Evaluación de Tecnologías Sanitarias y Productos Médicos

Dra. Victoria Wurcel
victoria.wurcel@gmail.com

Presentación

Esta presentación es el fruto de muchos años de formación y experiencia nacional e internacional en Evaluación de Tecnologías Sanitarias.

No necesariamente representa la opinión de la institución donde trabajo.

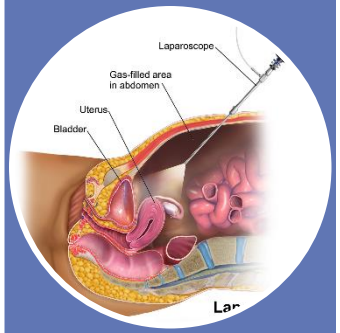
Tecnología Sanitaria

Programas preventivos

Test diagnósticos

Producto médico

Medicamento



Procedimiento

¿De qué estamos hablando?

Salud como derecho	Asegurar acceso a los cuidados de la salud más apropiados y de calidad (que genere buenos resultados de salud) para todos
	Donde se necesite, cuando se necesite
	Sin importar la habilidad del paciente para pagarlo

¿De qué estamos hablando?

Sustentable	Distribución equitativa de recursos finitos
	Que no lleve a la bancarrota al sistema ni a futuras generaciones

EQUALITY VERSUS EQUITY

In the first image, it is assumed that everyone will benefit from the same supports. They are being treated equally.

In the second image, individuals are given different supports to make it possible for them to have equal access to the game. They are being treated equitably.

In the third image, all three can see the game without any supports or accommodations because the cause of the inequity was addressed. The systemic barrier has been removed.

Preguntas ante la decisión de cobertura

Salud como derecho sustentable

- ¿Todo lo nuevo para todos o todo lo que se necesite para lograr el mejor resultado para ese paciente (lo más apropiado)?

¿Igualdad o Equidad?

¿El beneficio justifica el riesgo?

¿El beneficio justifica el precio?

¿Cuánta incertidumbre puedo tolerar en relación al balance riesgo-beneficio y a la confiabilidad de la evidencia?

¿Cómo voy a pagarlo?

¿Cuál es el costo de oportunidad?

¿Cómo voy a implementar la atención?

Evaluación de tecnología sanitaria

Una forma sistemática basada en la evidencia científica de investigar los resultados e impacto de las tecnologías sanitarias

Informa decisiones de cobertura, reintegro, adquisición, uso apropiado, desinversión

Informa sobre consecuencias deseadas e inesperadas o no deseadas, a corto y largo plazo.

Foco en el paciente, su familia, cuidadores, sistema de salud o institución sanitaria

Qué hace la ETS

Nos informa qué grado de confianza podemos tener en los beneficios de las tecnologías sanitarias.

Nos ayuda a determinar el beneficio médico agregado y el valor (por dinero) de esa tecnología en relación a lo que ya utilizo o cubro.

ETS como herramienta

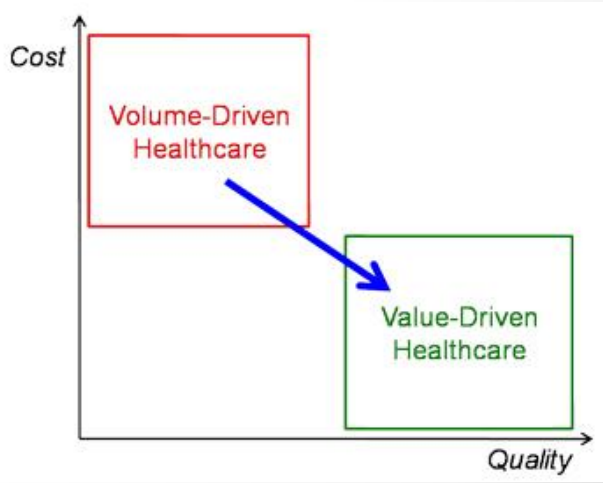
El propósito fundamental de los cuidados de salud es mejorar la calidad (valor) para los pacientes

$$\text{Valor} = \frac{\text{Resultados importantes para los pacientes con una condición de salud}}{\text{Costo relacionado a obtenerlos durante todo el ciclo de cuidados}}$$

Porter M. The Strategy to transform healthcare. OECD Policy Forum Paris, 2017

ETS como herramienta de un sistema de salud basado en el valor

(resultados/costo) de los servicios y no en el volumen



Se crea valor en el cuidado de la salud

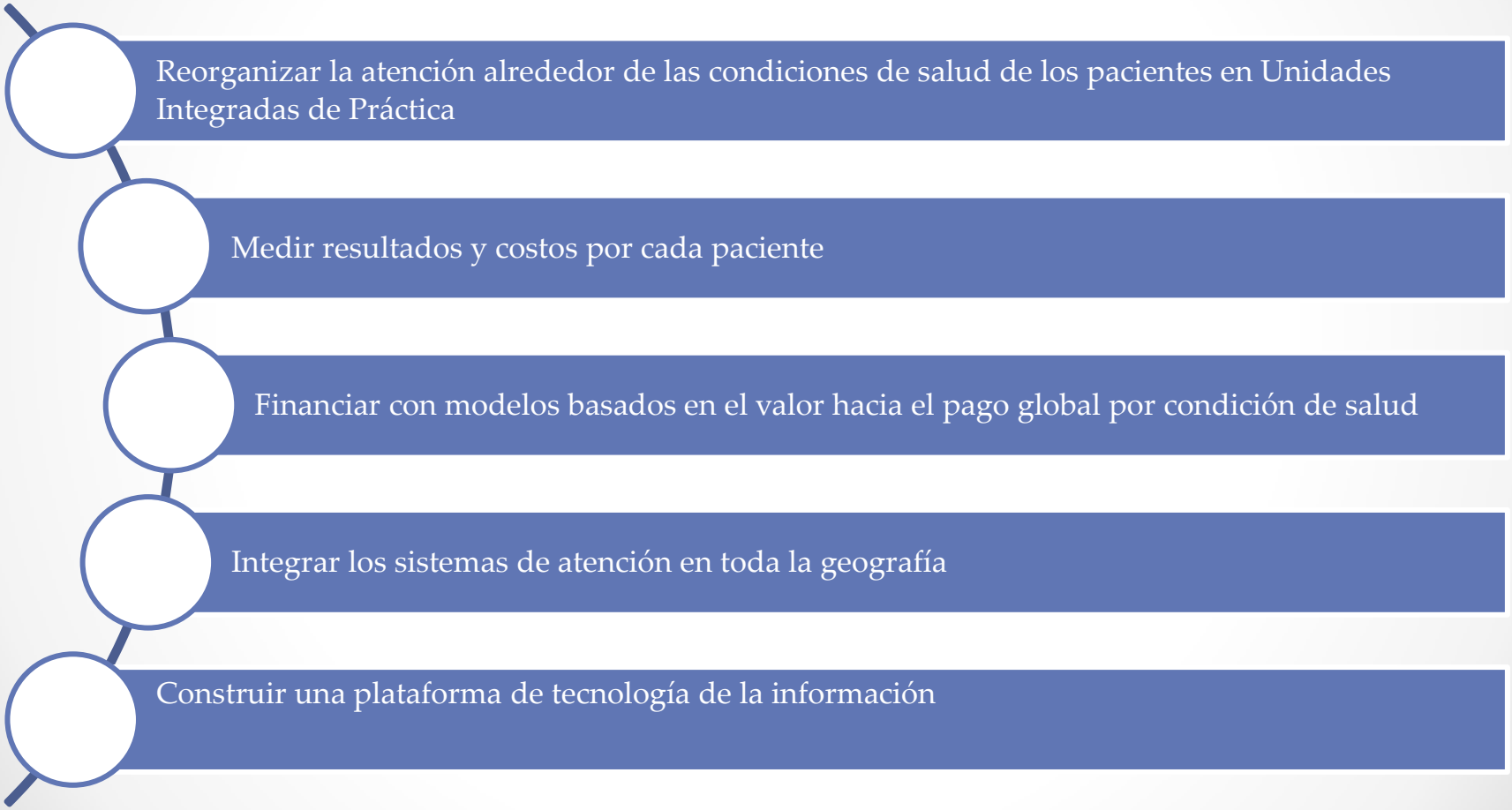
Por paciente con una condición de salud

Durante todo el ciclo de atención de salud

Para reducir costo y mejorar el valor hay que mejorar los resultados de salud

Porter M. The Strategy to transform healthcare. OECD Policy Forum Paris, 2017

Estrategia para la los cuidados de salud basados en el valor



Porter M. The Strategy to transform healthcare. OECD Policy Forum Paris, 2017

Examples from Sweden, payment models: Implementation of bundle payment for THR/TKR in Stockholm county resulted in lower cost and reduced complications

Context

Before 2009 – THR & TKR

- Waiting up to two years for surgery
- No systematic quality control from county

2009 – Introduction of bundle payment

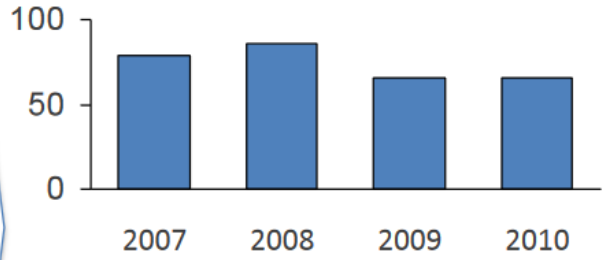
- Accreditation of providers and "patient free choice" of provider
- "Package price" for episode of care up to five years post surgery (Including "complication warranty")

Info on scope (so far):
- All providers
- ASA 1-2 patients

SVEUS develops next generation

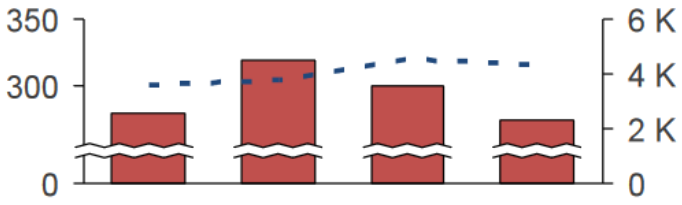
Experienced benefits

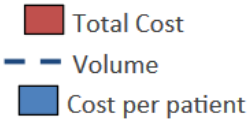
Cost per patient
SEK thousand



Total cost
SEK million

Volume
# of patients





- Average cost per patient as well as total cost dropped
- In addition
  - ~20-40 % reduced complication risks
  - Providers changed how they worked (e.g., new manuals and checklists, certification of personnel)

Review of Public Administration and Management

José Pereira et al., Review Pub Administration Manag 2015, 3:1
DOI: 10.4172/2315-7844.1000169

Commentary Open Access

Value-Based Health Care in a Public Hospital in Brazil

Adriano José Pereira, Leonardo José Rolim Ferraz, Gabriela Sato, Alberto Hideki Kanamura, Renato Tanjoni, Henrique Sutton de Sousa Neves and Eliezer Silva*

Hospital Israelita Albert Einstein, Sao Paulo, Brazil

Commentary

Healthcare associated costs are growing. For instance, in developed countries as in United States, they may reach sums that encompass 17% of the GDP. In Brazil, total healthcare costs comprise 9% of the GDP, with around half of that related to the public system [1]. Despite lower total and per capita expenses when compared to US, such costs suffered a 2-fold increase in less than 10 years, from 80 billion Brazilian Reais, in 2002, to 160 billion Brazilian Reais, in 2011 [2], what is considered to be insufficient to provide an adequate care to around 150 million citizens which depend on the public health system (approximately 50 million are insured by the private health system). Thereby, whereas public system provides care to 76% of the Brazilians, only 46% of the total healthcare costs are destined to it, resulting in a much lower public expenditure per capita than observed in the private system [3-5].

Demographic transition, population aging, increased costs of new procedures and technologies have imposed to healthcare systems worldwide a challenge, by which conflicting need to be confronted: improved outcomes and reduced costs. Researchers, non-profit organizations and governments have committed themselves, in the past few years, to pursue ways to optimize health systems performance. The concept of "value" in healthcare has been recently revisited and is currently understood as what really matter when delivering quality and effective care: the balance between outcomes and costs, naturally encompassing efficiency [6]. The way to assess value is by tracking patients and costs longitudinally, but shifting focus from volume to value is a huge challenge [7].

Outcomes, the numerator of the value equation is a complex

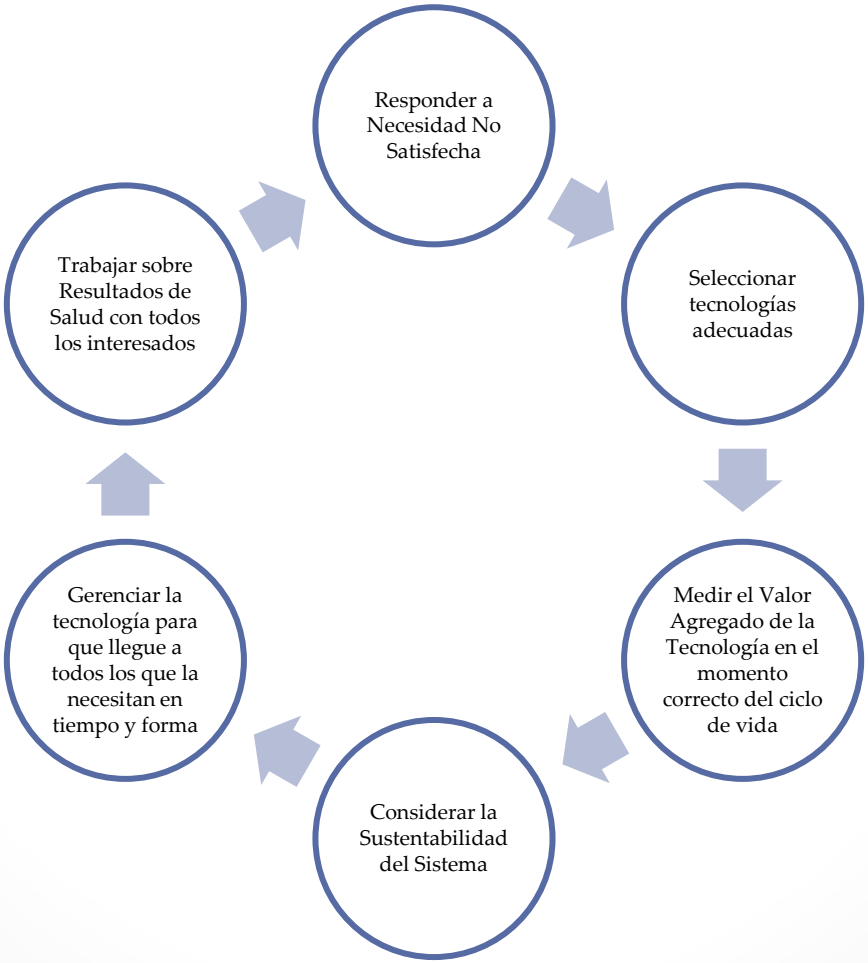
by demographic data, disease-related groups- DRG, adverse events and complications).

The other issue when discussing value in health systems is related to the methodology for cost determination. Usually, costs are not calculated after a complete treatment cycle, but by each department, each procedure, individual service or specialist involved [9]. Most of the total cost of a full cycle of care is attributed to shared resources as facilities, physicians, staff, and equipment, and it should be incorporated in total costs of the real and individual resource usage, and not as averages [7]. Considering what cannot be measured might not be managed, opportunities to reduce costs will be limited, and an efficient value-based health care system might not be implemented. Cost management in a health system entails process definitions, resource allocation, and establishment of standards in order to seek for quality and safety. In such context, quality indicators should more than process measurements, but true outcomes [7]. In the current project, costs will be analysed in detail by the methodology of the total absorption costing, executed by the accounting department of the hospital.

A specially developed and dedicated BI will integrate outcomes and costs data. Results will be summarized and analysed by a team of researchers and health managers at each 6-month. A quality and safety team will be responsible, as a part of the hospital management system, to propose value-based changes and share ideas with the different hospital departments, aiming to find opportunities for efficiency improvement. The context of this new public hospital, which runs based on process of care standardization and on outcomes and costs monitoring of the full cycle of care will favour minimization in the variability of care and

ETS

ETS para Acceso No barrera



Dimensiones del impacto de una tecnología

Seguridad comparada

- Es segura?
- Es igual o más segura que lo que ya hacemos?
- Cuáles son los efectos indeseados o inesperados?

Efectividad comparada

- En quién funciona y cuándo?
- Es mejor de lo que ya hacemos o tenemos?
- Utilidad

Eficiencia e impacto económico

- Provee valor por el dinero invertido?
- Podemos pagarlo?
- Cuáles son los intercambios que debemos hacer?
- Costo de oportunidad

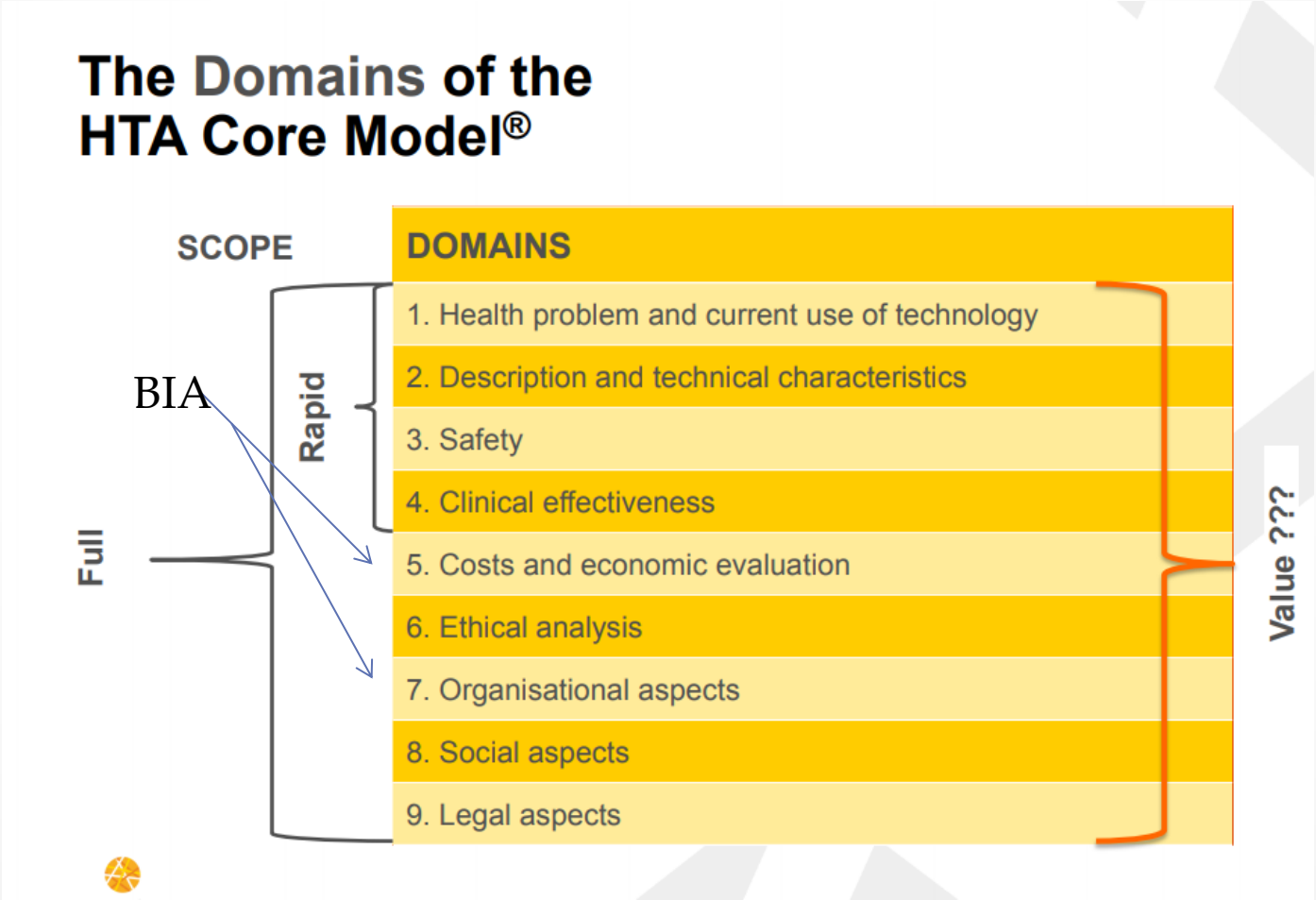
Impacto ético y social

- Cómo hago el balance entre los diferentes dominios?
- Equidad

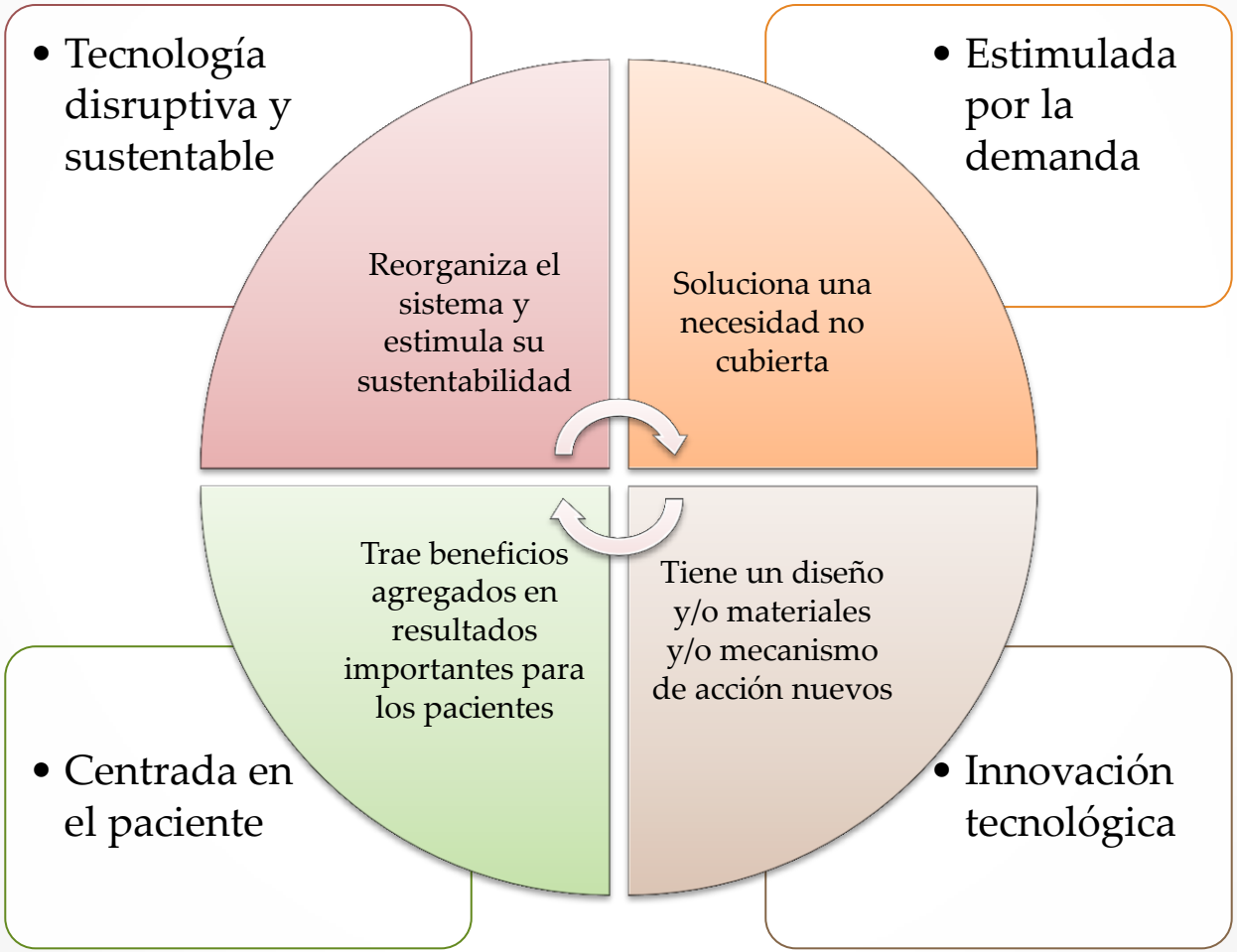
Aspectos legales

- Marco normativo

Marco de la Evaluación de Tecnologías Sanitarias



La innovación debe ser significativa y demostrar que agrega valor a la práctica habitual



Marco de valoración de la ETS en una presentación de dossier de un productor

La naturaleza de la evidencia para ETS

Adaptado de NICE y Dr Sophie Staniszewska, RCN Research Institute, University of Warwick

Resultados importantes para los pacientes

Análisis económicos en ETS

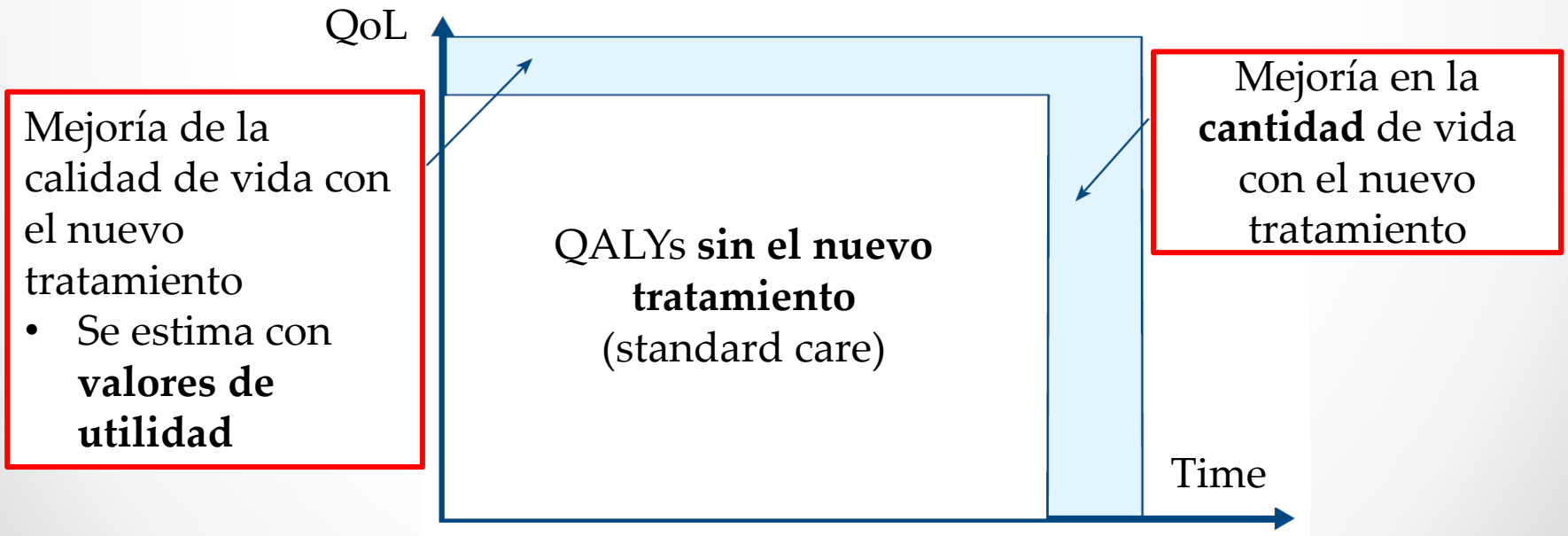
Costo-consequencia	Estima el costo y valor de las intervenciones, pero deja que las conclusions las saque el lector.
Costo-minimización	Compara costos, pero assume que los resultados son equivalentes (e.g., drogas bioequivalentes)
Costo-efectividad	Mide los costosen unidades monetarias y los resultados en unidades naturales (e.g., mmHg que reduce) or razones (diferencia en costo/ diferencia en resultados)
Costo-utilidad	Mide resultados basado en años de vida y calidad de vida obtenida con el tratamiento
Costo-beneficio	Enumera y compara costos y beneficios en términos monetarios
Impacto presupuestario	Estima los efectos de las intervenciones en el costo total de la organización o Sistema de salud

Costo de Oportunidad y ETS

- Si gastamos más en una cosa, temenos que hacer menos de otra.
- Podríamos hacer más bien gastando el dinero en otra cosa?
- El valor de la major alternativa de uso de recursos es el ´costo de oportunidad´

QALYs

- En el análisis de costo-utilidad, la efectividad se mide en años de vida ajustados por calidad (QALYs)
  - QALYs incorpora **tanto la calidad como la cantidad de vida ganada** con una intervención en una medida única de ganancia de salud



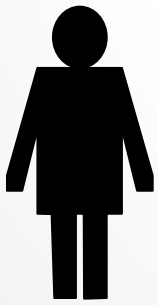
Adaptado de McCabe C. Hayward Group Ltd. 2009

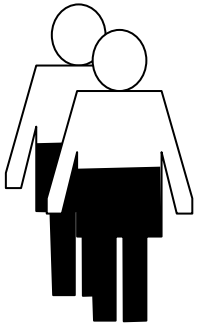
QALY

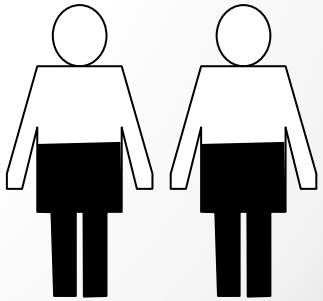
1 QALY = 1 año de salud perfecta para una persona

= 2 años de vida con QoL 0.5 para una persona

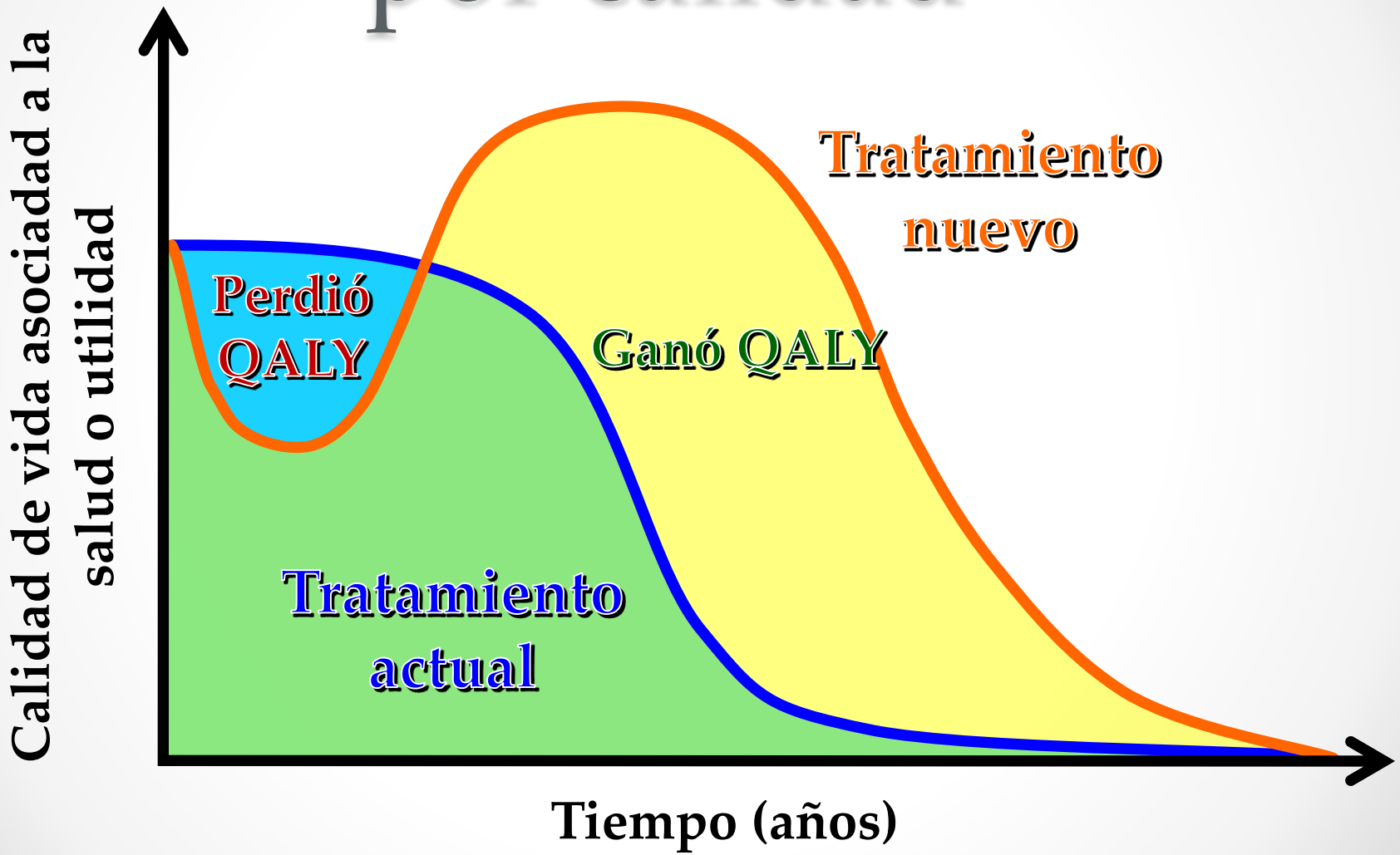
= 1 año de vida con QoL 0.5 cada uno para dos personas



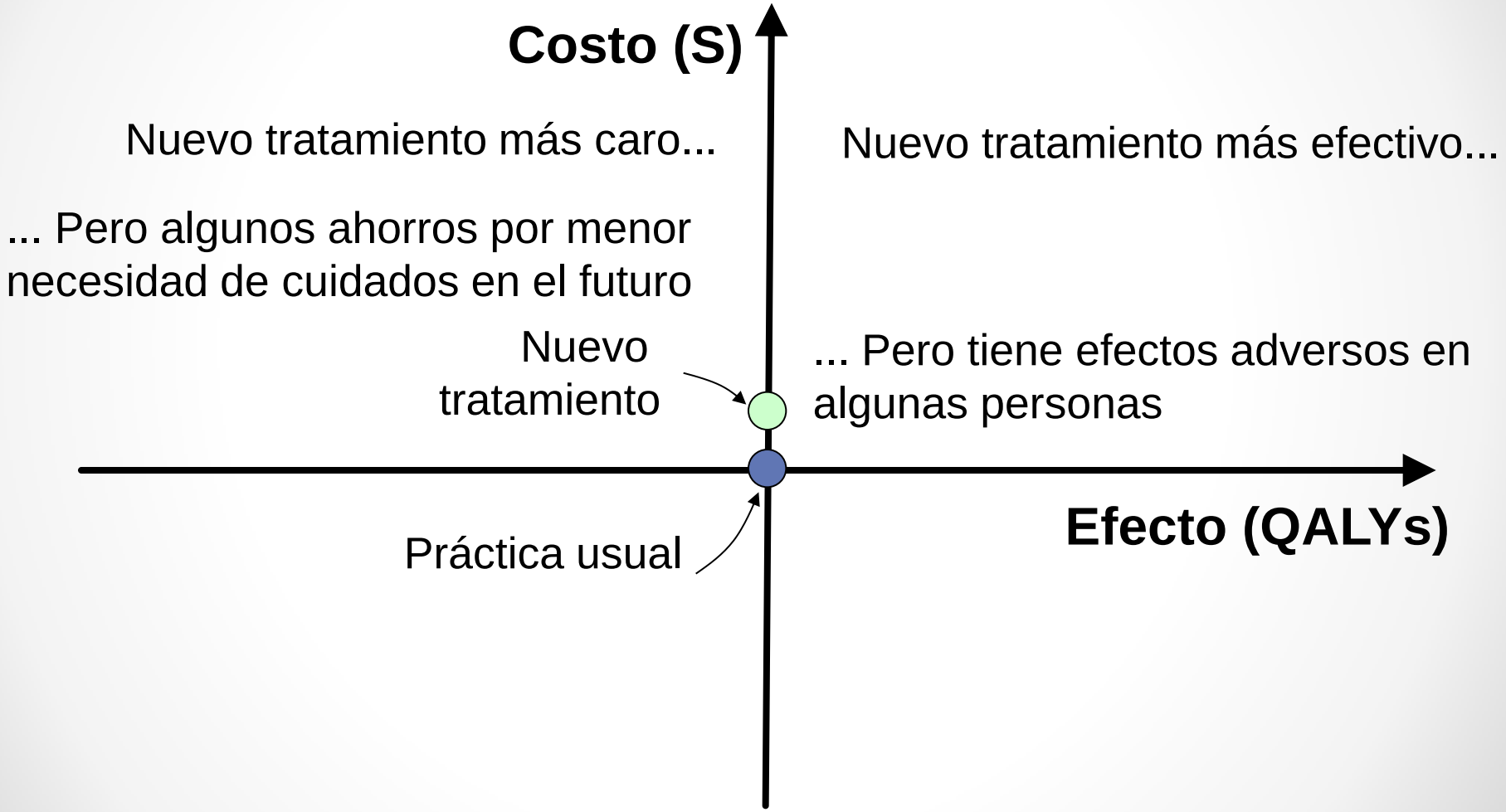




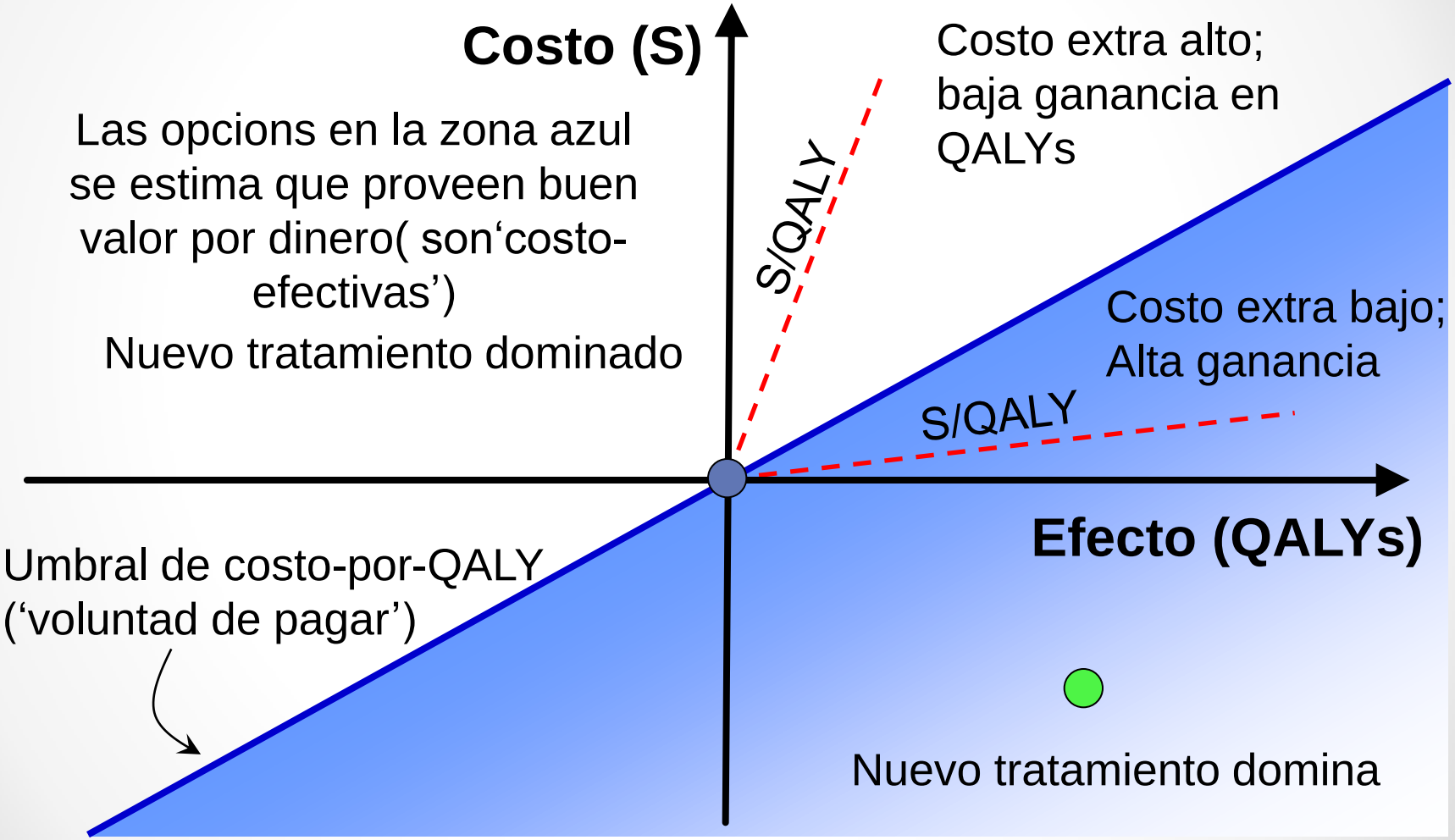
Años de vida ajustados por calidad



Considerando los beneficios, riesgos y costos

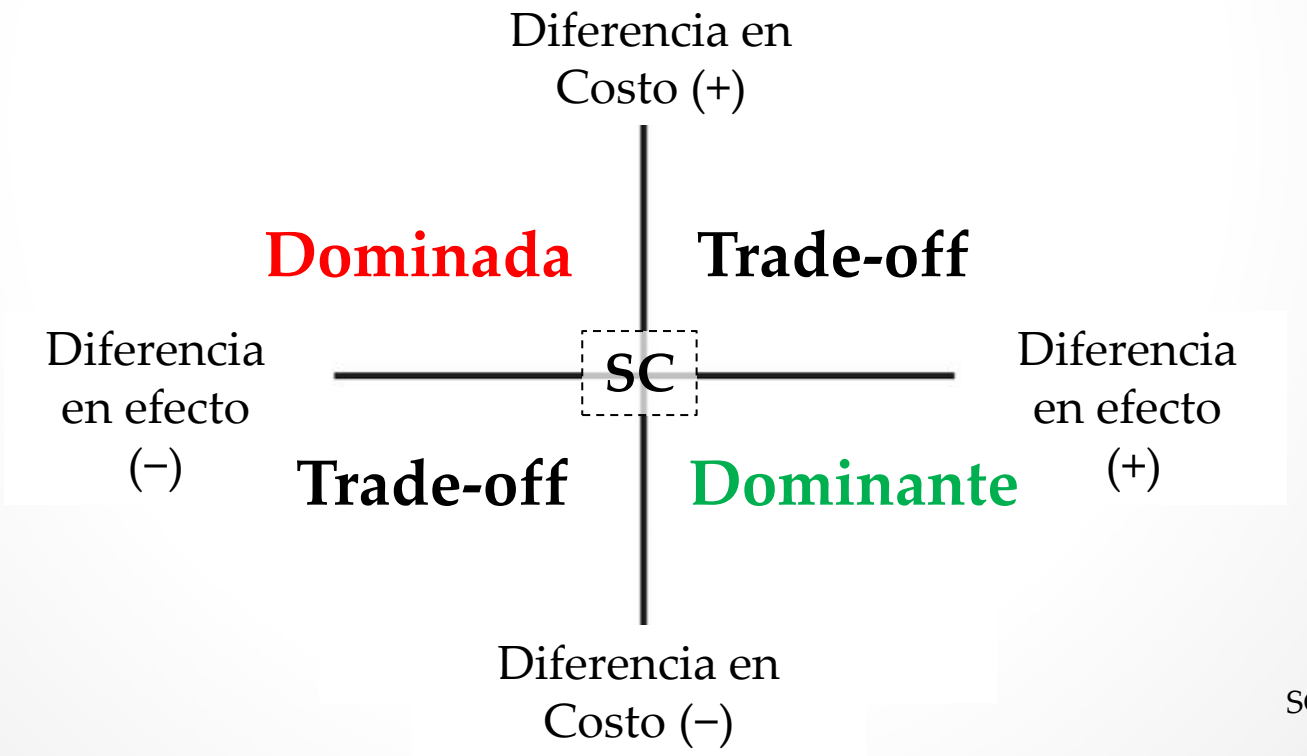


Valor por dinero



El plano de la Costo-Efectividad

- Un nuevo tratamiento puede ser comparado con un tratamiento existente basado en su efecto diferencial en el **costo** y efectividad



SC = standard care

ICER

- Indice de costo-efectividad incremental
- "costos por resultado" (análisis de costo-**efectividad**) or "costs por QALY" (análisis de costo-**utilidad**)

$$\frac{\text{Costs}_{\text{Treatment}} - \text{Costs}_{\text{Standard care}}}{\text{QALYs}_{\text{Treatment}} - \text{QALYs}_{\text{Standard care}}} = \text{ICER}$$

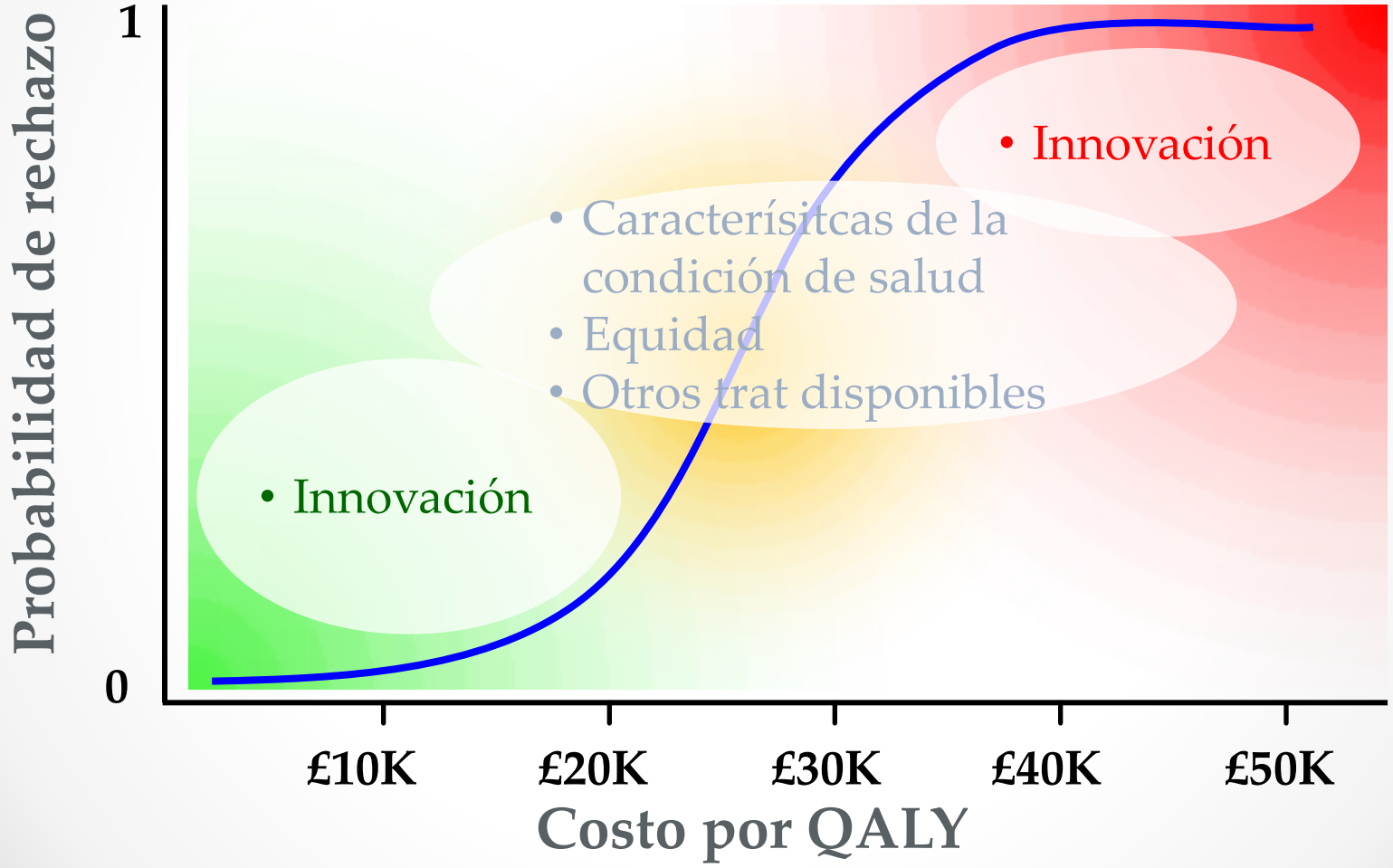
ICER

$$\frac{\text{Costs}_{\text{Treatment}} - \text{Costs}_{\text{Standard care}}}{\text{QALYs}_{\text{Treatment}} - \text{QALYs}_{\text{Standard care}}} = \text{ICER}$$

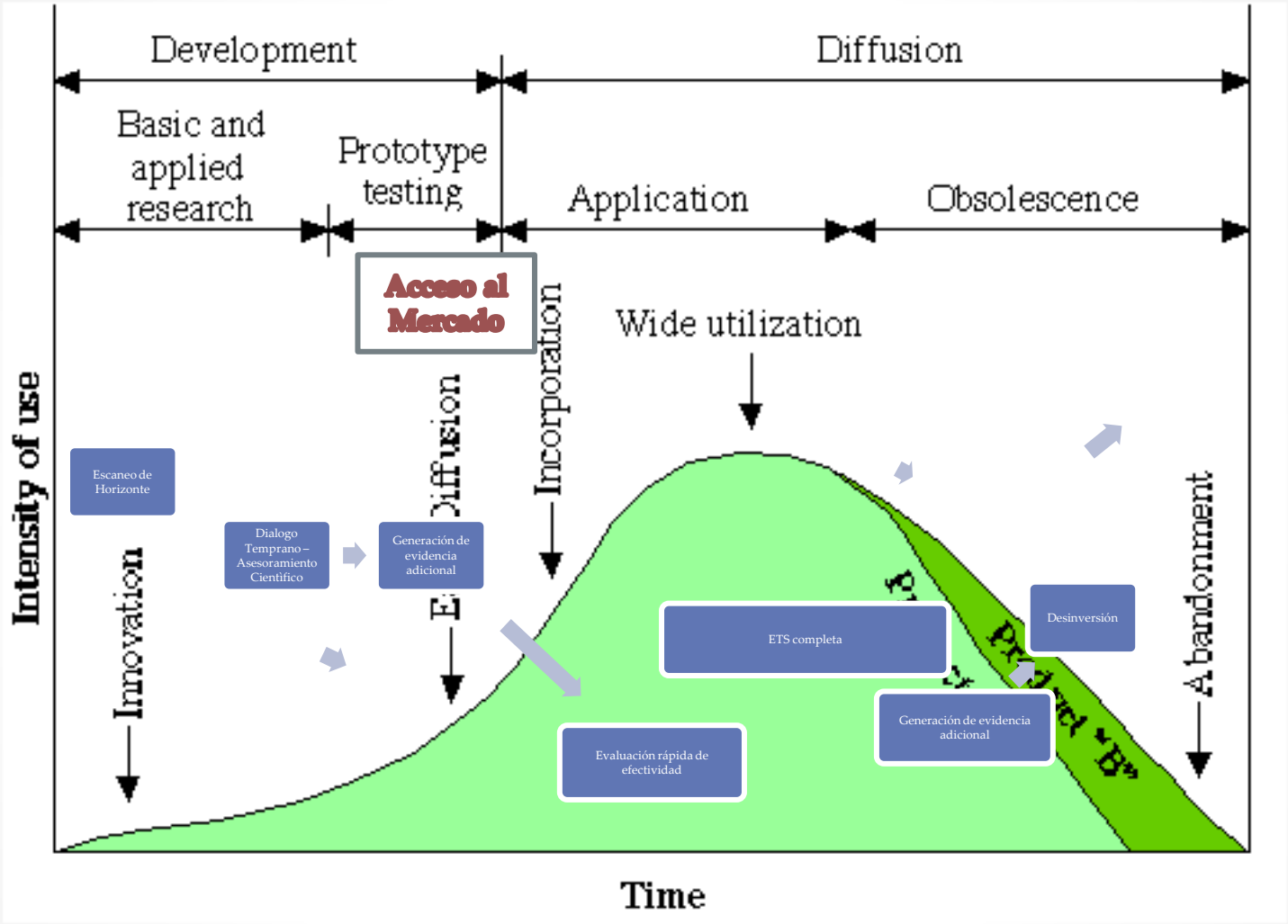
	Costo total	Años de vida ganados (LYG)	Utilidad por LYG	QALYs
Tratamiento	$20,000	7	0.5	3.5
Standard Care	$10,000	5	0.6	3.0

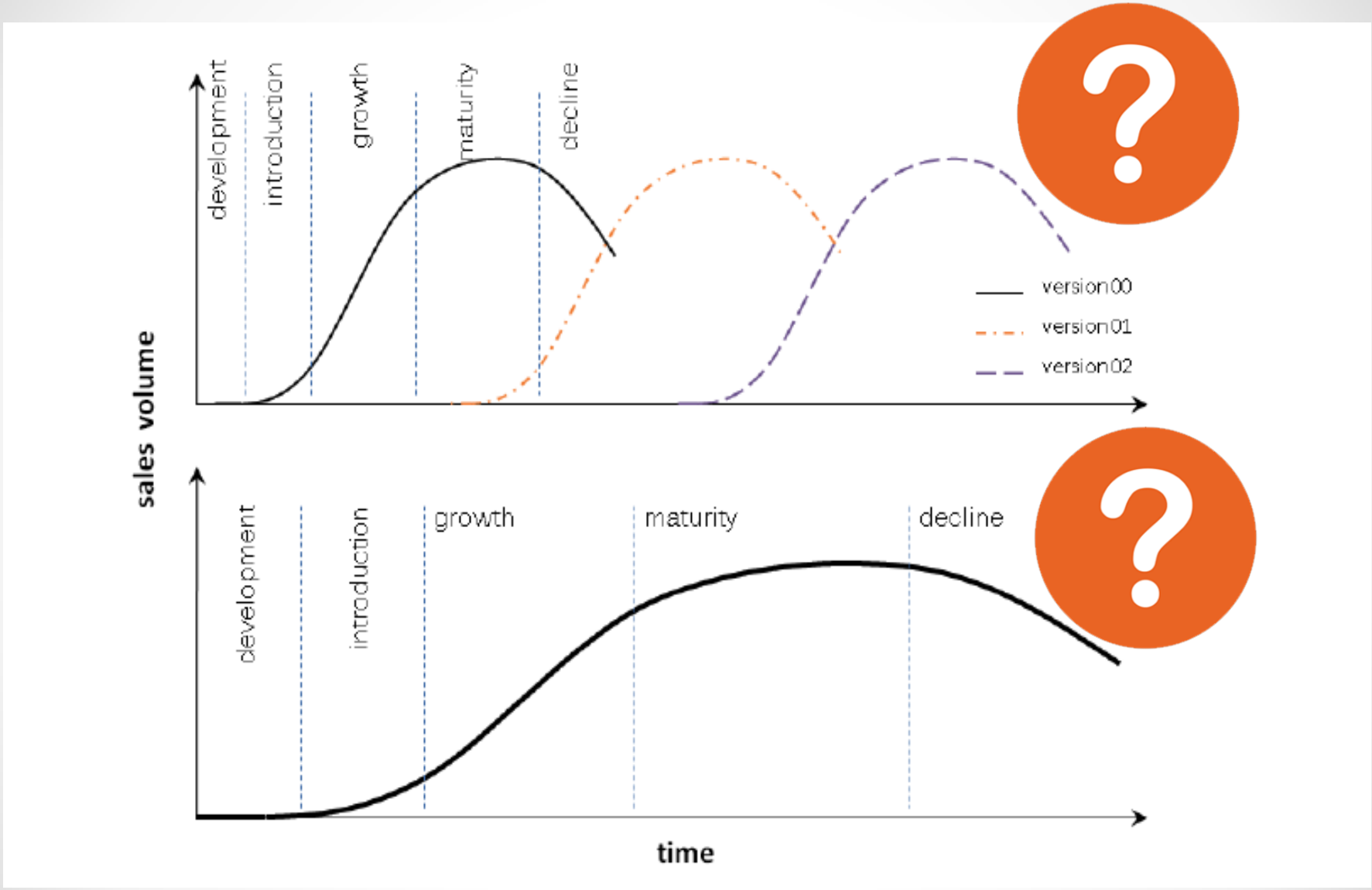
Incremental Costo incremental, tratamiento vs Std. Care	Años de vida incremento	Costo increm/LYG	Incremento QALYs	ICER cost/QALY
$10,000	2	$5000/year	0.5	$20,000/ QALY

El Umbral de la CE



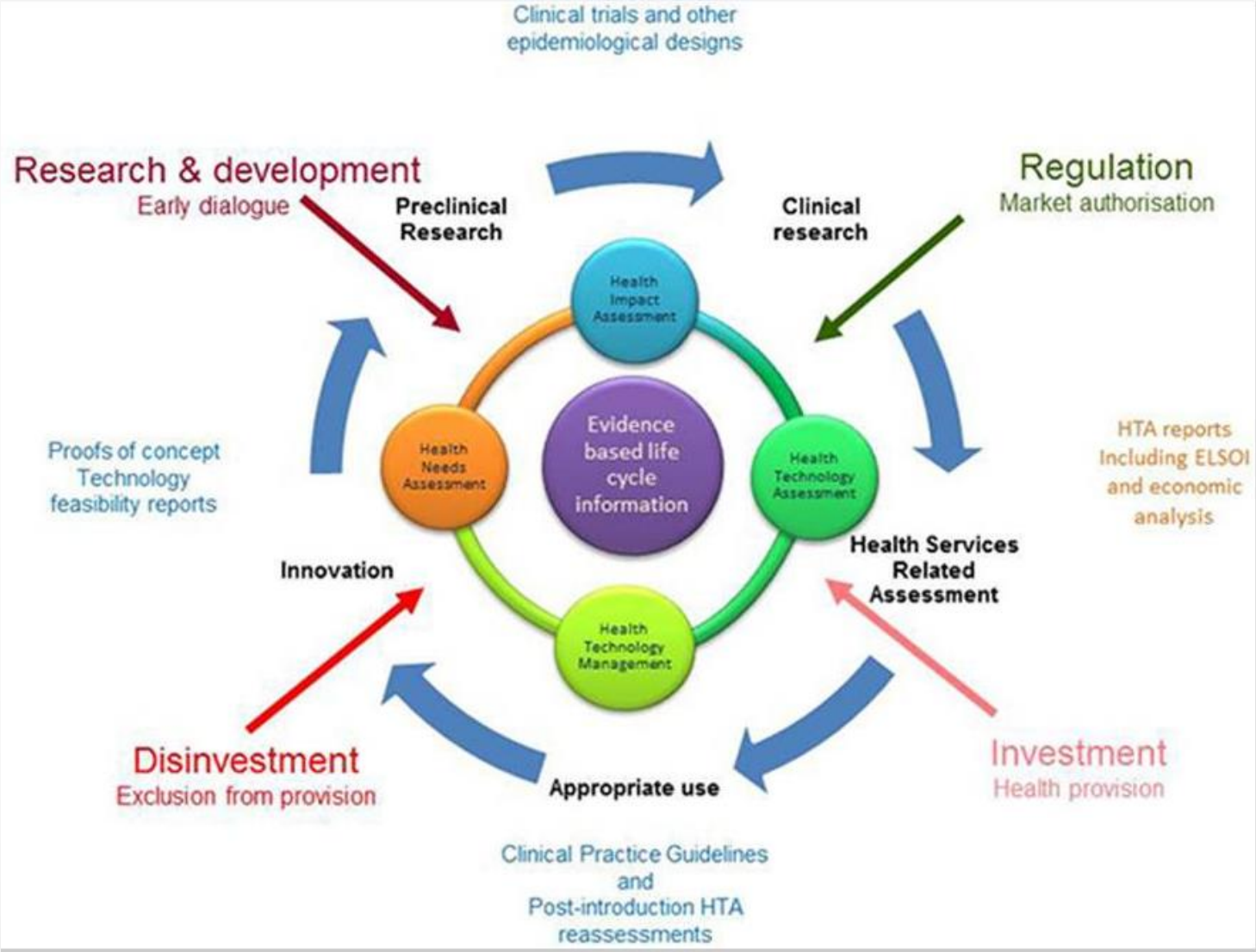
ETS en el contínuo de la vida de las tecnologías sanitarias





Santos IC, Gazelle GS, Rocha LA, Tavares JM. **Medical** device **specificities**: opportunities for a dedicated product development methodology. Expert Rev Med **Devices**. 2012 May;9(3):299-311

Ciclo de Vida de las Tecnologías Sanitarias



Gutiérrez-Ibarluzea I, Chiumente M, Dauben H-P. The Life Cycle of Health Technologies. Challenges and Ways Forward. *Frontiers in Pharmacology*. 2017;8:14.

Evaluación de tecnología sanitaria de dispositivos médicos

Miles de dispositivos y de compañías-PIMEs

Diferencias en evidencia clínica regulatoria – uso pretendido (performance) vs eficacia

Riesgo determina evidencia regulatoria

Cambian muy rápido (moving target) . Outcomes clínicos dependen del entrenamiento, competencia y experiencia del end user (curva de aprendizaje) -devices múltiples-ciclo corto de vida-ajuste necesarios- RCT ciegos muy difíciles -evidencia de la vida real

Evaluación económica más amplia –impacto organizacional- ¨beyond QALY)- precio más dinámico que para medicamentos, costos incluyen costo de compra, infraestructura asociada y equipo de capital, mantenimiento y consumibles

Industria de tecnología médica y ETS

- La mayoría SMEs
- Ciclo de producción corto
- Ciclo de vida corto (18 m)
- Innovación incremental
- Presupuesto para investigación limitado
- No protección extendida de patente
- Propuestas de valor generalmente relacionadas a costos y uso de recursos
- Requerimientos de evidencia regulatoria diferente a evidencia efectividad para HTA

Características clave en HTA de dispositivos médicos

- Intervenciones complejas – preferencias de los pacientes y cirujanos –contexto y curva de aprendizaje
- (i)Interacción operador-dispositivo pueden generar efectos de curva de aprendizaje que llevarán a sesgos en la estimación del tamaño del efecto
- (ii) Naturaleza incremental de la innovación (baterías más durables, mejoría de los sofwares, miniaturización) necesita considerarse identifiando las alternativas para el análisis comparativo e incremental
- (iii) El impacto organizacional más amplio (entrenamiento e infraestructura) asociado a precio dinámico, require una aproximación más flexible al costeo.

Evaluación de tecnología sanitaria de dispositivos médicos

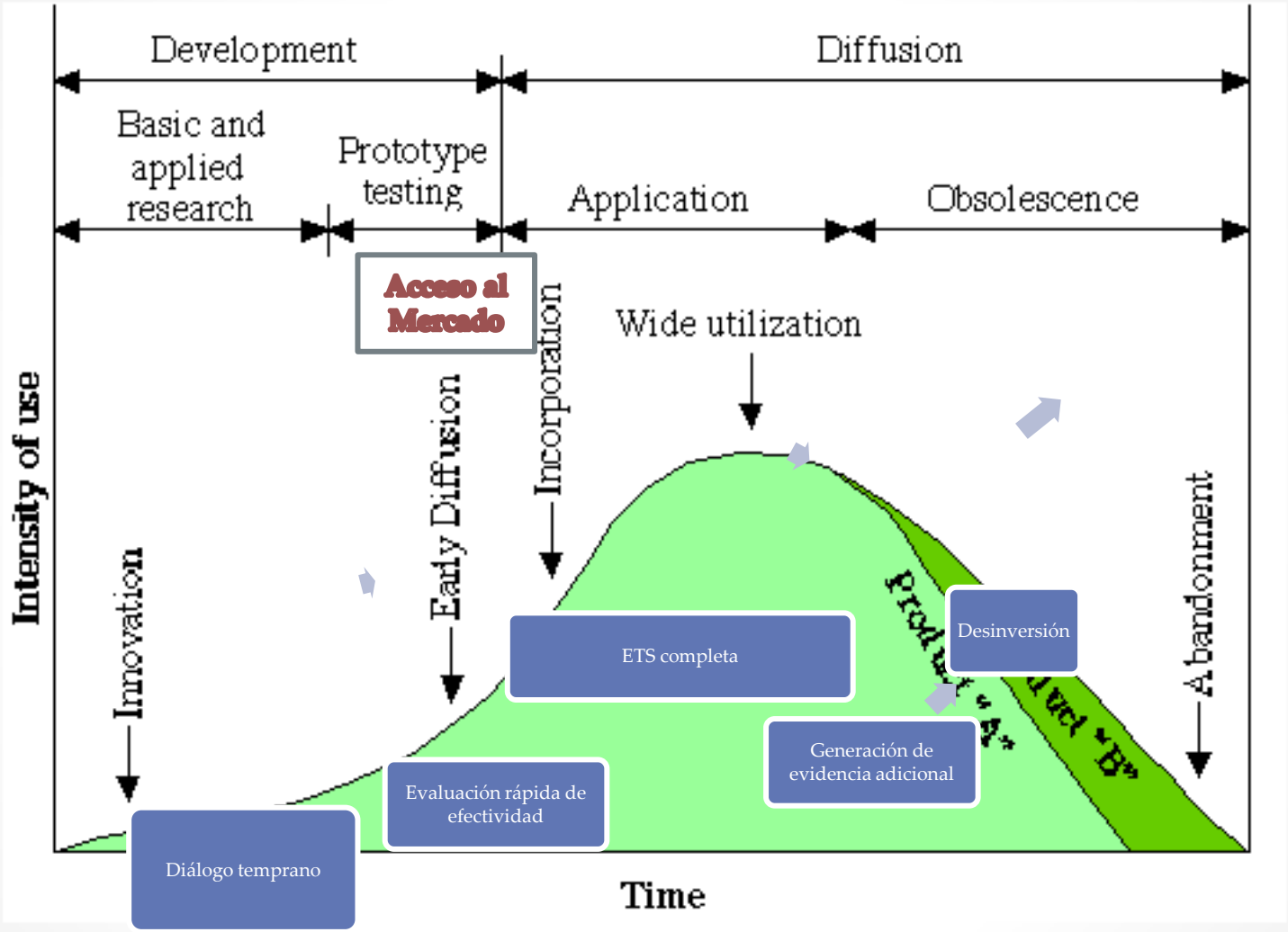
Baja capacidad y expertisse de evaluación

Gran gap eficacia-efectividad

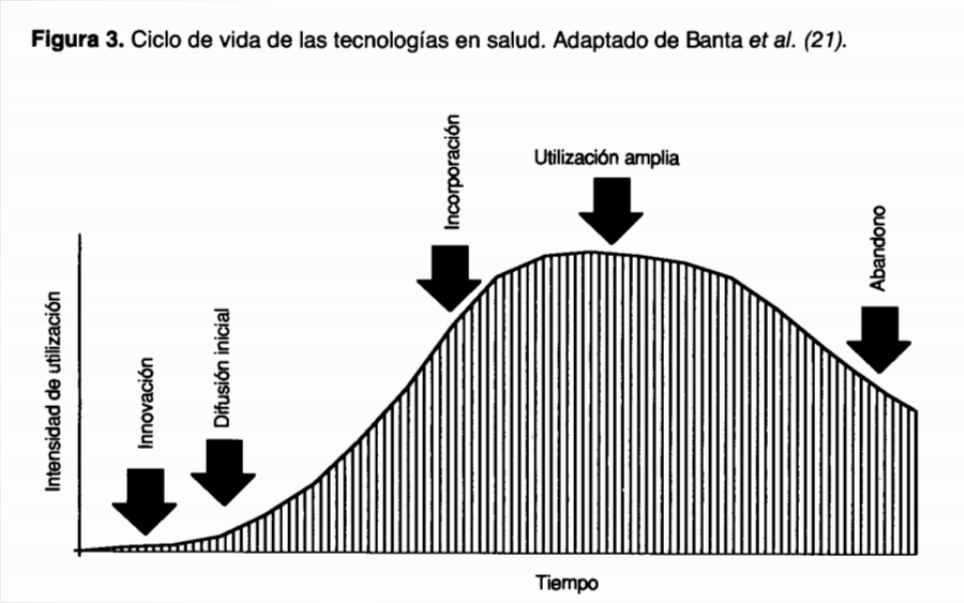
Baja transferabilidad de la evidencia

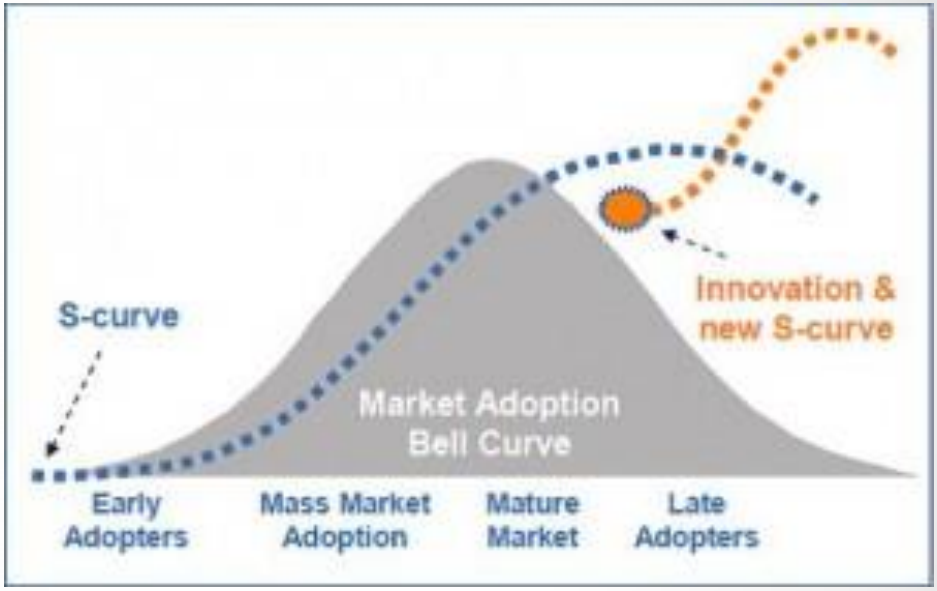
Diferentes niveles de evidencia?

ETS en el contínuo de la vida de las tecnologías sanitarias



Ciclo de vida de las tecnologías sanitarias





Medicamentos

Productos médicos

Evaluación de tecnología sanitaria de dispositivos médicos

RWE -registros

Cobertura condicional con desarrollo de evidencia

Ajustes por interacción usuario-device

Modelado y costeo específico

Guías y equipo específico

Challenges experienced by HIQA in assessing medical devices

- Difficulty identifying relevant medical devices and their CE status
- Availability of efficacy/effectiveness data
- Adverse events – device-specific or procedure-related?
- Incremental nature of innovation
- Learning curve effect due to device-operator interaction
- Consideration of broader organisational impact including training and infrastructure

NICE

Key finding: evidence generation

- Evidence used in the appraisal of medical devices may be of poor quality in terms of methodology, execution and reporting, and may not address any identifiable clinical question
- Poor quality evidence is related to
  - lack of understanding product value propositions in the NHS context
  - Limited industry resource and capacity
- Consequently guidance decisions may be made in the absence of strong evidence

Key finding: value proposition

- Problems arising in NICE's appraisal of medical technologies often arise from lack of manufacturer understanding of the value proposition
  - *Value proposition:* a clear and credible set of relevant claims capable being evidenced that provide value to healthcare providers and users …*our definition*
- This often results in:
  - a mismatch between manufacturer commissioned research and accepted standards for clinical evidence
  - research which does not address questions relevant to NHS needs

Key finding: complexity

- Some medical technologies are cost saving and resource releasing only in the context of wider service redesign
- Evidence generation may therefore be complex and expensive
- Safety value propositions predicated on preventing very rare events may present particular difficulties
- This may present barriers to appraisal of promising technologies using the MTEP Methods and Process as evidence may be lacking
- NICE however published Interim methods guide for developing service guidance in 2014 potentially providing a route for NICE to consider service change

Conclusion

- Methods to develop NICE advice and guidance are potentially robust but decision-makers may have only poor quality evidence on which to make decisions.
- Industry response to NICE model often shows poor understanding of:
  - value to the NHS
  - clinical evidence
  - Cost consequence analysis data requirements (comparative data, full costs)
- This response reflects industry characteristics (company size, R and D resource, product development cycle and marketing) and potential return on investment

http://www.medtechta.eu/wps/wcm/connect/site/medtechta/home | Gmail - Recibidos | MedtecHTA - Home | medtechta.eu

MedtecHTA

Methods for Health Technology Assessment of Medical Devices: a European Perspective

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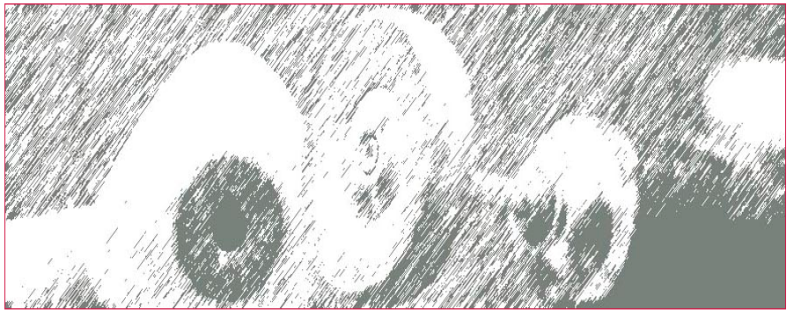

PROJECT PRESENTATION

The focuses of the MedtecHTA is on improving the existing methodological framework within the paradigm of Health Technology Assessment (HTA) for the assessment of medical devices, and to develop this framework into a tool that provides structured, evidence-based input into health policies.
The project aims at filling the gap on the current research debate on the challenges to the available methodological framework for HTA when applied to medical devices.

The MedtecHTA project is expected to make a substantial contribution for a wide range of key stakeholders (policy makers, scientific community, HTA agencies, healthcare providers, medical device industry and patients) to make informed decisions concerning the cost-effectiveness and appropriate use of and patients' access to medical devices.

The project will provide more than 280 person-months of scientific research effort.

Partners: 6 Universities & 1 Scientific Association

Countries: Austria, Germany, Italy, Slovenia & UK

Duration: 36 months

Starting date: 01/01/2013

LATEST NEWS

Presentations Medtechta Final Conference are now available! >>>

MedtecHTA final program >>>

Executive summary online! >>>

EVENTS

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1:26
21/10/2017

Table 1. MD Characteristics and Functionality, Impact on HTA Methods, Proposed Recommendations for HTA Guidelines, and Associated EUnetHTA Domains

MD characteristic and functionality	Impact on HTA methods	Proposed recommendations for HTA methods guidelines for medical devices	Associated EUnetHTA domains
Product lifecycle			
• Shorter lifecycle than drugs	• Shorter timeframe for HTA completion • Limited evidence available • Estimates of cost-recovery may be inaccurate in the cost-effectiveness analyses	• Obtain as much data as feasible to more accurately predict the MD lifespan • Use appropriate statistical methods (e.g., Bayesian methods) to analyze the different types of evidence on the effectiveness and safety of the MD • Conduct sensitivity analyses in economic model to measure the impact on the results of varying lifespans	• Description and technical characteristics technology (TEC) • Costs and economic evaluation (ECO) • Organizational aspects (ORG)
• Maintenance required	• Maintenance may impact costs, efficacy, effectiveness, satisfaction, and safety of the MD over its lifespan.	• Obtain additional insights about maintenance required • Use any of the following tools to further understand device maintenance requirements: o Domain analysi o User profile, stakeholder identification and analysi o Usability (e.g., ISO 9241-11:1998)(37) o Stakeholders (including patient and clinicians) experience (e.g. ISO 9241-210: 2010)(38) o IEC standards (e.g., costs, downtime, etc.) o Meantime between failures calculations	• Description and technical characteristics technology (TEC) • Costs and economic evaluation (ECO) • Organizational aspects (ORG) • Safety (SAF) • Clinical Effectiveness (EFF)
• Potential instability of individual parts (e.g. software)	• Risk of inaccurate data and device failure may impact safety, efficacy, effectiveness, and cost-effectiveness	• Consider conducting a risk assessment • Use appropriate and validated tool or standards to conduct a risk assessment (e.g., ISO 14971, IEC/TR 80002-1: 2009 MD software (39), etc.). • If feasible, conduct a simulation of use to empirically analyze the safety the device and define the processes of risk reporting , and to mitigate residual risks (e.g., ISO 62336-1 2015)	• Costs and economic evaluation (ECO) • Organizational aspects (ORG) • Safety (SAF) • Clinical Effectiveness (EFF)
• Possible interferences with other MDs (e.g., radiofrequency)	• There may be minimum requirements in terms of organization (e.g. personnel), technology (e.g. radiofrequency interferences) and structure (e.g.,	• Understand the setting and map the process of the device use • Increase health professionals and patient awareness of such possible interferences	• Organizational aspects (ORG)

Clinical evaluation			
• Longer learning curve	• Impact on the estimation of efficacy, effectiveness, user satisfaction, safety, cost-effectiveness, and service provision	• Use both pre-market (e.g., usability and risk assessment of the device use; ISO 62336-1 2015) and post-market data to capture impact of learning curve on outcomes • Collect and report data on the effects of learning on relevant procedural and clinical outcomes during clinical trials, both at the physician and centre levels • Collect registry data that allow the estimation of the learning curve based on routine use of the MD once it has been adopted in clinical practice • Ensure that device users enrolled in a trial have received appropriate material for the device use (guidelines and service process of use) and training to reduce the risk of bias in measuring clinical efficacy and effectiveness • Use appropriate statistical methods to incorporate the learning curve into the measurement of relevant outcomes and costs	• Costs and economic evaluation (ECO) • Organizational aspects (ORG) • Safety (SAF) • Clinical Effectiveness (EFF)
• Designing a randomised control trial (RCT) for a MD is more challenging than for drugs	• Blinding is a challenge in a study with MDs. • Unlike drugs, MDs are diagnostic and therapeutic, and they can influence the clinical decision making process and the patient's clinical care pathway.	• Adopt appropriate study designs for MDs. The design can include pre-liminary phases of clinical pathway mapping and qualitative analysis to identify the most appropriated setting, comparators and variables to be considered in a trial. • Reinforce the use of simulation in case of incremental innovation	• See above (i.e., longer learning curve)
Issues in use			
• Performance is stronger dependent on user and context of use	• See above (i.e., learning curve) • Efficacy and effectiveness, satisfaction (i.e., usability) are also dependent on user workload, stress level, etc… The performance in the use of a device is a context dependent factor. In this instance, the context is defined as "users, tasks, equipment (hardware, software and materials), and the physical and social environments in which a product is use"; ISO 9241-11:1998)(37)	• See above (i.e., longer learning curve) • Identify the setting and collect data on outcomes in the user training phase	• See above (i.e., longer learning curve)

Gaps in HTA methods guidelines for medical devices	Recommendations to address gaps	(IQR)	(%)
Product lifecycle			
Timeframe to perform a complete a HTA is much reduced in the MD lifecycle compare to drugs. Spending several months or years to conduct a HTA may result in an outdated or obsolete (e.g., a newer version of the device is available) report. o Limited evidence is available to meet the objectives of HTA o The time horizon of the economic evaluation may be inaccurate o Estimates of cost recovery may be inaccurate in the cost-effectiveness analyses	1. Use the available evidence to accurately estimate the cost-effectiveness of the MD and to quantify its uncertainty. When evidence is lacking, HTA experts could run clinical performance and usability analysis to gather relevant insights for their analysis.	4 (4,5)	31 (96.9)
	2. Use appropriate methods to assess the quality of modelling the effect of the different types of evidence on the effectiveness and safety of the MD.	4 (3,4)	31 (96.9)
	3. Conduct sensitivity analyses in economic model to measure the impact on the results of varying lifespans or incremental innovations.	4 (3,5)	31 (96.9)
Maintenance of the device and the characteristics of the services for the device may impact costs, efficacy, effectiveness, and safety of the MD over its lifespan.	4. Obtain additional insights about the maintenance required, and capture maintenance impact in the HTA by using appropriate methods of contextual inquiry. The context inquiry can include, for instance, gather information about the service requirements in terms of preventive maintenance planning, costs, downtime and by gathering qualitative data about the needs of the stakeholders of the service.	5 (4,5)	31 (96.9)
Instability of individual parts may impact the safety, efficacy, effectiveness, user satisfaction, and costs.	5. Conduct a risk assessment by using appropriate and validated tool or standards.	4 (4,5)	30 (93.8)
	6. Conduct, when necessary, a simulation of use to empirically analyze safety in use and define procedures of risk report, and processes to mitigate residual risks.	4 (4,5)	30 (93.8)
Majority of HTAs focuses one technology per time and dependences of this technology with surrounding ones are almost never considered.	7. Map the process of device use, and explicitly state the organizational constraints, technological and structural conditions in which the trial was performed.	5 (4,5)	31 (96.9)
	8. Conduct an analytic assessment to estimate "what if" the minimum requirements are not met.	5 (4,5)	31 (96.9)
	9. Manage and ensure processes of data exchange and interoperability of the device with hospital system and with other devices.	4 (3,5)	31 (96.9)
	10. Increase stakeholders (i.e., technicians, health care providers, and	4 (4,5)	30 (93.8)

Clinical evaluation			
Impact on the estimation of efficacy, effectiveness, satisfaction in use, cost-effectiveness, service provision.	11. Use both pre-market and post-market studies to capture impact of learning curve on outcomes. The evidence can include a risk and usability assessment.	4 (4,5)	30 (93.8)
	12. Collect and report data on the effects of learning on relevant procedural and clinical outcomes during clinical trials, both at the physician and health care system levels.	4 (4,5)	30 (93.8)
	13. Collect registry data that allow the estimation of the learning curve based on routine use of the MD once it has been adopted in clinical practice.	5 (4,5)	31 (96.9)
	14. Explicitly state the clinicians' experience with the specific procedure (e.g., number of hernia repairs performed on similar patients) and in particular with the device under assessment of a similar one (e.g., previous version, similar device), if any.	4 (4,5)	29 (90.6)
	15. Describe in detail the training and training materials for the device use (e.g., guideline of use and service process associated to the device use, etc.) provided to the users of the MD.	5 (4,5)	30 (93.8)
	16. Use appropriate statistical methods to incorporate learning curve corrections into the measurement of costs and relevant outcomes.	4 (4,5)	29 (90.6)
Unlike drugs, MDs can be both diagnostic and therapeutic, and they can influence the clinical decision making process and the patient's clinical care pathway.	17. Adopt appropriate study designs for MDs. The design can include preliminary phases of clinical pathway mapping and qualitative analysis to identify the most appropriated setting, comparators and variables to be considered in a trial.	5 (4,5)	30 (93.8)
	18. Reinforce the use of simulation (e.g., in silico trial) in case of incremental innovation.	4 (4,5)	29 (90.6)
Issues in use			
Same MD used by different users in different contexts may have different costs, efficacy, effectiveness, and safety, both in the short time (e.g., during the trial) and during its lifespan.	19. Use both pre-market and post-market data to capture impact of context of use variables (i.e., user, tasks, physical and social environment) on HTA outcomes.	5 (4,5)	30 (93.8)
	20. Simulate and use appropriate statistical methods to analyze the different types of evidence on the effectiveness and safety of the	4 (4,5)	30 (93.8)

	25. Use appropriate statistical methods to analyze the different types of evidence that reflects the learning curve with the MD.	4 (4,5)	29 (90.6)
Costs and economic evaluations			
Lack of evidence-based maintenance and service program formulation, manufacturer recommendations can be difficult to fulfill in budget-constrain circumstances and this can cause safety problems or affect MD effectiveness along the whole lifecycle. o Maintenance and installation procedures, and therefore their costs per each device, depend strongly on local clinical engineering and biomedical technician availability and expertise. This change significantly costs across different hospitals.	26. Understand and describe explicitly in the HTA report, all the possible maintenance, installation, and operational costs considered.	5 (4.25,5)	30 (93.8)
	27. Ensure that all reasonable maintenance, installation, and ongoing facilities costs are incorporated in the economic evaluation, or explicitly state the hypothesis of the study conducted.	5 (4,5)	30 (93.8)
	28. Describe the organizational model considered in the economic evaluation for maintenance and installation (e.g., internal clinical engineering service).	5 (4,5)	30 (93.8)
	29. If feasible, ensure that costs arising from missed maintenance are also considered.	4 (4,5)	30 (93.8)
Different financial models in acquisition of the technology (e.g., leasing) – scarce use of risk sharing agreements	30. Understand and ensure that the potential impact of financial models is represented in the economic evaluation.	5 (4,5)	29 (90.6)

HTA, health technology assessment; IQR, interquartile range; MD, medical device

H2020 projects: COMED (2018-2020)

- ✓ **WP1: RWD for economic evaluation of medical devices**
  - ✓ *Objectives : 1) identification of all sources of RWD (costs & health outcomes) on medical devices in EU countries, 2) methods for RWD collection and 3) methodologies for RWD analysis*
- ✓ **WP2: Use of surrogate outcomes for medical devices**
  - ✓ *Objective: recommendations on the use of various sources of evidence (including RCTs, observational studies, registries, surveys or routine administrative databases) to validate putative surrogate outcomes*

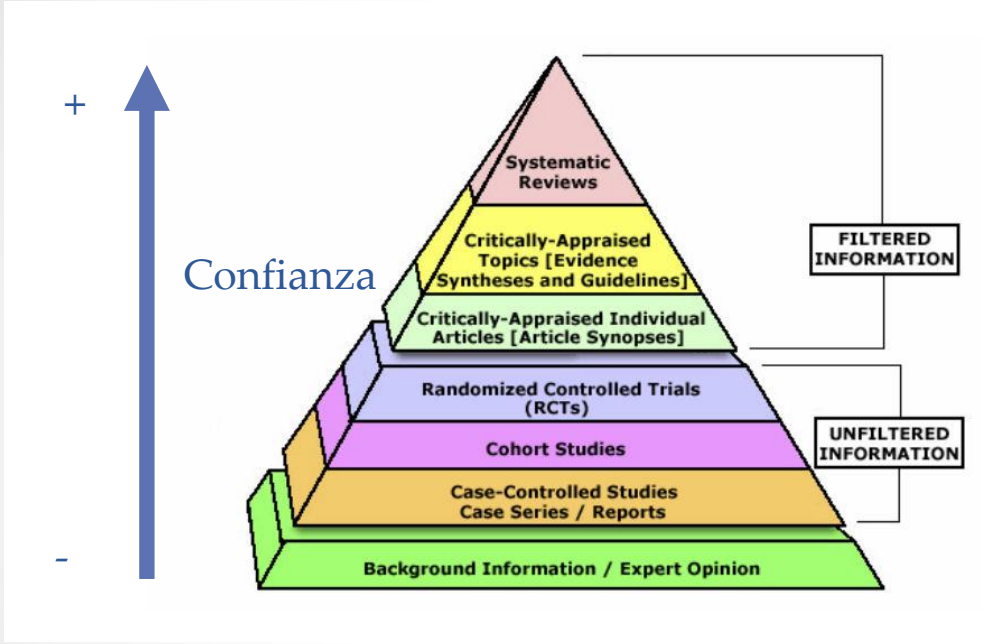
Evidencia y ETS

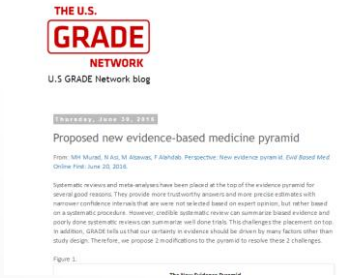
Diferentes fuentes

Diferente confiabilidad o niveles de calidad

Diferentes preguntas requieren diferente evidencia

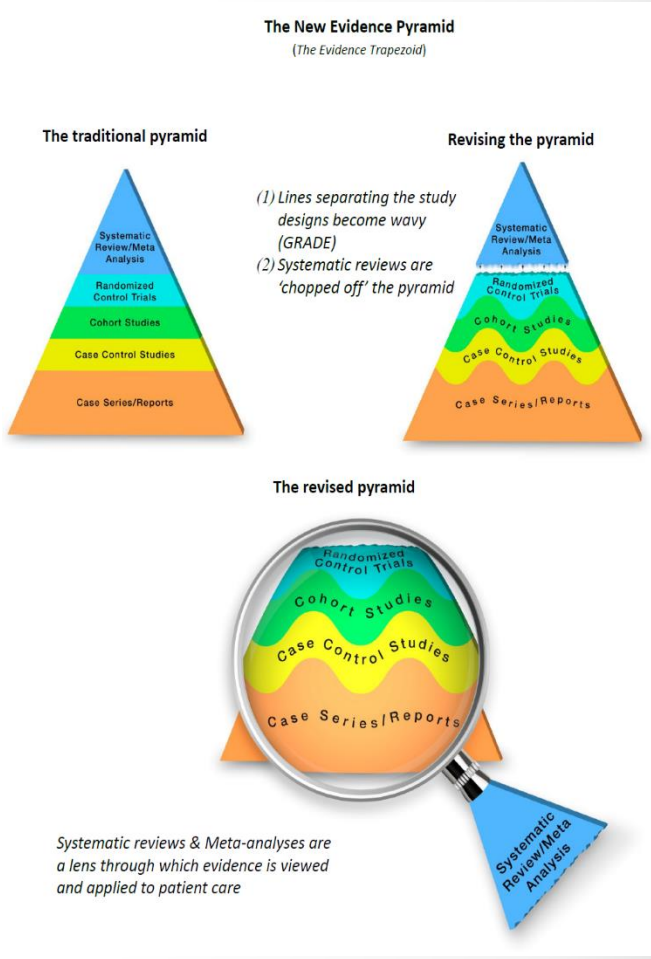
Evidencia y ETS




THE U.S. GRADE NETWORK

U.S GRADE Network blog

Proposed new evidence-based medicine pyramid

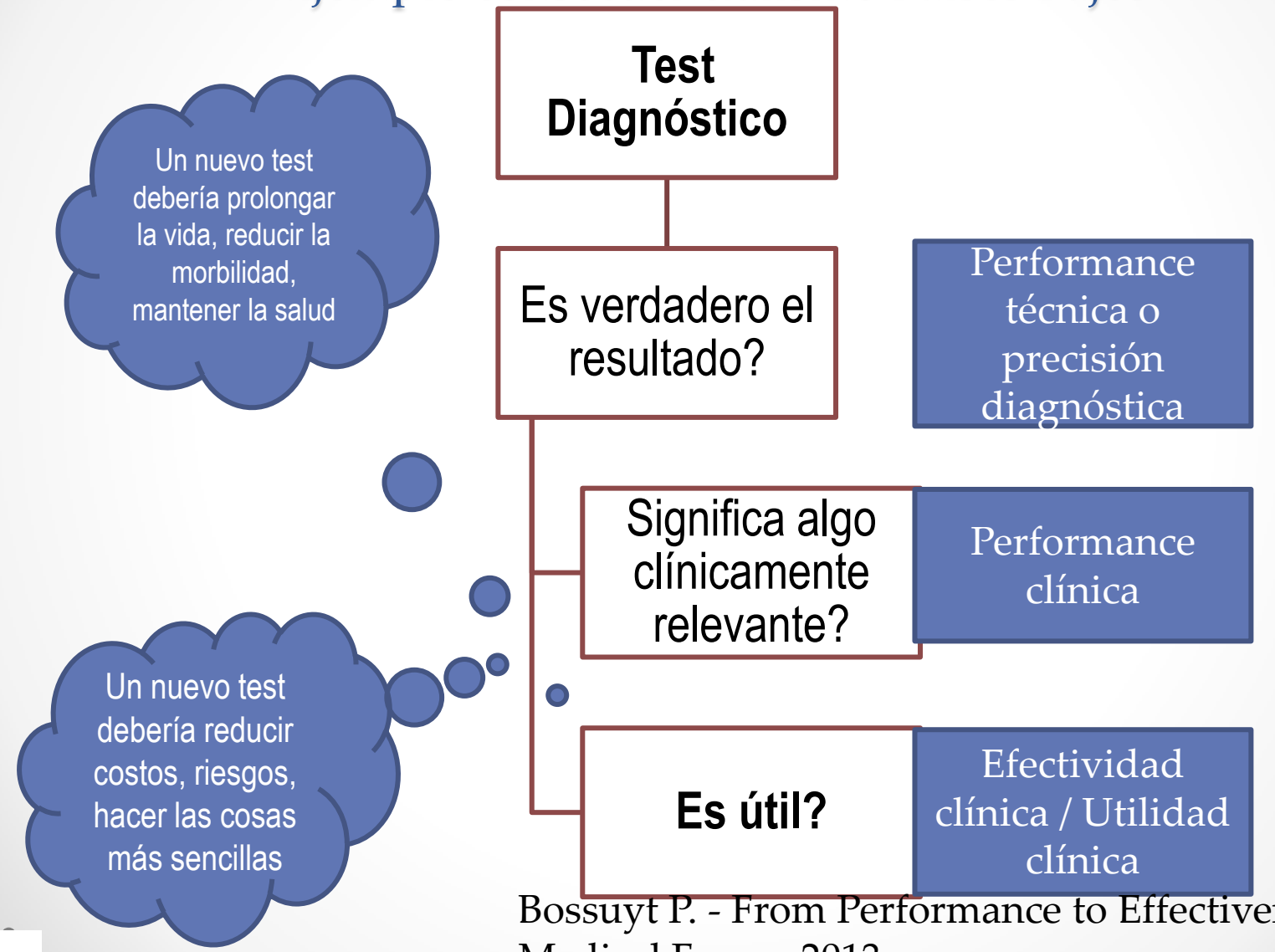


	Monodimensional	Multidimensional
Existencialismo	Consecuencialismo	Valor de la Información diagnóstica
Diagnóstico preciso	Utilidad Clínica Directa del tratamiento seleccionado por el test	Pacientes (valor de saber y descartar) HCP (disminución incerteza- change management) HC managers (ahorro por detección precoz y evitar complicaciones, selección de respondedores) Sistema Sociedad

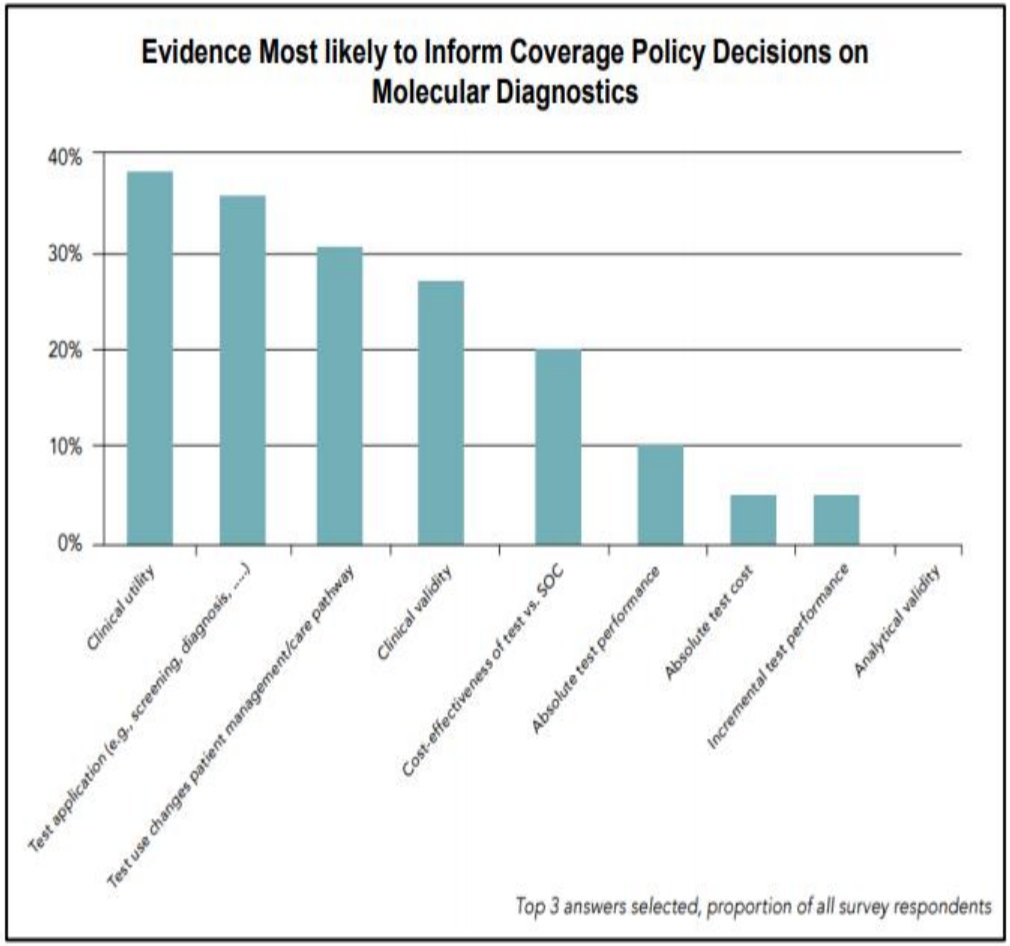
Valor del test

Tres preguntas para valorar tecnologías diagnósticas

Ejemplo consecuencialismo Países Bajos



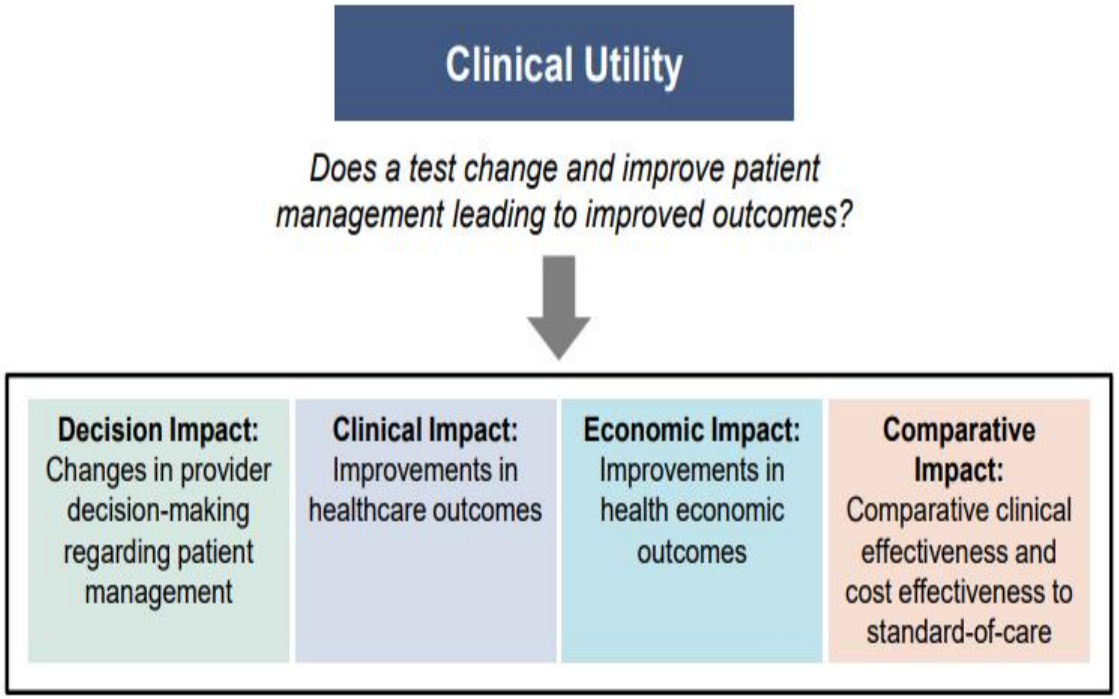
Bossuyt P. - From Performance to Effectiveness Oxford Medical Forum 2013



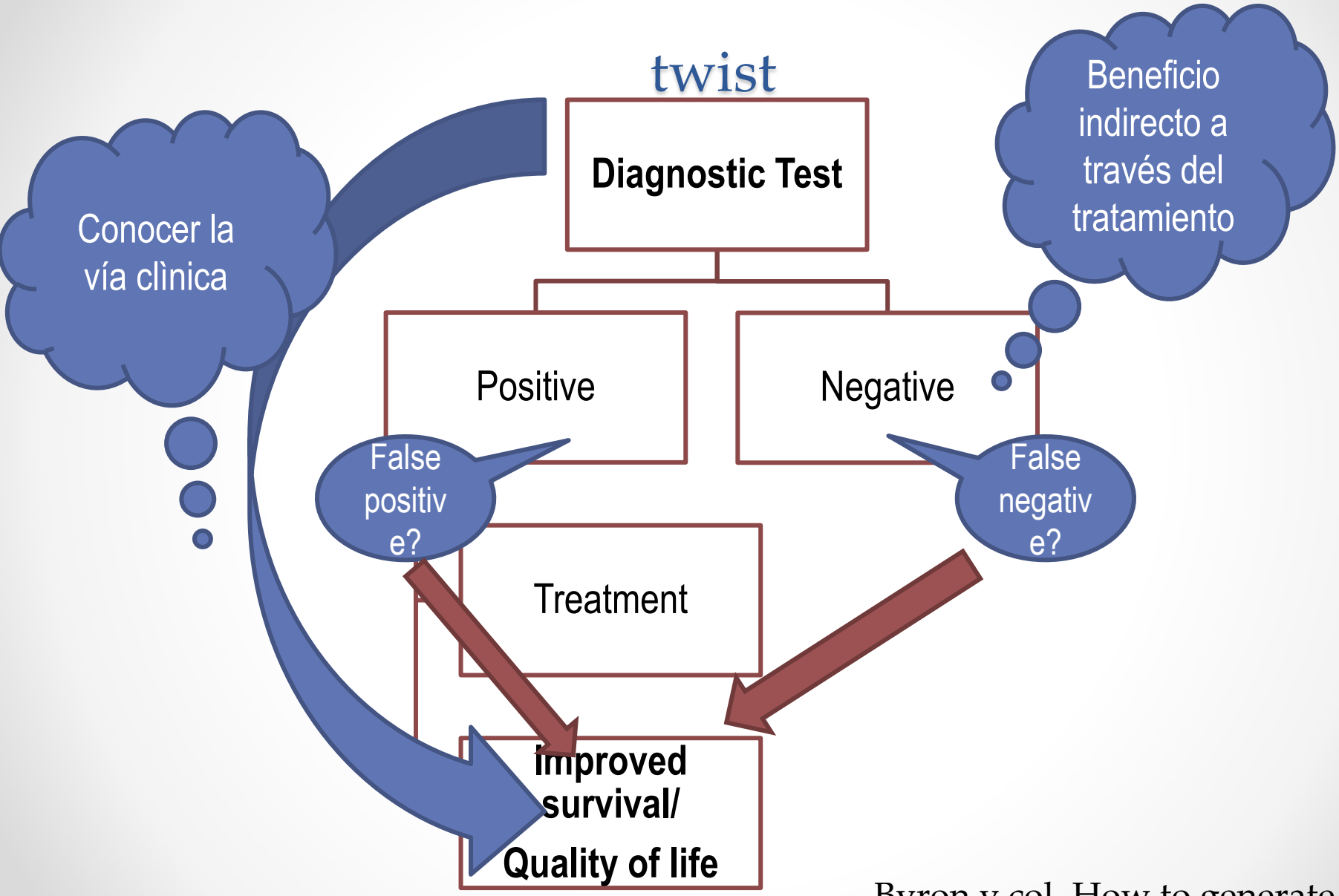
Faulkner, et. al. GBEMTI Perspectives – U.S. Managed Care Perspectives on Assessment and Uptake of Molecular Diagnostics: State of the Union and Areas for Additional Improvement. Journal of Managed Care Medicine. Vol. 18, No. 1, 2015

Definitions of Clinical Utility

- While clinical utility has been traditionally defined as a change in patient management that leads to improved patient outcomes, payers are also becoming interested in the health economic impact



NICE consecuencialista con un twist



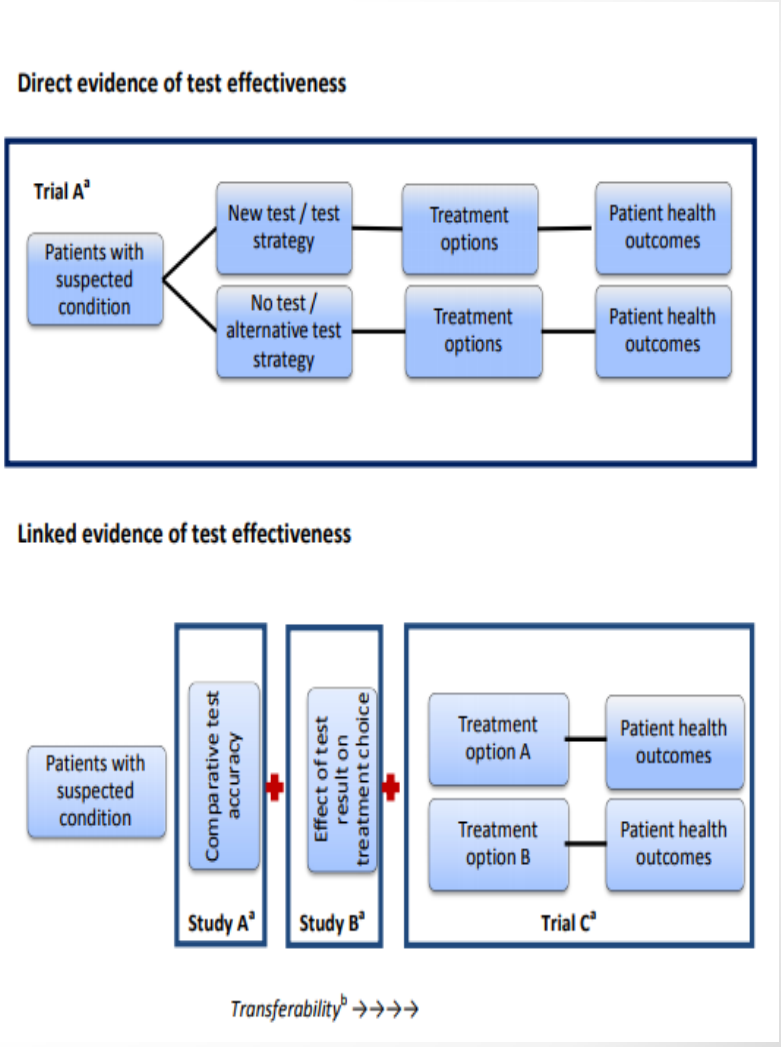
Byron y col. How to generate evidence for diagnostics 2014

La evidencia ideal generalmente no existe en dx

- Estudio end to end que siga al paciente desde el test pasando por tratamiento hasta outcome final generalmente no está disponible para las tecnologías diagnósticas
- Info de precisión del test, impacto directo en cambio de manejo clínico, efecto indirecto en resultados de salud y costos
- La evidencia puede ser combinada por medio del **linked evidence approach**

Linked Evidence Approach

- Marco de análisis utilizado en Australia desde 1999, mandatorio desde 2005
- Complementario ante evidencia directa insuficiente
- Evalúa beneficios y riesgos
- Revisión sistemática de cada elemento de la vía clínica de test – tratamiento para comparar la escenario con test vs sin test
- Precisión o performance diagnóstica comparada con un standard de referencia
- Impacto en toma de decisión comparada (cambio en el manejo clínico)
- ectividad clínica comparada de los



Merlin y col. HTA for evaluating

Aproximación metodológica

- Evidencia directa
- Evidencia directa + LEA completo
- Evidencia directa + LEA incompleta
- Evidencia directa + componentes de LEA
- Componentes de LEA

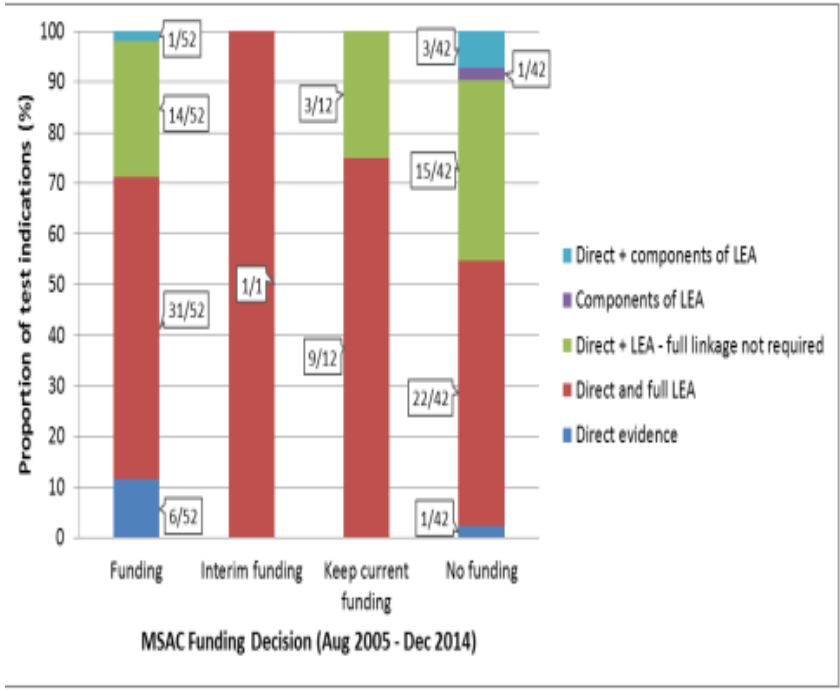
TABLE 1 CASE STUDIES OF PHARMACOGENETIC CO-DEPENDENT TECHNOLOGIES

Case study (biomarker/ therapy)	Decision-making body [therapeutic purpose]	Evidence quality	Evidence gaps (N=67 information items)[a]	Test reimbursed?[b]	Drug reimbursed?[b]
EGFR/gefitinib for non small cell lung cancer (2nd line)	PBAC [targeted treatment]	No direct evidence Linked evidence - moderate quality	8/67 (12%)	Not considered	Yes
K-RAS/ cetuximab for metastatic colorectal cancer (1st line)	PBAC [targeted treatment]	No direct evidence Linked evidence - poor quality	32/67 (48%)	Not considered	No
K-RAS/ panitumumab for metastatic colorectal cancer (2nd line)	PBAC [targeted treatment]	No direct evidence Linked evidence - poor quality	21/67 (31%)	Not considered	No
PDGFR re-arrangements/ imatinib for primary or secondary clonal eosinophilia[c]	MSAC [targeted treatment]	Direct evidence – poor quality *Plus* Linked evidence – moderate quality	3/67 (4%)	Yes	Yes
KIT D816V/ imatinib for aggressive systemic mast cell disease without eosinophilia (2nd line)	MSAC [rule out imatinib treatment]	Direct evidence – poor quality *Plus* Linked evidence – moderate quality	4/67 (6%)	No[d]	Yes

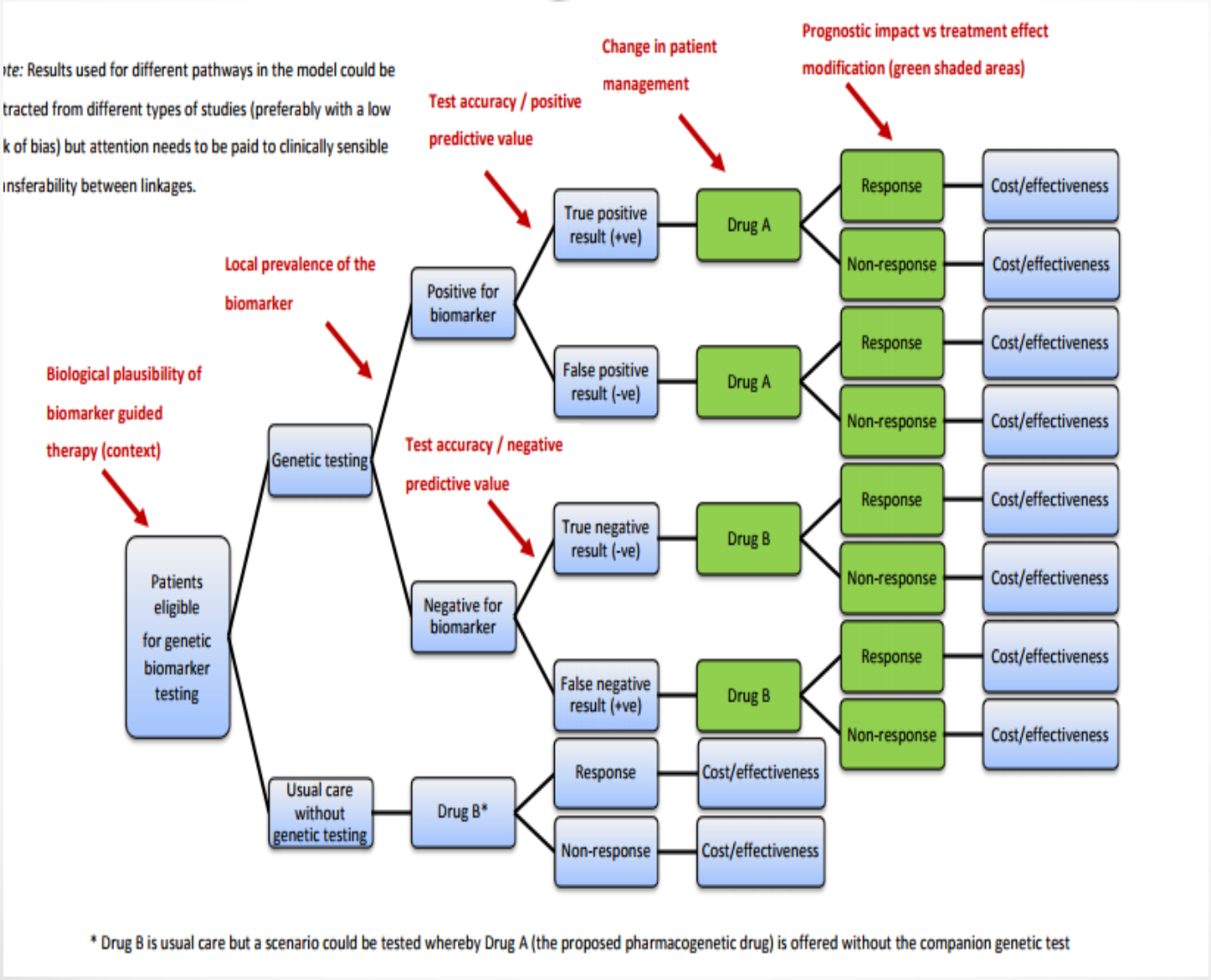
[a] 67 information items (denominator) were collated from submissions at the completion of Stage 1. Evidence gaps (numerator) were defined as a complete absence of information in the submission; however, please note that frequently the information items were only partially/inadequately addressed and in some instances items were not applicable; [b] decision at the time the framework was being developed; [c] systemic mast cell disease, hypereosinophilic syndrome and chronic eosinophilic leukaemia; [d] PDGFR rearrangements and the KIT D816V mutation are mutually exclusive so, as the PDGFR test was funded, there was no need to fund the KIT D816V test.

PBAC = Pharmaceutical Benefits Advisory Committee; MSAC = Medical Services Advisory Committee

157



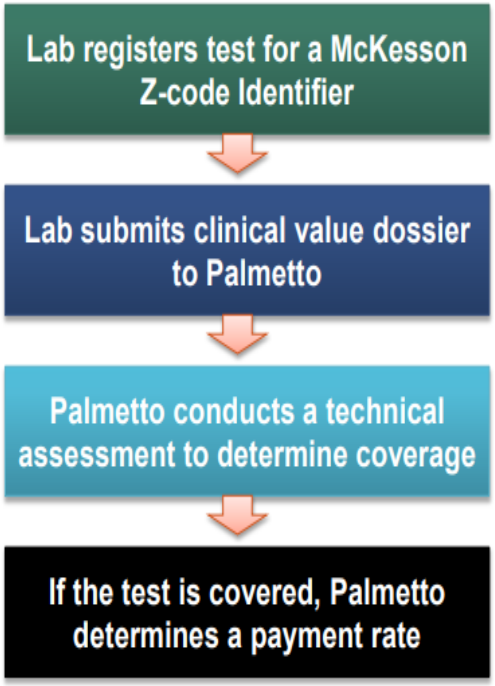
Usando LEA en CE en tecnología codependiente



Palmetto GBA MolDx

The Palmetto MolDx Program Aims to Standardize Coverage and Payment of Molecular Diagnostics

The MolDx Program



- Launched in 2012, the MolDx Program was designed to address Palmetto's concerns around lack of transparency in billing and payment for molecular testing
- The program currently applies to Palmetto's Jurisdiction 11 (WV, VA, NC, SC) and Noridian's Jurisdiction E (CA, NV, HI)
- All labs submitting Medicare claims in these jurisdictions must participate in the MolDx program in order for their claims to be paid

Center for Medical Technology Policy (CMTP) Major Coverage Recommendations for NGS Oncology Panels

CMTP

Green Park Collaborative

A partnership for innovation and effectiveness

Coverage of genomic sequencing procedures	• The GPC **recommends coverage of multiplex panels of up to 50 genes when a subset of 5+ genes are considered standard-of-care with a given diagnosis** • The GPC recommends coverage of panels greater than 50 genes only for limited indications, but further discussion is necessary to reach a consensus • The GPC does not recommend coverage of whole exome and genome sequencing, as they are considered investigational
Coverage of off-label NGS-directed therapies	• The GPC **supports coverage of off-label usage of drugs and biologics when an individual patient has shown benefit after 3 months of treatment with the agent**, which may necessitate asking drug makers to provide the agent free-of-charge during the initial three month trial • Substantial discussion is needed to develop a feasible framework for this arrangement

Development of policies to promote data generation	• The GPC recommends that payers develop program to promote high-quality evidence generation, which may include:
	  • Payment incentives to clinicians who refer patients to high-quality studies
	  • Payment incentives to laboratories for data sharing
	  • Payer participation in collaborative initiatives for enrolling patients into high-quality registries and clinical trials for biomarker evaluation (TAPUR, MED-C)

eunethta

EUnetHTA JA2
WP8 DELIVERABLE

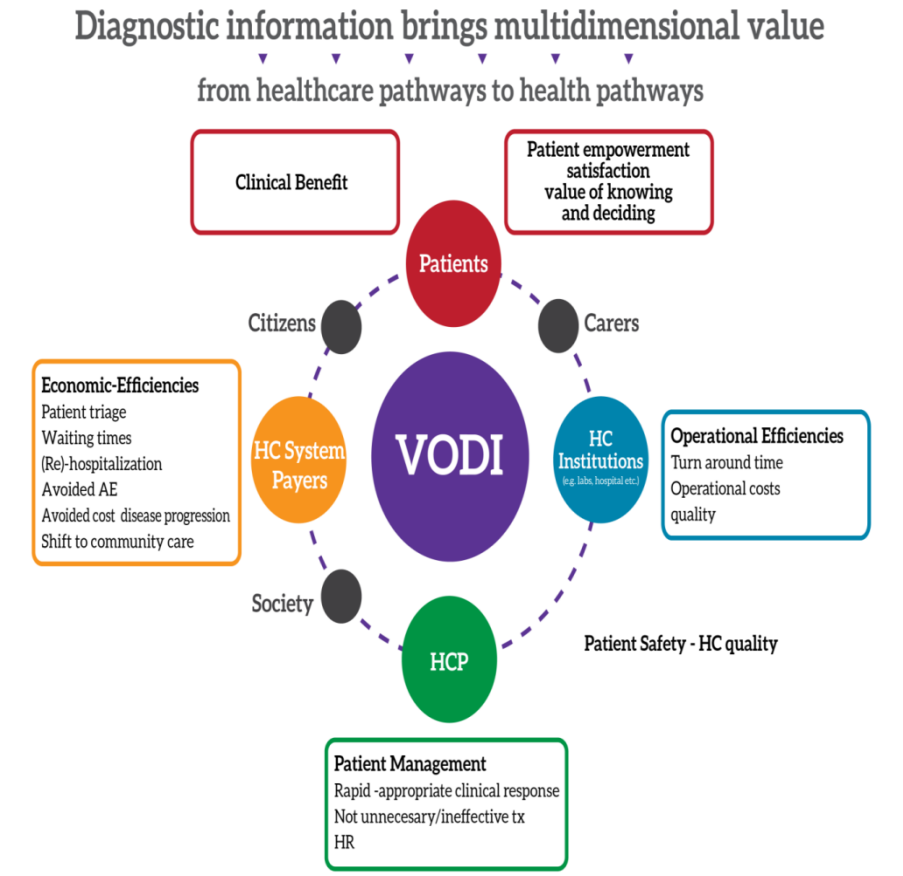
HTA Core Model
Version 3.0

for the full assessment of
Diagnostic Technologies,
Medical and Surgical Interventions,
Pharmaceuticals and

Nuevos marcos multidimensionales de evaluación

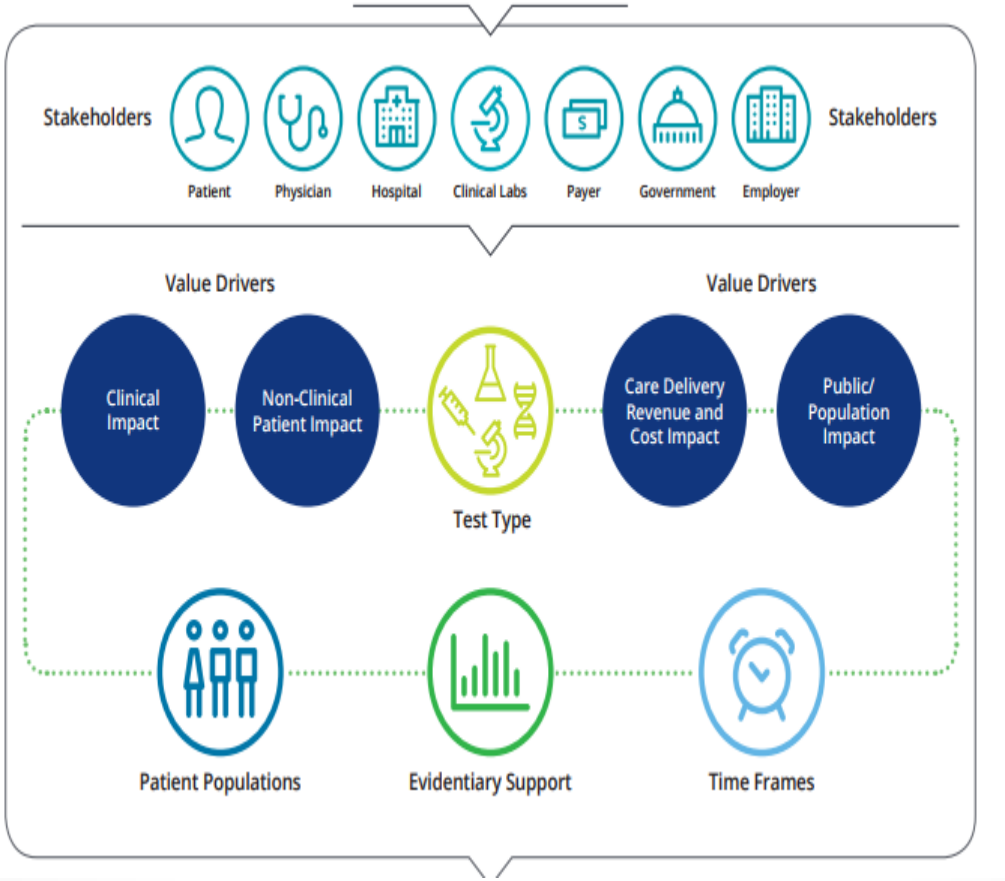
- Efectos directos más amplios
- Valor de la información diagnóstica
- Técnicas basadas en MCDA
- Resultados más amplios que criterios clínicos
- Costos totales de la vía clínica (costos evitados)
- Desarrollos metodológicos iniciales
- Desafíos

Value of diagnostic information



Wurcel y col. 2016

Advamed value framework



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Social Science & Medicine

Volume 188, September 2017, Pages 137-156

Multiple Criteria Decision Analysis (MCDA) for evaluating new medicines in Health Technology Assessment and beyond: The Advance Value Framework

Aris Angelis, Panos Kanavos

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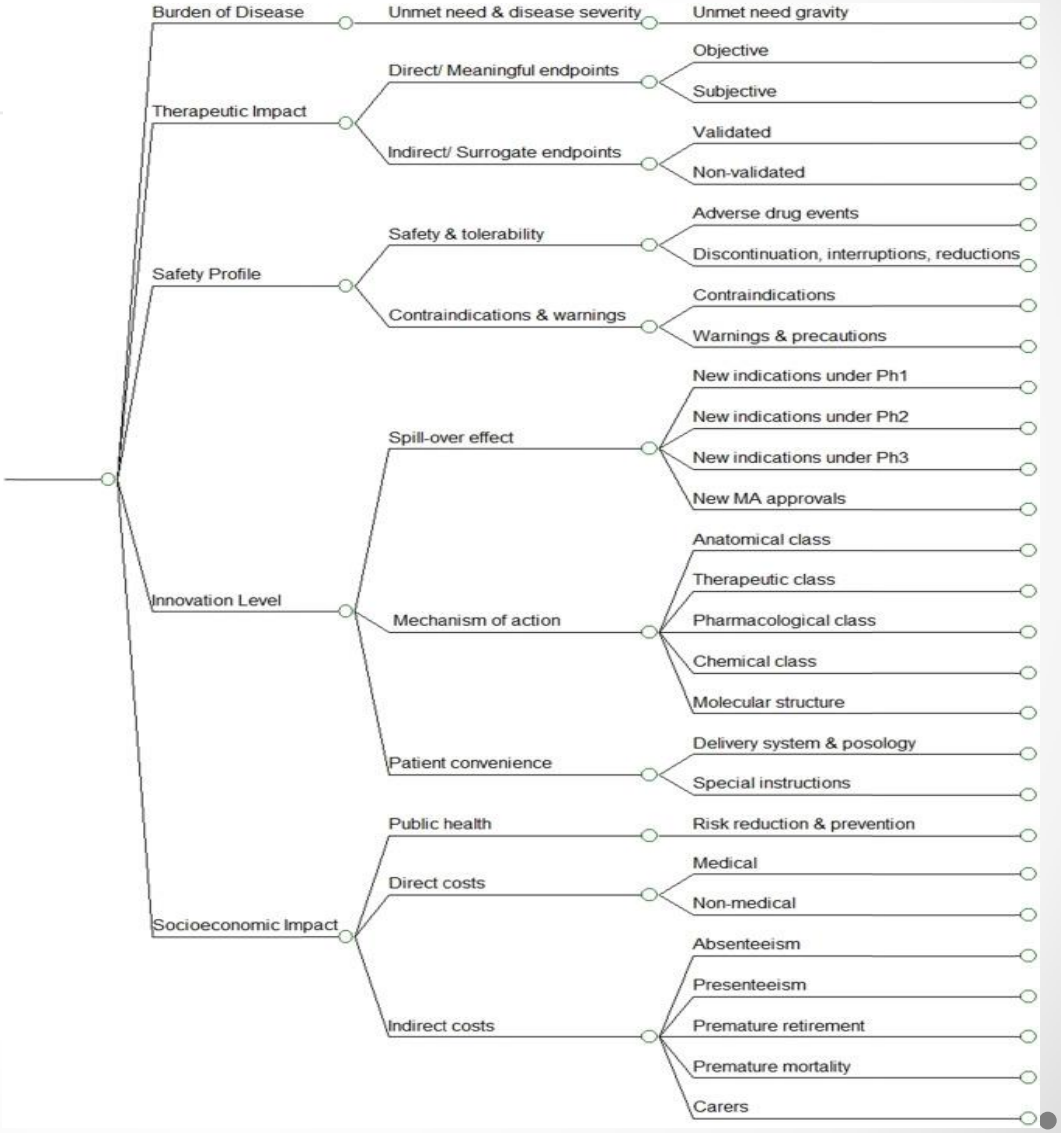
https://doi.org/10.1016/j.socscimed.2017.06.024



ELSEVIER

Journal of Clinical Epidemiology
Volume 67, Issue 7, July 2014, Pages 760-768

Original Article

Applying Grading of Recommendations Assessment, Development and Evaluation (GRADE) to diagnostic tests was challenging but doable ☆

Gowri Gopalakrishna [a], Reem A. Mustafa [b, c, d], Clare Davenport [e], Rob J.P.M. Scholten [f], Christopher Hyde [g], Jan Brozek [b, c], Holger J. Schünemann [b, c], Patrick M.M. Bossuyt [a], Mariska M.G. Leeflang [a], Miranda W. Langendam [a]

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https://doi.org/10.1016/j.jclinepi.2014.01.006

Abstract

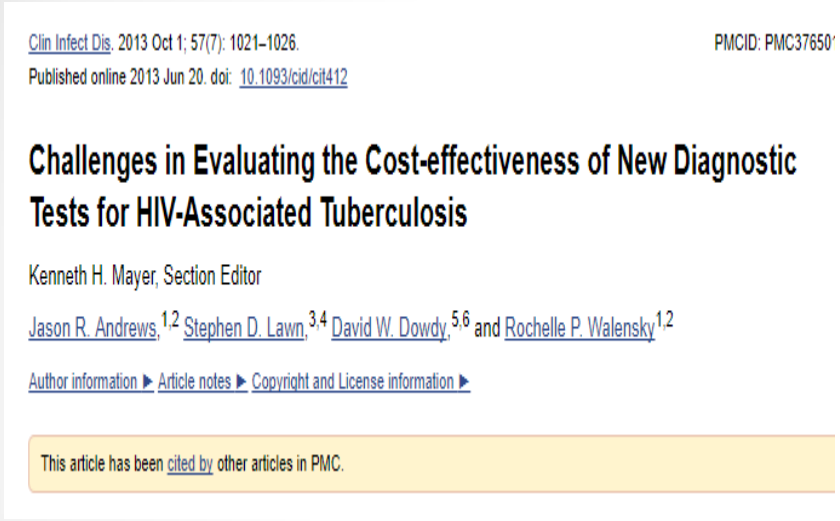
Objectives

The Grading of Recommendations Assessment, Development and Evaluation (GRADE)

Desafíos en ETS para tecnología diagnóstica

- Metodológicos (cuantificación y comparación de valor en dominios ampliados, evaluaciones económicas en test genéticos (Limitaciones del qualy y modelados específicos), probablemente requiere modificaciones en jerarquía de evidencia, foco en RWE soportada por big data)
- Validez clínica y lugar en la vía clínica de nuevas tecnologías diagnósticas (i.e. NGS)
- Implementación de ETS diagnóstica (requiere evaluadores específicamente entrenados, es recurso intensivo, programas o centros específicos, setting the RWE)
- Generación de evidencia lo más robusta posible
- Codificación y sistemas de pago para incentivar la generación de evidencia

Desafíos en evaluaciones económicas de test diagnósticos



Clin Infect Dis. 2013 Oct 1; 57(7): 1021–1026. PMCID: PMC37650
Published online 2013 Jun 20. doi: 10.1093/cid/cit412

Challenges in Evaluating the Cost-effectiveness of New Diagnostic Tests for HIV-Associated Tuberculosis

Kenneth H. Mayer, Section Editor

Jason R. Andrews,[1,2] Stephen D. Lawn,[3,4] David W. Dowdy,[5,6] and Rochelle P. Walensky[1,2]

- Dificultad de cuantificar el beneficio clínico de un mejor diagnóstico

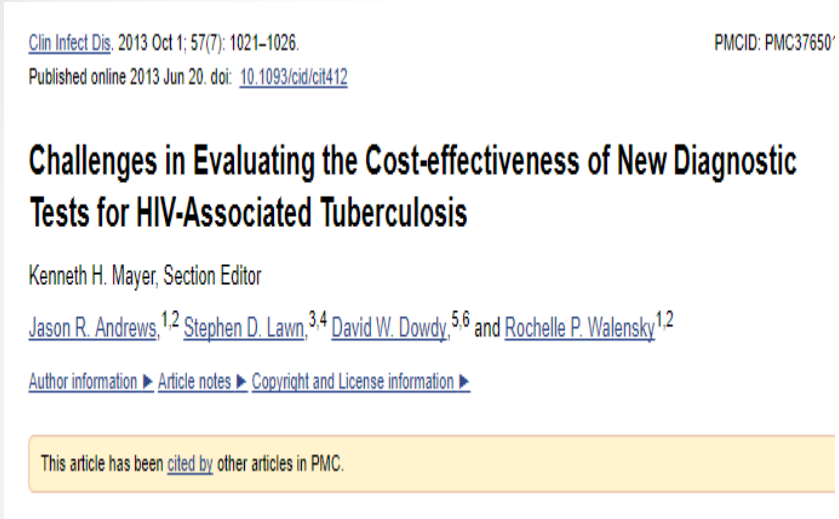
  Beneficio individual (evita morbilidad y mortalidad) +

  Beneficio poblacional (evita transmisión)

  Resultados de efectividad y no sólo de precisión diagnóstica

- Trials pragmáticos
- Modelado

Desafíos en evaluaciones económicas de test diagnósticos



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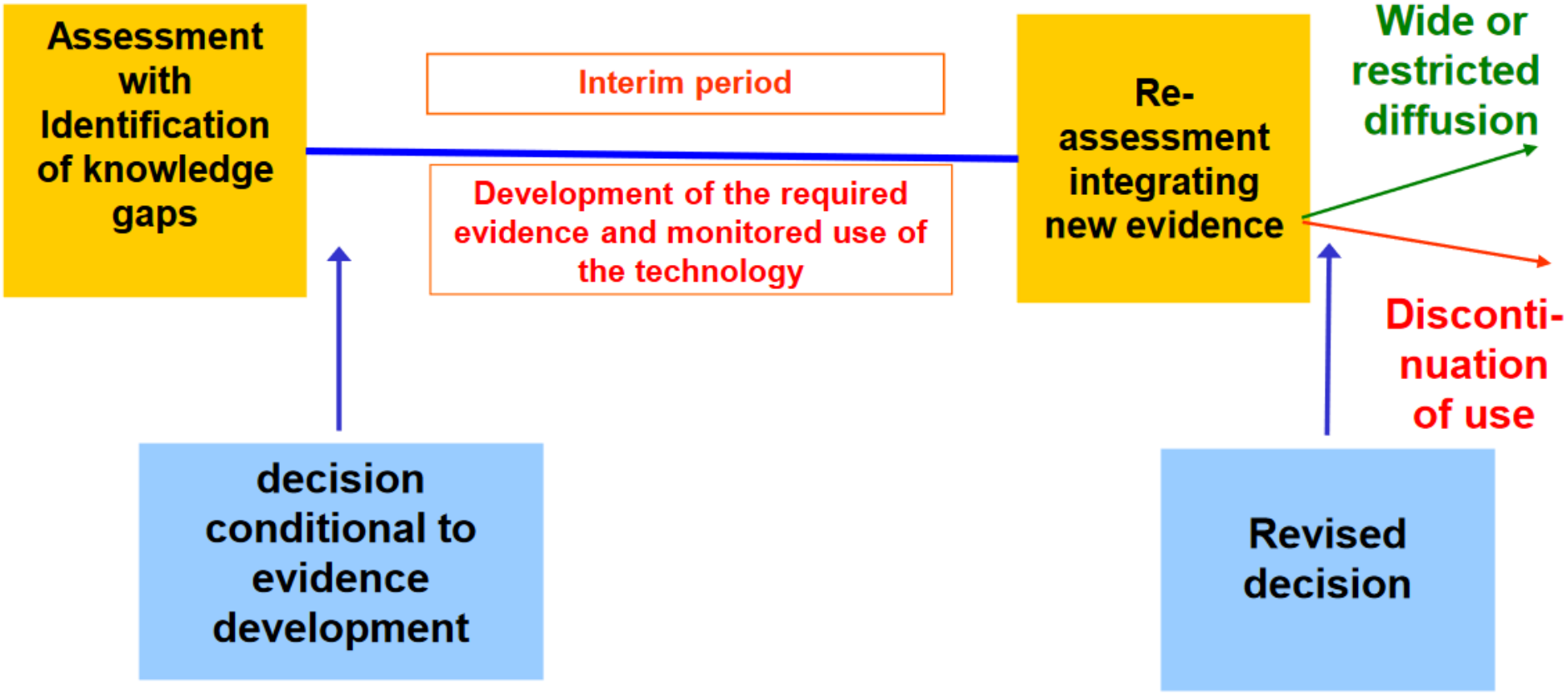
- Costeo del total de la vía clínica, incluyendo costos en exceso en falsos positivos y evitados en verdaderos positivos
- El tratamiento es el driver del costo. Los costos del diagnóstico generalmente se dan por única vez.

- Evaluar programas que incluyan el test diagnóstico
- Consideración cuidadosa de las consecuencias de costos post detección y perspectiva de análisis
- T

Importance of additional data collection



Key elements for success

- Scientific guidance → relevant evidence
- Funding for data collection and analysis
- Coordination of partners
- Regulatory framework → implementation of actions

PARENT
cross-border PAtient REgistries iNiTiative

Patient registries of Europe

ACTIVITIES

- Introduction
- Pick a view: EU
- Browse registries 227
- Register and get more
- Send us feedback

JOIN, REVIEW, IMPROVE, INTEROPERATE!

IN FOCUS

Cross-border registry challenges

Dealing with issues through interoperability

Featured Registry Country: Spain

Today and tomorrow of patient registries from the Spanish perspective

Event: Interoperable Patient Registries in EU in Zagreb, Croatia on Tuesday, 9th of June

The PARENT Joint Action invites you to the event

TIMELINE

PARENT Guidelines endorsed by eHealth Network
Date created: Oct-19-2015 15:57
PARENT Guidelines endorsed by eHealth Network

Guidelines wiki updated
Date modified: Oct-27-2015 07:19

New entry in glossary
Date modified: Oct-06-2015 12:55
Glossary item added: interoperability

Confronting rare deseases with better registry integration
Date modified: Sep-14-2015 10:06
Rare deseases as a perfect showcase for registry integration benefits

In Focus: registry assessment primer
Date modified: May-31-2015 11:07
New hands-on guidance section for registered registry owners

Gerenciamiento de Tecnología en Canadá (CADTH)

Health Technology Management Program

Rapid Response Service
Provides rapid reviews of health technologies to support timely health care decision-making.

Health Technology Assessment Service
Delivers a comprehensive assessment of the clinical and/or economic evidence on health technologies; may include ethical, legal, and social implications.

Optimal Use Service
Delivers a CADTH Health Technology Assessment, with recommendations from an expert panel or committee.

Environmental Scanning
Reviews current health care practices, processes, or protocols to enable a better understanding of the national or international landscape.

Horizon Scanning
Reviews new and emerging health technologies that are likely to have a significant impact on the delivery of health care in Canada.

Other Programs and Services

Scientific Advice
Offers pharmaceutical companies advice on their early drug development plans from a health technology assessment perspective.

MANUAL DEL USUARIO DE SOLICITUD DE EVALUACIÓN DE TECNOLOGÍAS SANITARIAS 2018

Superintendencia de Servicios de Salud
Gerencia de Gestión Estratégica
Coordinación ETS

Solicitud de Evaluación de Tecnologías Sanitarias - SECCIÓN II

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*Obligatorio

Autorización de la tecnología sanitaria - Nivel Nacional

Número de Disposición/año, que autoriza la indicación en ANMAT *

El número de Disposición que autoriza el uso de la tecnología para la indicación para la cual esta siendo evaluada.

Tu respuesta

Especificar la indicación para la cual presenta la solicitud

Nota: la indicación debe estar aprobada por ANMAT. (hasta 1.500 caracteres)

Tu respuesta

Adjuntar informe de evaluación de ETS en ANMAT (en caso de existir)

El archivo que se adjunta debe tener extensión pdf y el nombre debe tener el siguiente formato: (ANMAT - TECNOLOGÍA- FECHA DE ULTIMA ACTUALIZACION)

AGREGAR ARCHIVO

Número de certificado de inscripción en el Registro de Especialidades Medicinales (REM)

Tu respuesta

Adjuntar certificado de inscripción en el REM

AGREGAR ARCHIVO

La droga a evaluar se encuentra bajo la Disp. ANMAT N° 10401/16, Régimen de Acceso a Excepción a Medicamentos (RAEM)

- [ ] SI
- [ ] NO

DE SERVICIOS DE SALUD

Ministerio de Salud
Presidencia de la Nación

Solicitud de Evaluación de Tecnologías Sanitarias - SECCIÓN II

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Especificaciones del Producto Médico

Nombre Técnico

Tu respuesta

Nombre Comercial - Marca

Tu respuesta

Código de identificación GMDN

Tu respuesta

Modelo

Tu respuesta

Clasifique el riesgo de acuerdo a la Disposición ANMAT N° 2318/2002

1	2	3	4
○	○	○	○

El producto medico a ser evaluado:

SI	NO

SUPERINTENDENCIA DE SERVICIOS DE SALUD

Ministerio de Salud
Presidencia de la Nación

INSTITUCIONAL PRENSA CONTACTO

Inicio / Resolución 370-E/2017 S.S.SALUD

Evaluación de Tecnologías Sanitarias

Formulario solicitud ETS Res 370 SSSalud especificidades para productos médicos

DOCUMENTACION COMPLEMENTARIA

Aquí usted tiene la posibilidad de incluír información que no ha podido incluir previamente, tales como

PARA: Medicamentos - Productos médicos

- ✓ Estudios observacionales que deben ser descriptos de acuerdo al esquema combinado STROBE checklist for cohort, case-control, and cross-sectional studies (combined)

SSSalud
SUPERINTENDENCIA DE SERVICIOS DE SALUD

https://www.strobe-statement.org/index.php?id=available-checklists

PARA Productos médicos

a. Puede adjuntar diagrama, foto o ilustración, detallar materiales y accesorios requeridos (incluyendo aquellos que son descartables, y si tienen compatibilidad estándar)
b. Describir los diferentes modelos disponibles de la tecnología y sus diferencias principales
c. Describir el propósito de la tecnología y cómo es utilizada
d. Describir el contenido del paquete del producto médico y si algún accesorio o sustancia anexa se encuentra incluída en el mismo.
e. Describir el contexto y nivel de atención en donde se utilizará el producto medico
g. Describa los requisitos de infraestructura, servicios y complejidad necesarios para el uso de la tecnología.
h. Describa equipamiento accesorio necesario

Formulario solicitud ETS Res 370 SSSalud especificidades para productos médicos

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    g. Describa los requisitos de infraestructura, servicios y complejidad necesarios para el uso de la tecnología.
    h. Describa equipamiento accesorio necesario.
    i. Describa insumos necesarios.
    j. Describa si la tecnología es parte de un procedimiento. En caso afirmativo describa el tipo (directo, perctuáneo, vascular, endoscópico, etc), si requiere guía por ejemplo ultrasonido, etc. y personal que debe estar incluído (ej anestesista, etc)
f. Describa el uso propuesto de la tecnología, las necesidades no satisfechas en el manejo de la condición de salud o enfermedad y cómo la tecnología ayudaría a mitigarlas.
g. Describa los cambios necesarios en la organización y funcionamiento de los servicios de salud que se necesitan para adoptar la tecnología incluyendo nuevos tests diagnósticos, equipamiento, infraestructura, programas de entrenamiento o servicios nuevos, cuidados auxiliares.
h. Describa además los tests, intervenciones, infraestructura, tecnologías y/o cuidados que serían reemplazados en caso de adoptar la nueva tecnología

Formulario solicitud ETS Res 370 SSSalud especificidades para productos diagnósticos

En el caso de las tecnologías diagnósticas debe calcular la tabla de 2 *2

Estos cálculos puede adjuntarlos en la sección IV INFORMACION COMPLEMENTARIA

Test outcome (index test)	*Disease status (reference standard result)*		
	Diseased (D+)	*Non-diseased (D-)*	*Total*
Index test positive (T+)	True positives (a)	False positives (b)	Test positives (a+b)
Index test negative (T-)	False negatives (c)	True negatives (d)	Test negatives (c+d)
Total	Disease positives (a+c)	Disease negatives (b+d)	N (a+b+c+d)

La precisión diagnóstica o accuracy

$$\text{accuracy} = \frac{TP + TN}{TP + TN + FP + FN}$$

Formulario solicitud ETS Res 370 SSSalud especificidades para productos diagnósticos

PARA: Productos diagnósticos

Describir las consecuencias que podrían resultar de la adopción de la tecnología diagnóstica considerando los siguientes dominios del valor de la información diagnóstica

a. Paciente (mejores resultados de los tratamientos posteriores, valor de saber y reaseguro de no enfermedad)
b. Familia y cuidadores
c. Profesionales de la salud – cambio de manejo clínico o quirúrgico y cómo se asociarían a mejores resultados sanitarios
d. Organización del sistema de salud y uso de recursos
e. Beneficios socio-económicos

Justificar y adjuntar estudios asociados incluyendo aquellos que hayan utilizado el Linked Evidence Approach (LEA) si existen.

¿Preguntas?

Muchas Gracias

Dra. Victoria Wurcel
vwurcel@sssalud.gob.ar

¿Preguntas?

Muchas Gracias

Dra. Victoria Wurcel
victoria.wurcel@gmail.com