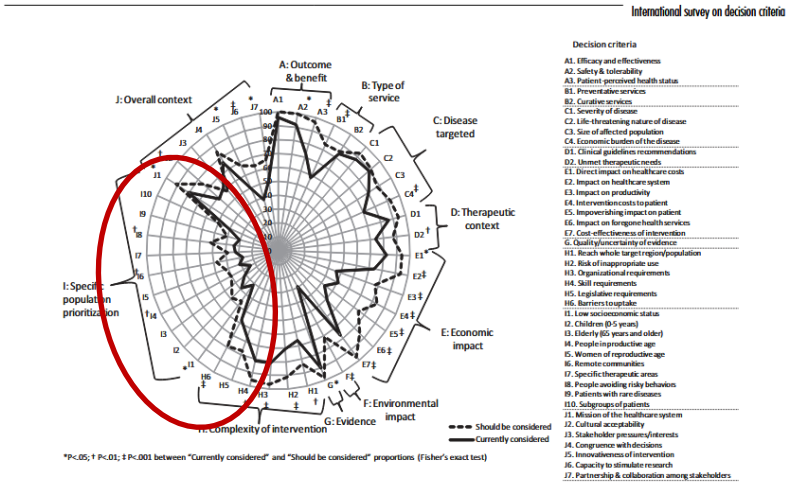


Figure 1. Percentages of respondents reporting that a specific criterion is currently considered or should be considered.

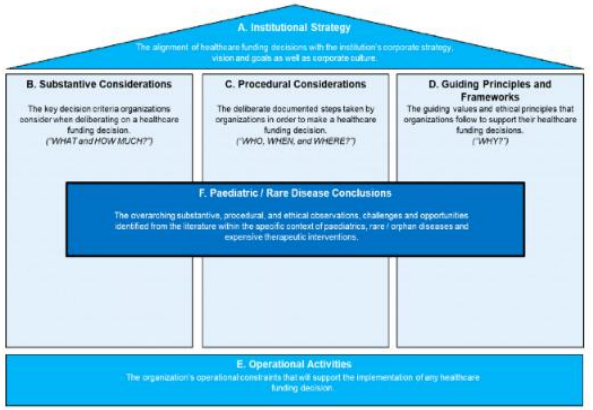
- A total of 140 decision makers (1/3 clinical, 2/3 policy) from 23 countries in five continents completed the survey. The most relevant criteria were
  - Clinical efficacy/effectiveness,
  - Safety,
  - Quality of evidence,
  - Disease severity, and
  - Impact on healthcare costs.
- Organizational and skill requirements were frequently considered but had relatively low weights.
- **No patient preferences/involvement**
- Statistically significant differences across several comparisons were found for: Population priorities, Stakeholder pressure/interests, Capacity to stimulate research, Impact on partnership and collaboration, and Environmental impact.

Evaluation criteria

Framework review

- The way to organize the dimensions is diverse, and the discussion rolls around how to better categorize the dimensions
  - Typically, they would consider institutional, substantive, procedural and operational considerations
  - … and organize them in
    - **STRUCTURE**
    - **PROCESS**
    - **RESULT / OUTCOME**

Common organization of drivers of the Evaluation Criteria within Healthcare Organizations



- However, there are differences in the weight given to the different attributes according to **stakeholder groups, geographies, healthcare system organization***

* examples/reviews can be found in the back-up section

Evaluation criteria

Framework Review Mental Health (DCE)

- This study (framed in Mental Health) shows the importance of process dimensions in the evaluation process
  - When considered together (structure, process and outcome), process is cited more times than cost.

- […] Tallying the top two preferred attributes, **efficacy** was identified as the most important in 50% of patient-specific studies. **Safety** and **process attributes** were ranked as the top two most important attributes 12 times each (24% each). The **cost** attribute was amongst the top two attributes only once. Similarly, in the physician sample, efficacy was identified within the top two most important attributes in 57% of the studies.
  However, safety (29%) appeared more among the top two attributes for physicians than process attributes (14%). **Cost was never considered in the top two most significant attributes for physicians**. **Efficacy was revealed to be the most important treatment attribute for patients and physicians**.

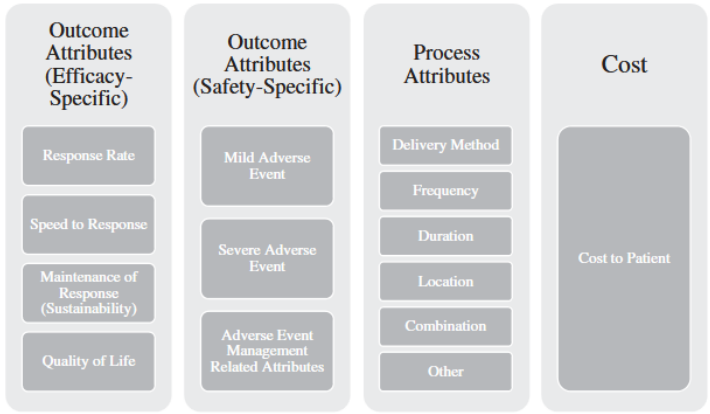


Figure 2. The final categorization of all the attributes included in the 25 DCE studies evaluated in this review.

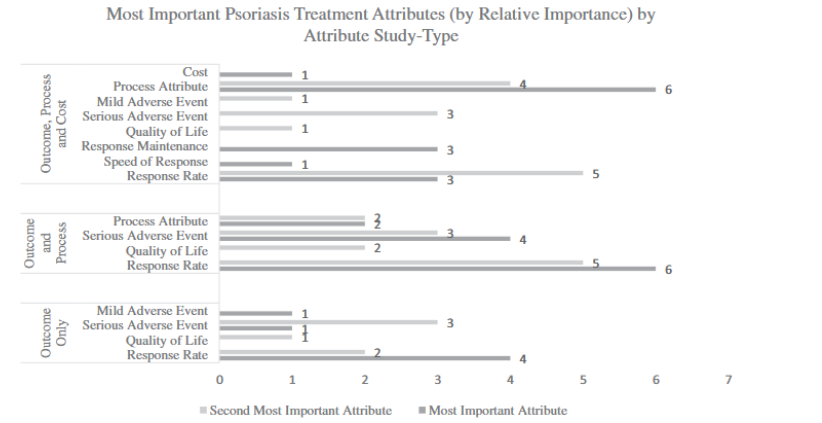


Figure 3. Identification of the most and second most important treatment attributes, differentiated by outcome only, outcome and process and outcome, process and cost studies.

Evaluation criteria

Framework Review Vaccines

- There is evidence showing discrepancies between the perception / requirements of the different stakeholders The voice of the different stakeholders.
- The current evaluation frameworks does not capture appropriately the weight of the different attributes when making a final decision

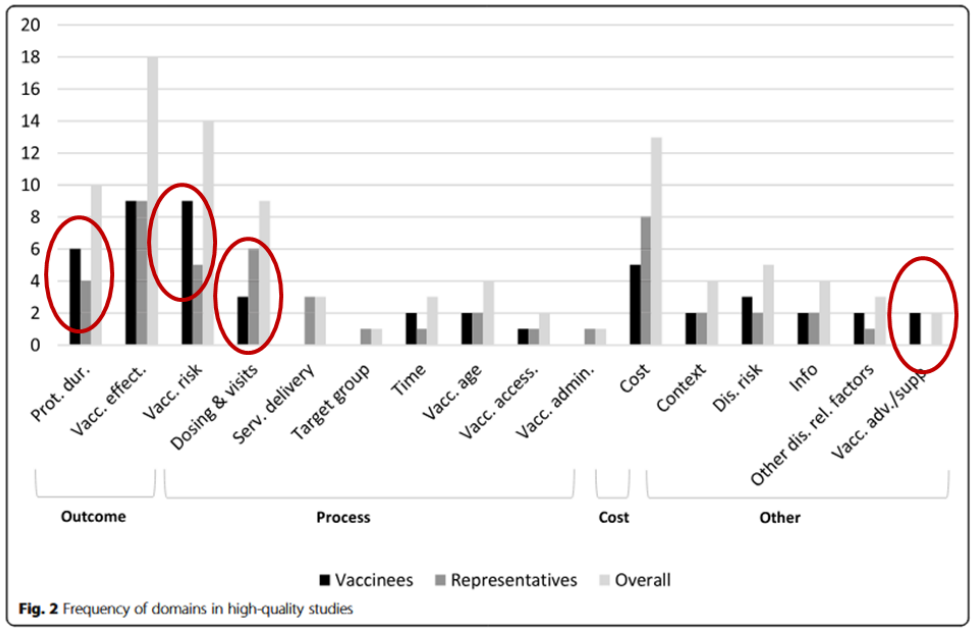


Fig. 2 Frequency of domains in high-quality studies

Evaluation criteria

Comparing Physicians vs Patients (DCE)

- The majority of studies we reviewed found more evidence of mixed concordance and discordance (n=28) or discordance of patient and healthcare provider preferences (n=12) than of concordant preferences (n=4).
- **A synthesis of concordance suggested that healthcare providers rank structure and outcome attributes more highly than patients, while patients rank process**

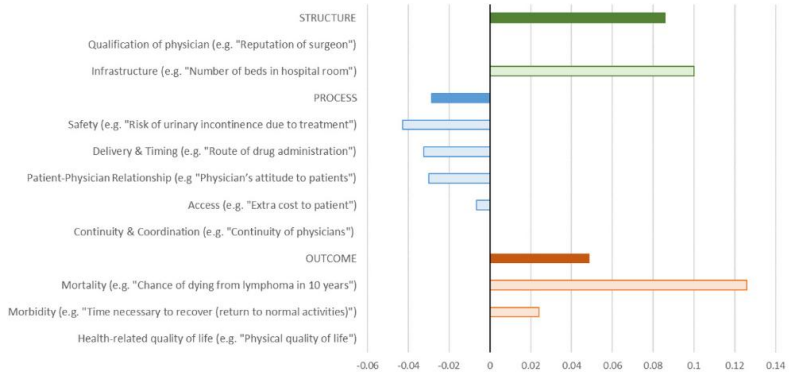


Figure 2 Synthesis of concordance between patient and physician preferences for different types of attributes. Bar colours. Solid: concordance score for all attributes classified in this category. Transparent: concordance score for all attributes in subcategory. Concordance scores. Positive: physician ranks attribute higher than patient. Negative: patient ranks attribute higher than physician.

Evaluation criteria

Framework review

- The weight given to different attributes does change depending on geography.
  - Efficiency and equity attributes are perceived largely different by constituencies

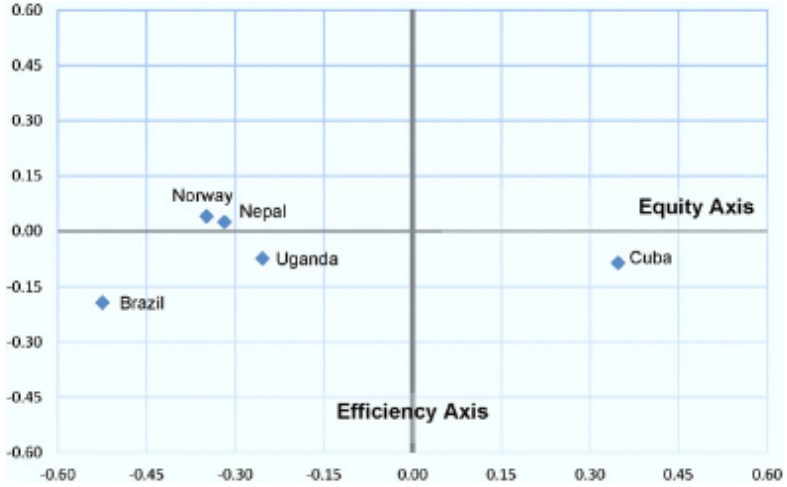


Fig. 1 – Country differences in probability of selection for interventions of efficiency and equity.

Table 2 – Model (heteroskedastic MNL) results for six policy criteria, by country.

	All	Brazil	Cuba	Uganda	Norway	Nepal
Disease severity	0.468‡ (0.000)	0.501‡ (0.000)	−0.158 (0.153)	0.698‡ (0.000)	0.682‡ (0.000)	0.538‡ (0.000)
Total beneficiaries	0.354‡ (0.000)	0.660‡ (0.000)	−1.032‡ (0.000)	0.355† (0.012)	0.238† (0.028)	0.484‡ (0.000)
Target age mid	−0.0705 (0.249)	−0.386‡ (0.001)	0.810‡ (0.000)	−0.137 (0.408)	−0.243 (0.133)	0.358‡ (0.002)
Target age high	−0.453‡ (0.000)	−0.0928 (0.342)	0.284* (0.051)	−0.719† (0.026)	−0.978‡ (0.000)	−0.833‡ (0.000)
Individual benefits	0.451‡(0.000)	0.507‡ (0.000)	−0.258‡ (0.002)	0.200 (0.222)	0.688‡ (0.001)	0.579‡ (0.000)
Propoor (WTS)	0.162‡ (0.000)	0.0101 (0.926)	0.604‡ (0.000)	0.221 (0.247)	0.203 (0.110)	0.235‡ (0.001)
Cost-effectiveness	0.871‡ (0.000)	1.498‡ (0.000)	0.150* (0.067)	0.444‡ (0.002)	0.936‡ (0.000)	0.510‡ (0.000)
Scale						
Brazil	0.158 (0.211)					
Cuba	−15.26 (0.977)					
Uganda	−0.235 (0.184)					
Norway	0.126 (0.309)					
Chi-square test equality of scales	5.34 (0.255)					
Log-L	−2047.7	−484.6	−346.7	−148.9	−270.9	−617.9
LR test equality of parameters	357.3 (0.000)					
No. of observations	7178	2126	1144	518	1024	2366
No. of individuals	225	73	37	17	32	66

Note. P values in parentheses. LR test calculated as $-2[LL_{Pooled} - (LL_{Brazil} + LL_{Cuba} + LL_{Uganda} + LL_{Norway} + LL_{Nepal})]$.
LR, likelihood ratio; MNL, multinomial logit; WTS, willingness to subsidize.
* $P < 0.1$.
† $P < 0.05$.
‡ $P < 0.01$.

HTA Criteria (2008)

- Several frameworks have been suggested for HTA. In 2008, key criteria were proposed to undertake an HTA. The participation of key stakeholders (patients/caregivers) did not stand out.

- Principle 1: The Goal and Scope of the HTA should Be Explicit and Relevant to Its Use : A detailed scoping document should be developed before initiation of the HTA process, with broad, multidisciplinary, stakeholder involvement. The document should focus on defining the questions to be addressed by the HTA, plus the link between the HTA and any decisions about the use of the Technology
- Principle 2: HTA Should Be an Unbiased and Transparent Exercise: Given the inherently complicated and controversial nature of HTA-based decisions and their importance to multiple decision makers and stakeholders, the HTA process is best conducted independently of the body that ultimately will be responsible for adopting, paying and implementing the HTA decisions. Furthermore, the HTA process and the detailed basis on which recommendations and decisions are made must be transparent.
- Principle 3: HTA Should Include All Relevant Technologies: Because potential inefficiencies exist in all forms of health-care, all health technologies should be potential candidates for HTA. Otherwise, decision making concerning the use of resources is likely to be distorted.
- Principle 4: A Clear System for Setting Priorities for HTA Should Exist: A clear process for prioritizing and selecting topics needs to be established, because in situations where not all technologies are assessed, there will be distortions in decision making about the investment and use of resources
- Principle 5: HTA Should Incorporate Appropriate Methods for Assessing Costs and Benefits Development and consistent implementation of rigorous, analytical methods is required to engender stakeholder and public trust in the process and its findings. This requires clarity of HTA process and methods, as well as access to experts with appropriate clinical and multidisciplinary methodological training.
- Principle 6: HTAs Should Consider a Wide Range of Evidence and Outcomes HTAs require use of data from experimental, quasi-experimental, observational, and qualitative studies, integration of both endpoint and validated surrogate data, and assessment of the incremental impact of and trade-offs among multiple clinical, economic and social outcomes in clinically relevant populations.
- Principle 7: A Full Societal Perspective Should Be Considered When Undertaking HTAs HTAs should adopt a broad societal perspective to optimize efficiency and societal benefit and to avoid and identify potentially distorted clinical decisions and health policies resulting from adoption of narrower perspectives used by various healthcare system stakeholders
- Principle 8: HTAs Should Explicitly Characterize Uncertainty Surrounding Estimates : All data are imperfect point estimates of underlying distributions that incorporate a variety of errors. All analytical methods are subject to biases and limitations. Thus, extensive sensitivity analyses are required to determine the robustness of HTA findings and conclusions. The limitations of the analysis should always be acknowledged.
- Principle 9: HTAs Should Consider and Address Issues of Generalizability and Transferability: Examination of the generalizability and transferability of HTA findings across clinical populations and policy relevant perspectives is required, given the inherent variability of disease, intervention responses, and outcomes across patients, populations, providers, healthcare delivery sites and healthcare systems.
- **Principle 10: Those Conducting HTAs Should Actively Engage All Key Stakeholder Groups: HTA programs should actively engage all key stakeholders in all stages of the HTA process, as this is likely to result in technology assessments of higher quality that are more widely accepted and stand a greater chance of being implemented. Moreover, such an open process will enhance transparency and trust in the process as stakeholders develop a greater understanding of the criteria and standards used**
- Principle 11: Those Undertaking HTAs Should Actively Seek All Available Data: Those conducting HTAs should actively seek all available data, whether confidential or not. In situations where confidential data are used, confidentiality should be defined as narrowly as possible and efforts should be made to make it publicly available as soon as possible, in the interests of maintaining transparency and engendering understanding of and trust in decisions.
- Principle 12: The Implementation of HTA Findings Needs to Be Monitored: Implementation of HTA findings need to be monitored, both to ensure that the original investment in conducting HTAs is valuable and to ensure that findings are being implemented in a fair and even-handed manner.
- Principle 13: HTA Should Be Timely: HTAs should be conducted when they can inform key decisions in the diffusion and use of health technologies, and assessments should be kept up-to-date. To accomplish this goal requires timely conduct of studies by manufacturers and other advocates and, in selected circumstances, requires limited reimbursement conditional upon enrollment in a study to inform safety, effectiveness, and cost-effectiveness.
- Principle 14: HTA Findings Need to Be Communicated Appropriately to Different Decision Makers: Given the multiple audiences for HTA findings, effective communication strategies need to be developed to meet the disparate needs of different users.
- Principle 15: The Link Between HTA Findings and Decision-Making Processes Needs to Be Transparent and Clearly Defined: A clear distinction needs to be made between the HTA itself and the resulting decisions. The link between the assessment and the decision will be different in various settings, but in all cases it should be transparent.

Generalised CEA

WHO approach (2000)

- Expanding from traditional HTA frameworks, in 2000 the WHO proposed the idea of Generalized Cost-Effectiveness Analysis, explicitly including context elements into the evaluations.

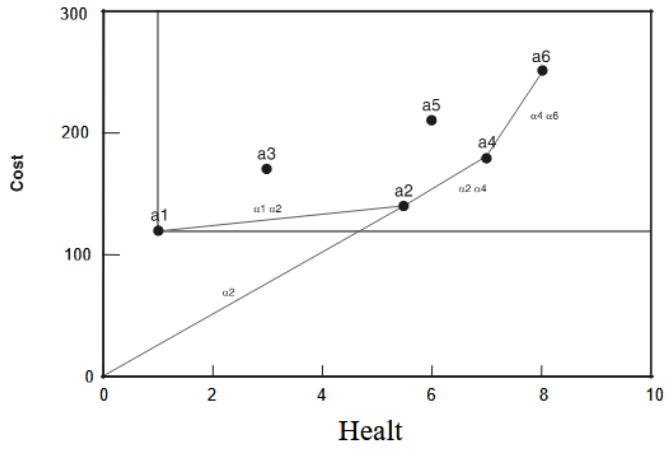


Figure 1. Costs and benefits of six mutually exclusive

WHO guidelines on generalized CEA propose the application of CEA to a wide range of interventions to provide general information on the relative costs and health benefits of different interventions in the absence of various highly local decision constraints. This general approach will contribute to judgements on whether interventions are highly cost-effective, highly cost-ineffective, or something in between.

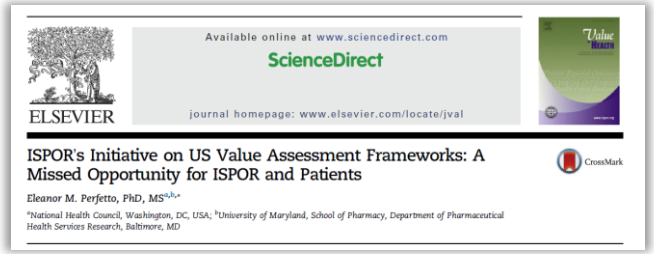
Generalised CEA (2017)

- The Value Flower proposal stemmed in a thorough analysis of the determinants of healthcare, but it was deemed not patient centric

Impact Inventory Template

Sector	Type of Impact (list category within each sector with unit of measure if relevant)[a]	Included in This Reference Case Analysis From...Perspective?		Notes on Sources of Evidence
		Health Care Sector	Societal	
Formal Health Care Sector				
Health	Health outcomes (effects)			
	Longevity effects	☐	☐	
	Health-related quality-of-life effects	☐	☐	
	Other health effects (eg, adverse events and secondary transmissions of infections)	☐	☐	
	Medical costs			
	Paid for by third-party payers	☐	☐	
	Paid for by patients out-of-pocket	☐	☐	
	Future related medical costs (payers and patients)	☐	☐	
	Future unrelated medical costs (payers and patients)	☐	☐	
Informal Health Care Sector				
Health	Patient-time costs	NA	☐	
	Unpaid caregiver-time costs	NA	☐	
	Transportation costs	NA	☐	
Non-Health Care Sectors (with examples of possible items)				
Productivity	Labor market earnings lost	NA	☐	
	Cost of unpaid lost productivity due to illness	NA	☐	
	Cost of uncompensated household production[b]	NA	☐	
Consumption	Future consumption unrelated to health	NA	☐	
Social Services	Cost of social services as part of intervention	NA	☐	
Legal or Criminal Justice	Number of crimes related to intervention	NA	☐	
	Cost of crimes related to intervention	NA	☐	
Education	Impact of intervention on educational achievement of population	NA	☐	
Housing	Cost of intervention on home improvements (eg, removing lead paint)	NA	☐	
Environment	Production of toxic waste pollution by intervention	NA	☐	
Other (specify)	Other impacts	NA	☐	

Fig. 1 – Impact inventory template. *Source:* **From Neumann et al. [2].**



[…] The STF describes this evolving field and suggests promising new methods under development. Yet, its recommendations fall back on a staid and unilateral approach, one that has clearly been rejected by a number of stakeholders both in and outside the United States. The STF appears to assume that value frameworks are interchangeable with a QALY-based CEA metric. On this basis, the report goes as far as explicitly recommending that Health plan coverage and reimbursement decisions be based on CEA.

[…] **Any approach to defining value cannot be overly rigid or allow a single metric to dominate what should be a multifaceted approach.**

[…] Assessing healthcare value is no different and patient centricity must be front and center. We need strong leadership to provide direction and guidance on frameworks and methods that transcend a narrow, QALY-centric approach, taking us to a sound, transparent, patient-centric approach. The STF has chosen not to lead this movement. Unfortunately, the result is a missed opportunity for the field and for patients whose access depends on it.

Evaluation of Innovation criteria (2024)

- The HTA framework has further been explored as a tool for the evaluation of innovation

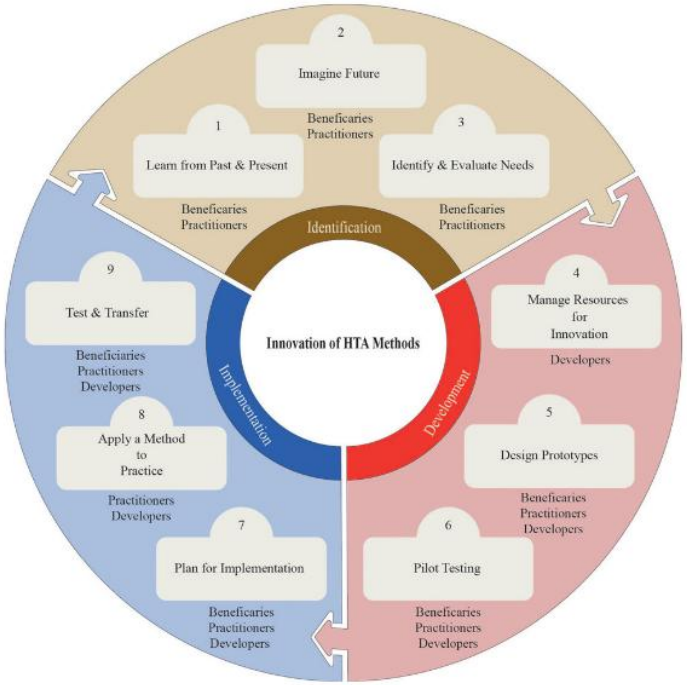


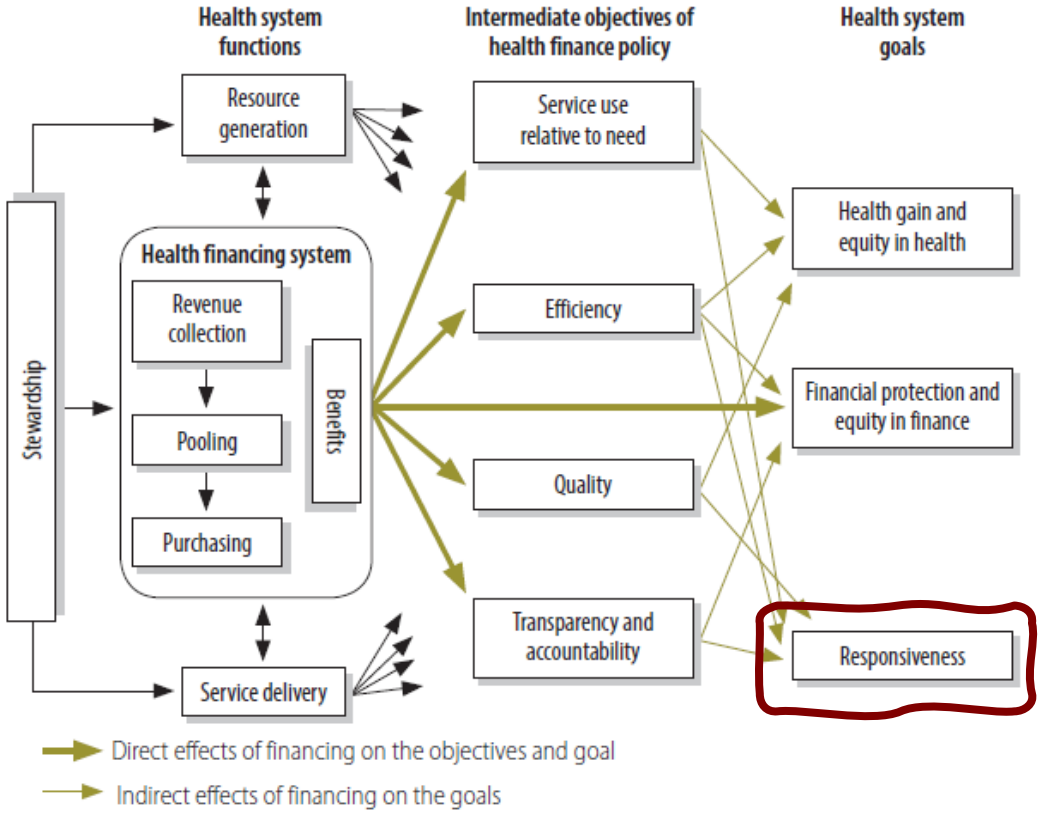
Figure 3. A generic process on how HTA methods are innovated. This concept map illustrates all key concepts of the IHTAM framework: (1) concepts relevant to a generic innovation process with three phases (i.e., "identification," "development," and "implementation," which are distinguished by three colors) and nine subphases (in white boxes with numbers from 1 to 9); (2) roles of HTA stakeholders in innovation in each subphase (attached under each white box).

- The IHTAM framework has been recently developed by HTA experts (EU Research project)
- It focuses on qualifying the innovation rather than technology itself
- Interestingly, they bundle together all types of potential users as 'Beneficiaries', including but not limited to Patients. This is a way to recognize the externalities of an innovation

why it matters to patients

Goals of a Healthcare System

Fig. 2. **Health system goals and health financing policy objectives**



WHO_WHR2000

Why is it important for the patients?

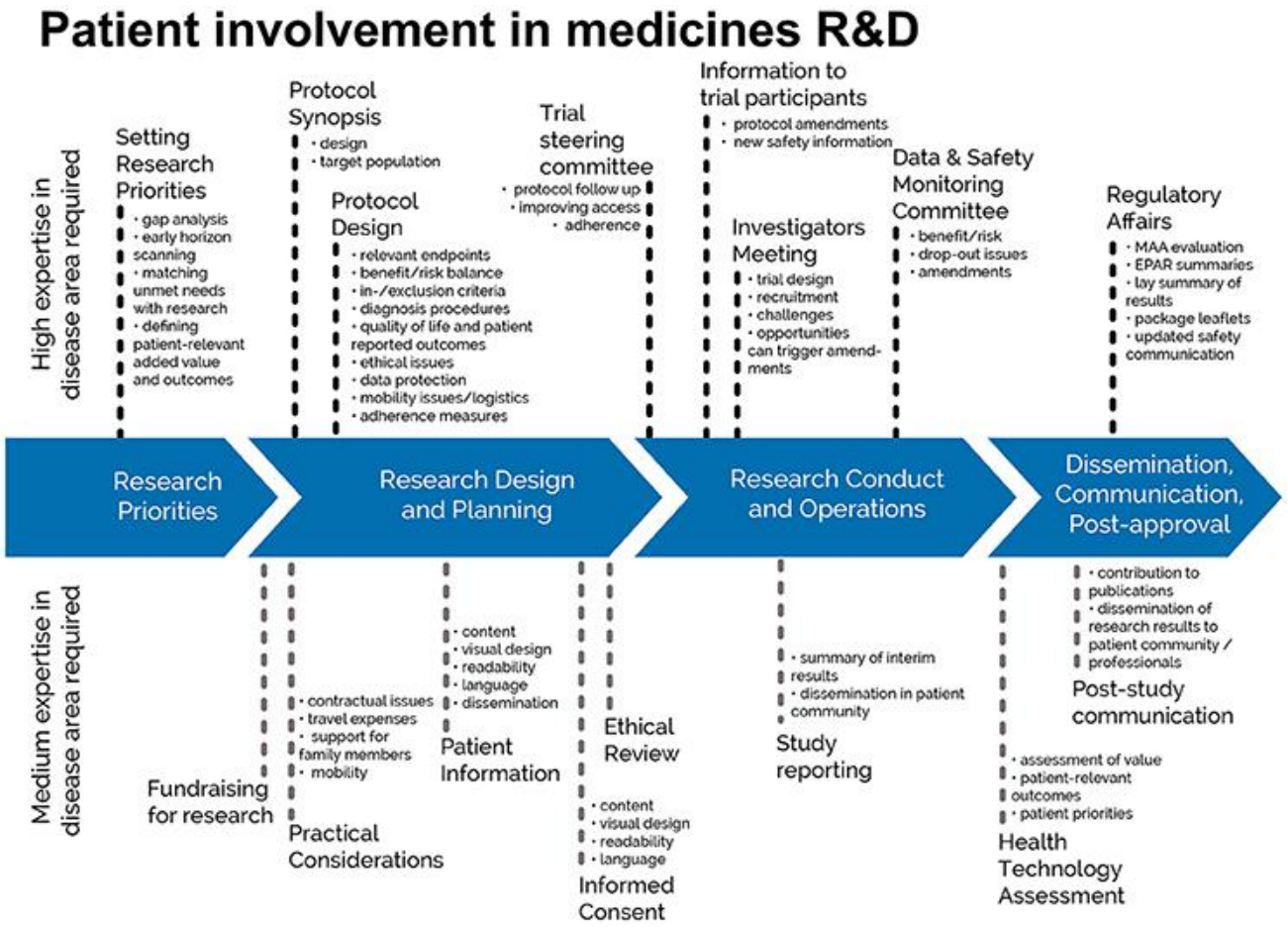
"Critique must take the language of the artists. Because the terms of the *cénacle* are slogans. And only in the slogans is the battle cry heard" (Walter Benjamin, Einbahnstraße, 1928)

- The "flower of value" does not take into account the patient's perspective or the patient's experience
- Understanding the disease is doctor-led
- Patients do not participate in the debate
- They lack knowledge of highly skilled terminology
- The patient as a representative of the citizenry

- The first argument builds on the Alma-Ata Declaration, which holds that patients have a right and duty to have a say in the planning and delivery of their health care, individually and collectively. Where **HTA is used to determine** access to technologies and services, we argue that patients have a right to be heard. The second argues that decisions about treatments and services need to be **aligned with the core values and morals of the patients** whom the health system serves. The third argues that **patients have unique knowledge** and insights about living with a health condition and their needs for services and treatments regarding that condition, which can add to the knowledge base and value of the HTA process. The fourth argues that involvement of patients can **facilitate methodological advancement of HTA**, in areas such as early scientific advice and managed entry withevidence development

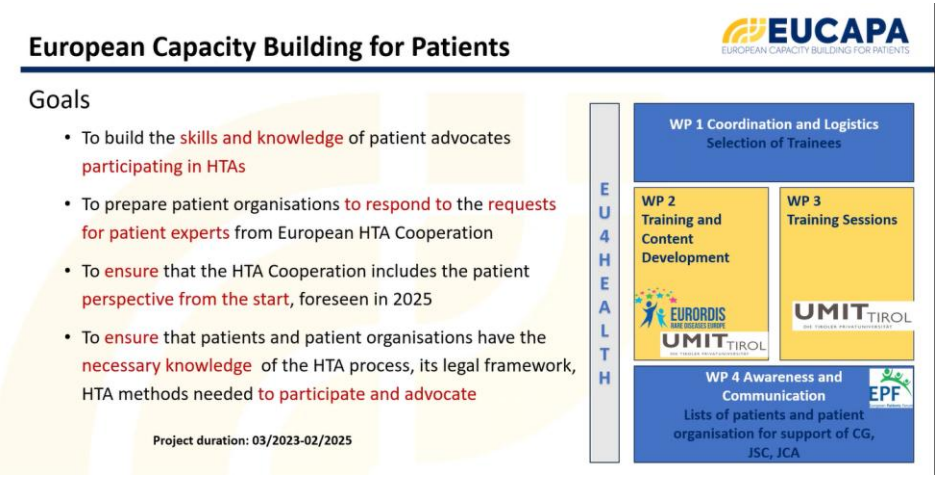
  - **International Journal of Technology Assessment in Health Care, 33:1 (2017), 1–4**

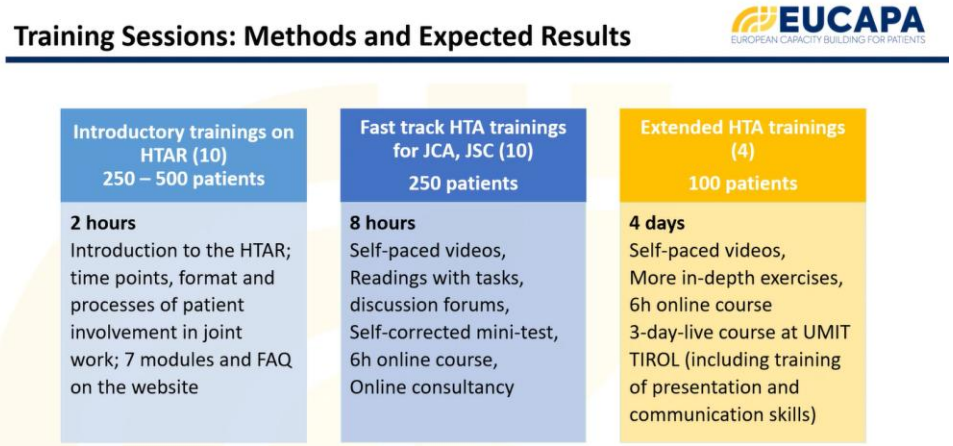
Why it matters to patients?



https://www.frontiersin.org/articles/10.3389/fmed.2018.00231/full

Training Resources







Advancing Patient Involvement in Health Technology Assessment:

A proposal and initial validation of concrete strategies for educational, methodological and institutional improvements.

da Camino Soligo, Tess Marie BSc; Solà-Morales, Oriol MD PhD | Fundació HiTT

Background

- ✓ **Patient involvement in Health Technology Assessment (HTA) improves transparency and relevance of decisions. Implementation remains inconsistent across countries.**
- ✓ **Key barriers: limited patient education, lack of methodological guidance, insufficient institutional support.**

Objective

- ✓ To gather evidence supporting concrete **strategies for advancing meaningful and efficient patient involvement in** HTA, focusing on Patient Education, Methodological guidance and Institutional integration

Methods

1. Targeted literature review to identify key recommendations.
2. Development of a 16-statement survey covering four domains.
   - Patients' education and participation in HTA (S1-6)
   - Methodological guidance and evaluation of patient involvement in HTA-agencies (S7-11)
   - Awareness and education among HTA-personnel about the benefits of patient involvement (S12-S14).
   - Additionally, need for financial support for patients participating in HTA activities (S15) and involving either patients or citizens in HTA processes (S16).
3. Distribution among stakeholders: general public, pharmaceutical industry, HTA experts, and healthcare professionals

Results

- ✓ a total of 40 responses were collected, response rate of 4%.
- ✓ The sample included respondents from the pharmaceutical industry (28%), HTA-experts (1%) and members of the GP (20%). In addition, the sample included healthcare professionals, payers and non-governmental organisation representatives.
- ✓ Participants were based in various countries, with Spain (48%) and the UK (18%) being most represented. The remaining responses came from various other European countries or the USA

Conclusion

- ✓ **Stakeholders broadly support more structured and demanding approaches to patient involvement in HTA, particularly in terms of education and methodological clarity.**
- ✓ **The recommendations presented in this report can serve as a valuable starting point for enhancing meaningful and sustainable patient involvement in HTA.**
- ✓ **Future research should focus on developing accessible training programmes and implementing formal guidelines to ensure systematic and meaningful patient participation.**

Mean scores ($\bar{x}$) and standard deviations (SD) for all statements on patient involvement in HTA; Likert Scale 1-5 (5 strong agreement)

	Statement	($\bar{x}$)	SD
	Section 1 - Patients education and participation in HTA		
S1	Written or online training materials (e.g. books, e-learning) are appropriate supporting material to prepare patients for meaningful participation in HTA.	3.78	0.89
S2	**Face-to-face interactions (e.g. workshops, lectures) are necessary for adequately training patients in HTA.**	4.33	0.69
S3	Self-education is insufficient to prepare patients for meaningful and informed participation in HTA processes.	4.00	0.91
S4	A training program for patient involvement in HTA should last at least 20 hours to be effective.	3.23	0.86
S5	An engaging continuous training program is needed to sustain patient motivation for active involvement in HTA.	3.68	0.83
S6	Continued education is essential to maintain and update patients' knowledge for continued engagement in HTA.	3.78	0.77
	Section 2 - Methodological guidance and evaluation on patient involvement in HTA bodies		
S7	**The role (expected input and output) of patients in HTA decision making should be clearly defined in official documentation of every organization**	4.40	0.63
S8	**Patients should be involved as early as possible in the HTA process**	4.20	0.85
S9	Each HTA agency should have a designated staff member responsible for coordinating patient involvement.	4.03	0.83
S10	It is important to define specific KPIs to evaluate patient involvement in HTA.	4.03	0.77
S11	A structured framework based on clear recommendations (GRIPP or similar) will help improve the quality, transparency and comprehensiveness of patient involvement in HTA activities.	4.05	0.71
	Section 3 - Awareness and education among HTA-personnel about the benefits of patient involvement		
S12	Accreditation or certification should be required for HTA professionals involved in patient engagement.	3.43	0.93
S13	**HTA professionals should be trained on how to effectively involve patients in HTA processes.**	4.13	0.65
S14	HTA processes without validated process of participation of patients should not be accepted	3.33	1.12
	Section 4 - other		
S15	Patients should be financially compensated for their participation in HTA activities.	3.33	1.02
S16	Involving individual patients provides more relevant insights than involving citizens or the general public	3.58	1.13

Expert Proposals

Participación de pacientes en la toma de decisiones sanitarias

Marco para una integración efectiva en el Sistema Nacional de Salud (SNS)

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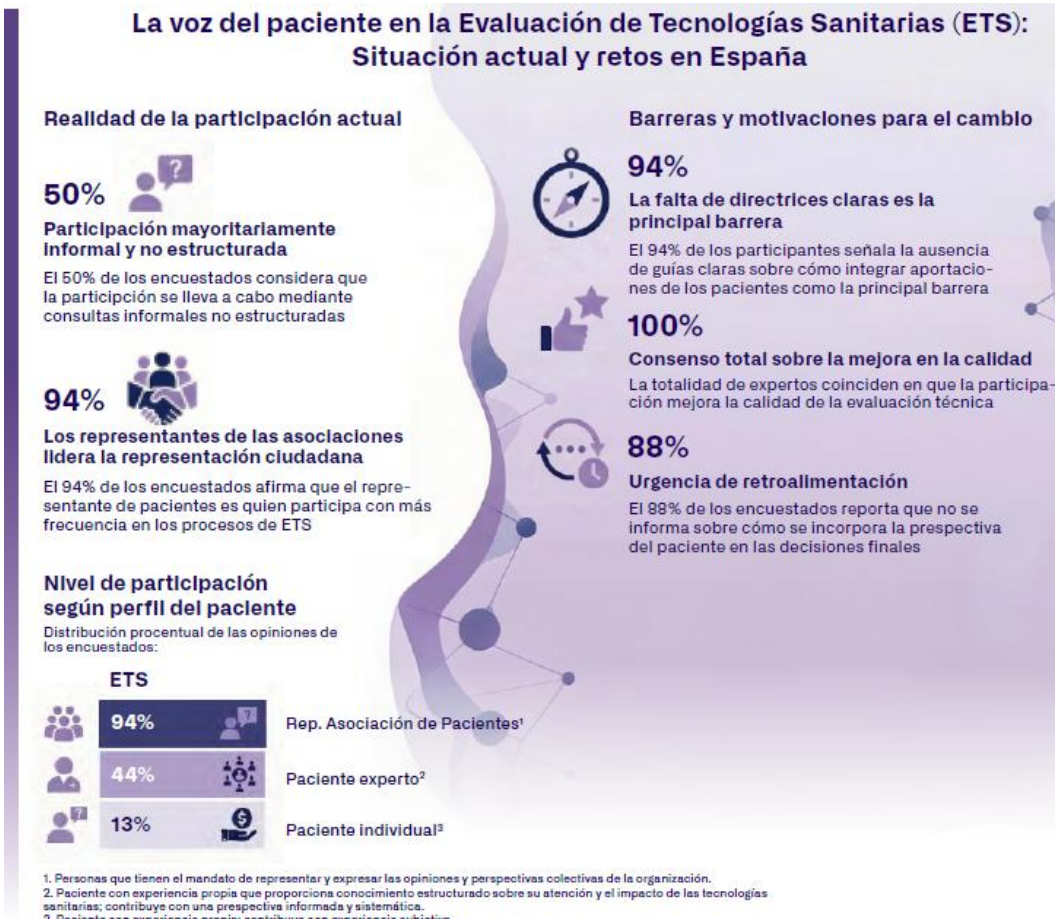


Expert Proposals: Legal Framework

Marco Legal de la Participación del Paciente en la ETS en España

FUNDAMENTOS LEGALES

Estabilidad y Transparencia Institucional

El marco legal establece un orden estable para asegurar que los procesos de toma de decisiones sean transparentes y predecibles para todos los actores.

El Paciente como Parte Interesada

Reconocimiento jurídico de los pacientes como agentes con derecho a participar, ser consultados y estar representados en decisiones que afectan la financiación y el reembolso

Real Decreto de ETS

Norma fundamental que otorga espacios formales a las organizaciones de pacientes para el análisis del impacto real de las tecnologías y la identificación de necesidades

Futura Ley de Organizaciones de Pacientes

Base jurídica que consolidará el estatus, derechos y obligaciones de las asociaciones, creando un registro oficial para su integración estable en órganos de decisión.

IMPLEMENTACIÓN

Indicador Clave de Éxito

Se mide a través del número de evaluaciones de tecnologías sanitarias que cuentan con la participación de al menos un representante de pacientes.

¿Quién participa?

Participantes integrados (perspectiva general de los usuarios) y testimonios (experiencia directas de afectados por la patología evaluada).

¿Cómo se contribuye?

A través de participación con derecho a voto / calidad consultiva, aportación de evidencia escrita y definición de resultados relevantes (PICO).

¿Cuándo se participa?

En hitos clave como comités deliberativos, consultas públicas, audiencias e investigación cualitativa durante el ciclo de vida de la tecnología.

REFERENTES INTERNACIONALES

Canadá (CDA-AMC)

Utiliza un modelo de presentaciones estructuradas de aportaciones de pacientes y participación en comités de expertos.

Reino Unido (Ley NHS)

Los pacientes y cuidadores actúan como miembros legos en los comités, presentan pruebas escritas y comentan en consultas públicas.

Italia (AIFA Ascolta)

La agencia AIFA ha creado canales de participación específicos para que las necesidades de los pacientes lleguen directamente a los evaluadores.

Alemania (G-BA)

Basado en el Libro de Código Social V, otorga a los representantes de pacientes el derecho a voz y propuesta dentro de los subcomités.

Evaluación de Tecnologías Sanitarias (ETS): proceso multidisciplinario que utiliza métodos explícitos para determinar el valor de una tecnología sanitaria en diferentes puntos de su ciclo de vida, con el fin de fundamentar la toma de decisiones equitativas, eficientes y de alta calidad en el sistema de salud.

Formación para la Participación del Paciente en la ETS en España

FUNDAMENTOS Y OBJETIVOS

Necesidad de Competencias Técnicas

Para interactuar eficazmente con las agencias de ETS, es imprescindible que los pacientes desarrollen habilidades organizativas y conocimientos técnicos sobre procesos regulatorios y evaluación.

Programas Formativos de Referencia

Se destacan iniciativas clave como EUCAPA (fundamentos de la ETS), EUPATI (capacitación a pacientes), EURORDIS Summer School de Plataforma de Malalties Minoritàries y los programas nacionales de POP y FEP en colaboración con la administración.

Participación de Alto Valor

El objetivo es que las instituciones reciban aportaciones fundamentadas que puedan integrarse sistemáticamente en la toma de decisiones finales.

IMPLEMENTACIÓN Y HOJA DE RUTA

Contenidos del Modelo Formativo

Debe incluir conceptos básicos de farmacoeconomía, beneficio clínico, impacto sobre la Calidad de Vida Relacionada con la Salud (CVRS), metodología de investigación, lectura crítica, ética y equidad.

Indicadores de Éxito

El progreso se medirá a través del número de pacientes formados y acreditados, pacientes que participan en procesos, así como mediante encuestas de satisfacción de los participantes e impacto en los procesos.

Cronograma

El plan contempla una revisión de los cursos existentes en los meses 0-3 y el diseño del nuevo modelo formativo estructurado entre los meses 6 y 12, y la definición de cuestiones organizativas, ediciones y calendarización.

REFERENTES INTERNACIONALES

Canadá (CADTH/CIHR-SPOR)

Ha institucionalizado la formación y participación de pacientes en ETS mediante marcos y guías desarrollados.

Inglaterra (NICE)

Proporciona materiales de apoyo, orientación y soporte específico para preparar a los pacientes expertos y facilitar una participación informada en los comités de ETS.

Alemania (G-BA)

Ofrece un sistema de formación, acompañamiento y soporte continuado a los representantes de los pacientes durante todo el proceso de evaluación.

Francia (HAS)

Programa formativo específico para comprender la ETS y el rol de pacientes y ciudadanía en estos procesos, complementado por la formación ofrecida por asociaciones.

Resulta de interés identificar y difundir casos de éxito donde los pacientes puedan observar el impacto de su participación.

Compensación de la Participación del Paciente en la ETS en España

FUNDAMENTOS DE LA COMPENSACIÓN

Objetivo del Marco

Garantizar una estructura equitativa y transparente que permita reconocer formalmente la participación del paciente en los comités de evaluación y compensar adecuadamente su dedicación.

Qué se cubre

La compensación abarca gastos de viaje, tiempo de trabajo, desplazamientos, alojamiento, dietas y materiales necesarios para la actividad.

Propósito Social

El fin primordial es eliminar cualquier barrera económica que impida una participación plena, libre y verdaderamente representativa de la diversidad de pacientes

IMPLEMENTACIÓN Y HOJA DE RUTA

Metodología de Trabajo

Definir un baremo transparente y equitativo, seguido de un pilotaje en al menos 3 procesos de ETS con reconocimiento equivalente a la de otros participantes expertos.

Indicadores Clave (KPIs)

Inclusión del modelo en marcos normativos, porcentaje de procesos compensados y alcanzar un nivel de satisfacción de los pacientes superior al 80%.

Cronograma de Integración

3-6 6-12 15-18

Diseño del baremo (mes 3-6), fase de pilotaje (mes 6-12) e integración definitiva en la normativa nacional de salud (mes 15-18).

REFERENTES INTERNACIONALES

Reino Unido (NICE)

El National Institute for Health and Care Excellence ofrece pagos dinerarios directos como reconocimiento por la participación en sus procesos.

Alemania (G-BA)

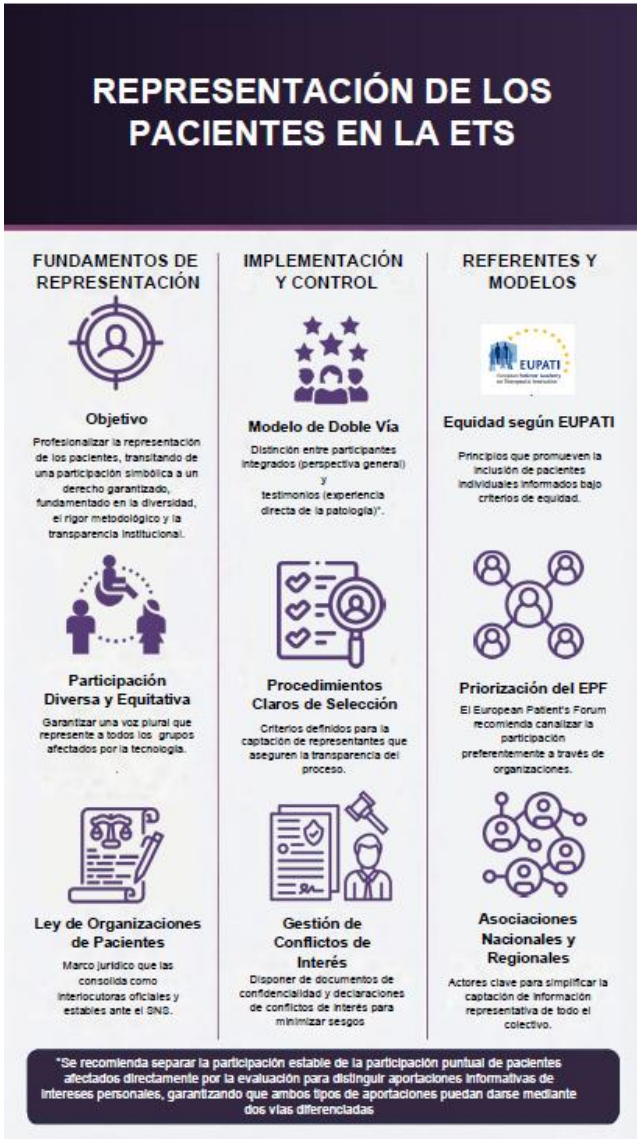
Proporciona apoyo financiero para cubrir gastos de viaje y otorga pequeñas cantidades adicionales en concepto de honorarios por la representación

Recomendaciones Globales

Organizaciones como EUPATI y PCORI abogan por remunerar el tiempo total invertido y los gastos bajo estrictos criterios de transparencia y responsabilidad.

Para el éxito del modelo es imprescindible un presupuesto específico, soporte jurídico administrativo y herramientas digitales para la gestión y registro de las participaciones

Expert Proposals: Representation

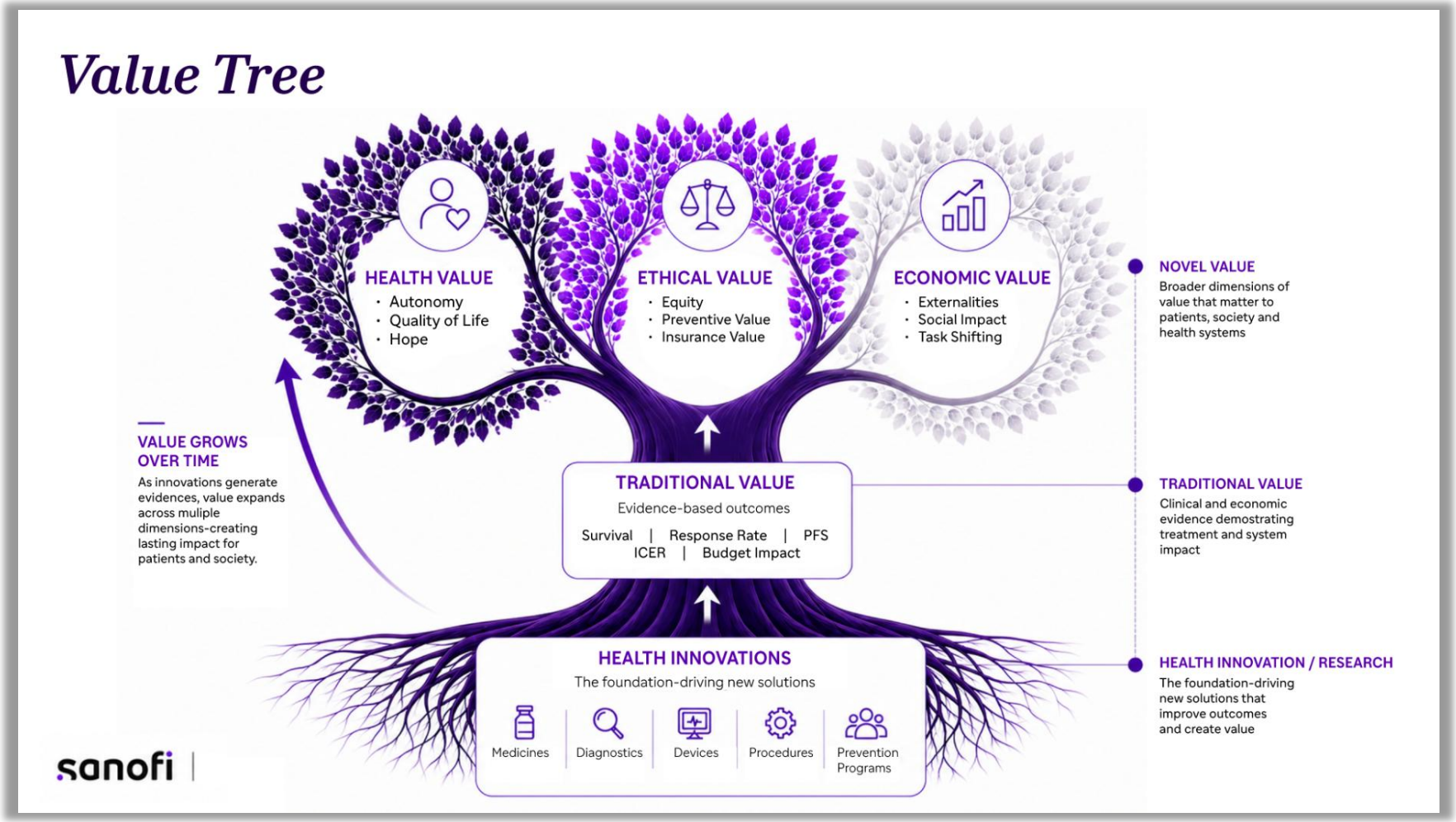




Expert Proposals: Evaluations



Expanding the Value from RnD



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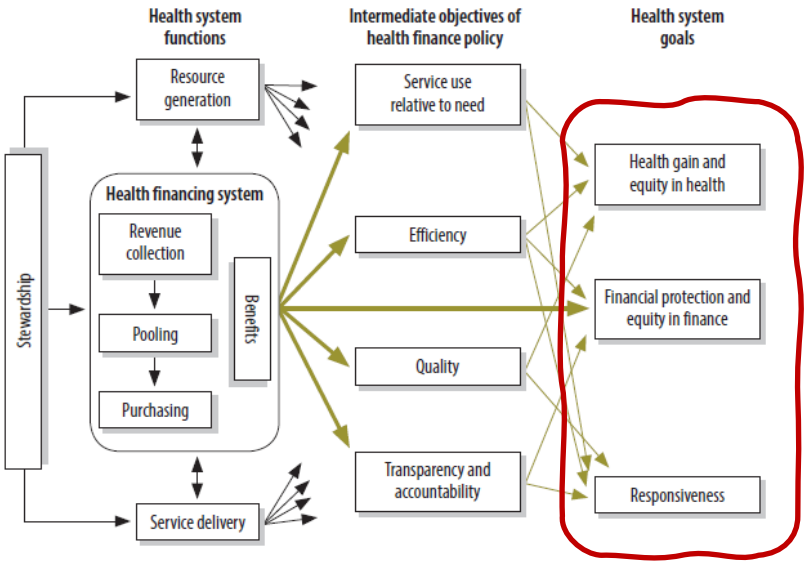
Conclusion

- The current HTA framework is provider-centric, not patient centric
- Having a Responsive HTA means giving equal floor to patients
  - Patients would need some training
- Significant efforts are being made to incorporate those values





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