

Η Αξιολόγηση Τεχνολογιών Υγείας: Η Προβληματική με βάση τη Διεθνή Εμπειρία

Αντώνης Καρόκης Διευθυντής Εταιρικών Υποθέσεων, MSD



HTA (Health, Technology, Assessment)

- H Health: a state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity
- T Technology: drugs, vaccines, devices, materials, procedures, and organizational and support systems in the field of healthcare
- A Assessment: any process of examining and reporting properties of a medical technology used in healthcare



Τι είναι η αξιολόγηση των τεχνολογιών υγείας;

Η αξιολόγηση Τεχνολογιών Υγείας συνδυάζει τα Οικονομικά της Υγείας, την Φαρμακοοικονομία και την Έρευνα Υπηρεσιών Υγείας για να εξετάσει τις βραχυπρόθεσμες και μακροπρόθεσμες συνέπειες της εφαρμογής μιας τεχνολογίας υγείας

Οικονομικά Υγείας:

The discipline that deals with the application of economic principles and theories to health and the health care sector (eg: supply/demand of healthcare, healthcare financing, optimization of hospitals, healthcare as economic activity, pharmaceutical pricing and reimbursement)

Φαρμακοοικονομία¹:

The discipline that assesses the overall value of pharmaceutical care addressing clinical, economic and humanistic aspects.

HTA1

(Health Technology
Assessment) is a form of
policy research that examines
short- and long-term
consequences of the
application of a health
care technology

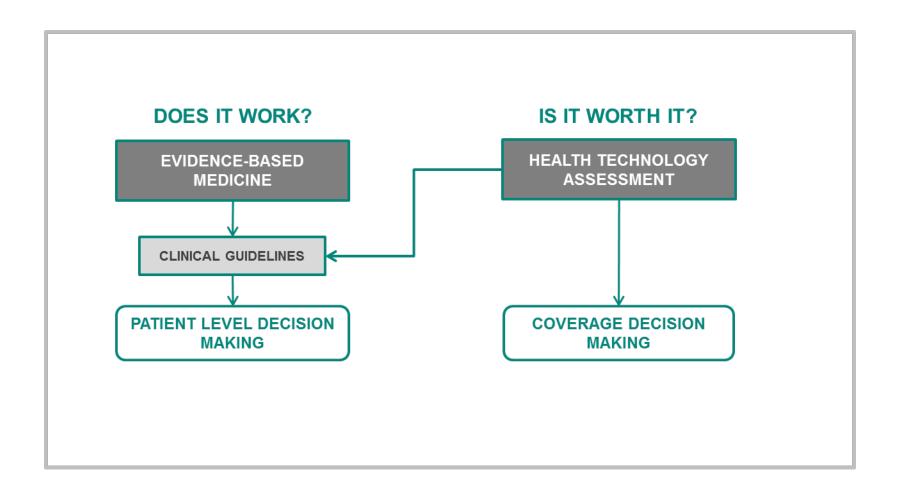
Έρευνα Υγειονομικών Εκβάσεων Health Outcomes Research¹

The discipline that evaluates the effect of healthcare interventions on patient-related clinical, economic and humanistic outcomes, usually comparing treatment alternatives. Outcomes data that are reported directly by the patient are called PROs (Patient Reported Outcomes).

Source: Simon-Kucher & Partners *Definitions have been interpreted by SKP from: 1. Marc Berger et.al. ISPOR Book of Terms Health care cost, quality, and outcomes", ISPOR, 2003; and 2. Lieven Annemans Health economics for non-economists, An introduction to the concepts, methods and pitters of the economic evaluations" Gent Academia Press, 2008

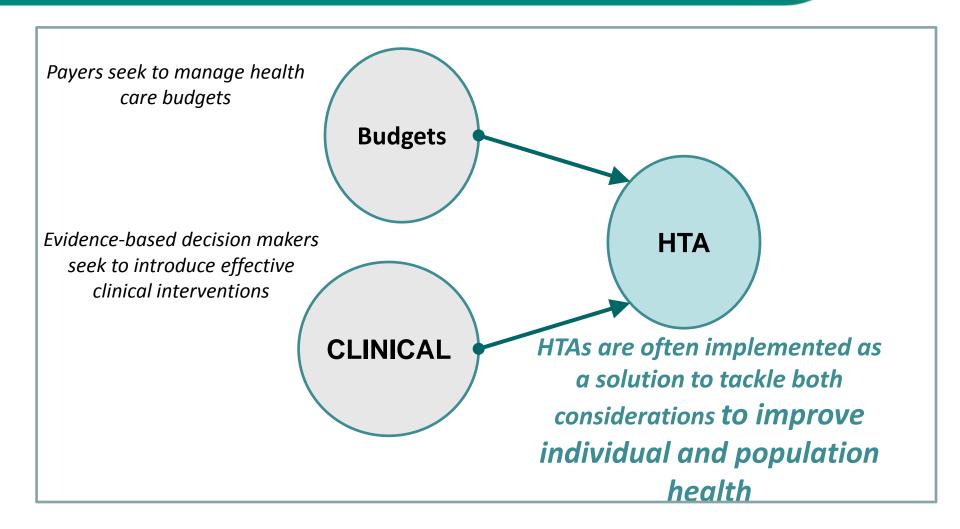
Be well

HTA: Αποφάσεις τιμολόγησης και αποζημίωσης αλλά και βελτίωσης της κλινικής πρακτικής





Συγκερασμός οικονομικών και κλινικών επιδιώξεων για να βελτιωθεί η υγεία του πληθυσμού





Η αξία της τεχνολογίας υγείας

Clinical
outcomes
(survival,
progression of
disease, AEs)

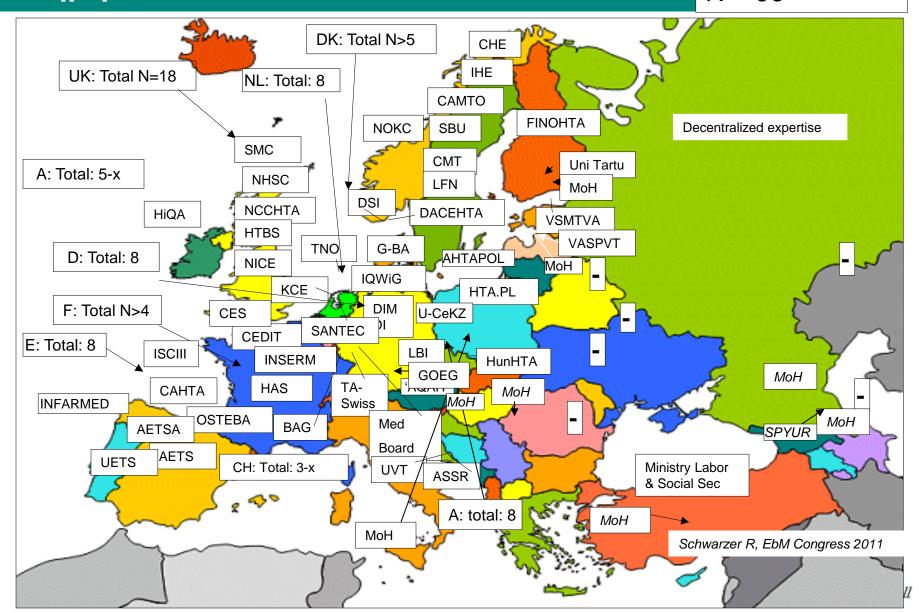
Economic impact (budget impact, cost effectiveness, etc.)

Wider social benefits

(quality of life, reduced hospitalization, productivity, innovation, etc.)



Ποιοι οργανισμοί αξιολογούν τις τεχνολογίες υγείας σήμερα; N = 96



Ο Ρόλος των Οργανισμών Αξιολόγησης

- Η αξιολόγηση τυπικά περιλαμβάνει δύο στάδια:
 - Αξιολόγηση οφέλους, κόστους και συγκριτικής αποτελεσματικότητας που συνοδεύεται από...
 - Αποτίμηση (δηλαδή αιτιολόγηση και πόρισμα) των δεδομένων ώστε να προχωρήσουμε σε αποφάσεις αποζημίωσης και ενίστε τιμολόγησης
 Τα δύο στάδια μπορεί να εκτελούνται από διαφορετικούς οργανισμούς
- Οι οργανισμοί ΗΤΑ διαφέρουν συχνά ως προς την επιρροή στη λήψη αποφάσεων και την αυτονομία τους ως προς την κυβερνητική δομή
 - Άλλοι εκτελούν ρυθμιστική λειτουργία (αποφασίζουν για την τιμολόγηση ή αποζημίωση)
 - Άλλοι επιτελούν συμβουλευτικό ρόλο σε θέματα τιμολόγησης και αποζημίωσης,
 ενώ η κυβέρνηση διατηρεί την αποφασιστική αρμοδιότητα
- Επίσης διακρίνονται σε αυτούς που
 - «παράγουν» ΗΤΑ δηλαδή εκτελούν επισκοπήσεις, έρευνες, υποδείγματα κλπ.
 - Κυρίως «χρησιμοποιούν» αξιολογήσεις που υποβάλλονται από κατασκευαστές τις οποίες αξιολογούν και αποτιμούν



Αποτίμηση της Ευρωπαϊκής και Διεθνούς εμπειρίας

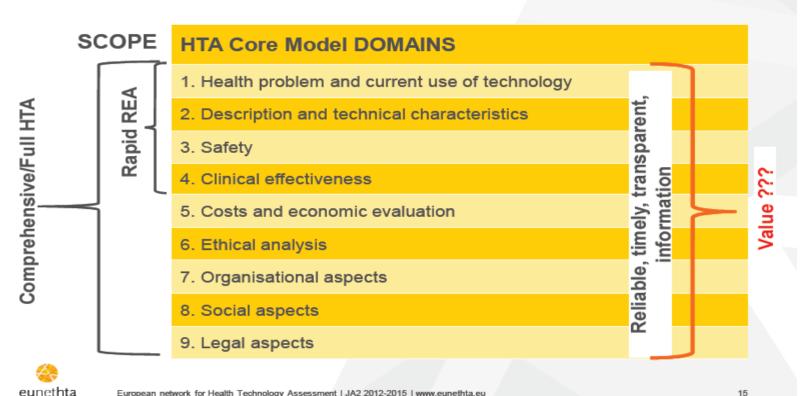
- Μπορούμε να διαμορφώσουμε μια τυπολογία των Οργανισμών Αξιολόγησης Τεχνολογιών Υγείας με βάση δύο κριτήρια:
 - Τον τρόπο με τον οποίο «ρυθμίζουν» ή «επιτελούν» την αξιολόγηση και αποτίμηση σύμφωνα με τις διαστάσεις που έχει καθορίζει το Ευρωπαϊκό Δίκτυο Οργανισμών Αξιολόγησης των τεχνολογιών Υγείας
 - Το κύριο κριτήριο στο οποίο βασίζουν την αποτίμηση της τεχνολογίας που αξιολογούν



Το Ευρωπαϊκό Δίκτυο Οργανισμών Αξιολόγησης Τεχνολογιών Υγείας έχει προσδιορίσει το βασικό πλαίσιο των ζητημάτων που σχετίζονται με την αξιολόγηση

The Domains of the HTA Core Model®

assessing dimensions of value





Μήτρα Αξιολόγησης

						Equity
	Conditional reimbursement	Subgroup data	Real life studies			Cost- effectiveness
	After launch regular revision	Compliance/ convenience	Modelling		WTP	Budget impact
Mandates Guideline	Ad hoc revision	Quality of Life	Indirect /network analysis	Best possible care	Cost/benefit	Innovation
Mandates Price	After launch new evidence	Mortality	Meta-analysis	Cheapest	CUA with thresholds	Patient convenience
Mandates Access/Reimb.	After launch new indication	Morbidity	RCT vs comparator	Most frequent	Cost utility	Comparative effectiveness
Advisory	At launch by indication	Efficacy surrogate	Any RCT	Active control	Cost- Effectiveness	Efficacy Safety
Reporting only	At launch by chemical entity	Safety	Low evidence, Unpublished data	Placebo	Cost - minimalization	Disease burden/severity
Influence	Submission Requirement	Required clinical	Evidence Required	Comparator	HECON Metrics	HTA Decision Criteria

endpoint

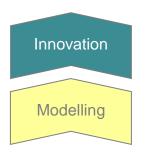


Η μήτρα αξιολόγησης των οργανισμών τεχνολογιών υγείας σύμφωνα με το πρότυπο του EUNEHTA

Κριτήρια:

- Επιρροή,
- Πότε χρειάζεται υποβολή φακέλου αξιολόγησης,
- ποια κλινικά κριτήρια απαιτούνται,
- τι δεδομένα χρειάζονται,
- ποιες είναι οι τεχνολογίες ελέγχου,
- ποιες οικονομικές παράμετροι αξιολογούνται,
- ποια είναι τα κριτήρια της αποτίμησης

Στην παρουσίαση των οργανισμών παρακάτω οι χρωματικοί συνδυασμοί σημαίνουν:



Πράσινο κουτί: Η παράμετρος απαιτείται, εφαρμόζεται υποχρεωτικά

Κίτρινο κουτί: Προαιρετική εφαρμογή



Τυπολογίες συστημάτων ΑΠΟΤΙΜΗΣΗΣ Τεχνολογιών Υγείας





Τυπολογία 1: Cost effectiveness

ACOST (+) More effective Less effective More costly More costly (+) (-) Less effective More effective (-) Less costly Less costly

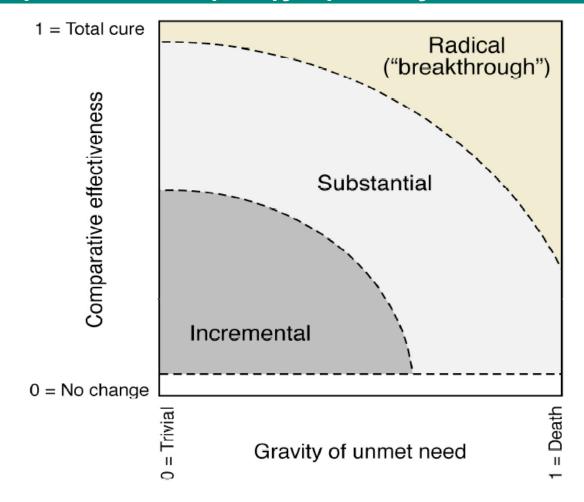
AEFFECTIVENESS

Adapted from: Klok RM, Postma MJ (2004): Four quadrants of the cost-effectiveness plane: some considerations on the south-west quadrant. Expert Rev. Pharmacoeconomics Outcomes Res. 4(6)





Τυπολογία 2: Συγκριτική κλινική αποτελεσματικότητα 2.1. Η αξία της καινοτομίας με βάση την βαρύτητα της νόσου και το εκτιμώμενο αποτέλεσμα της θεραπείας







Τυπολογία 2: Συγκριτική κλινική αποτελεσματικότητα 2.2. Έμφαση στον ασθενή

Assesses the benefits and harms of interventions to inform decision making, highlighting comparisons and outcomes that matter to people

addressing burden to individuals, resource availability, and other

Optimizes outcomes while

Based on www.pcori.org

Incorporates a wide variety of settings and diversity of participants to address individual differences and barriers to implementation and dissemination

Includes an individual's preferences, autonomy and needs, focusing on outcomes that people care about (survival, functioning, symptoms, and HRQoL)

Patient-related outcomes may consist of:

- An improvement in health status:
- A shortening in the duration of the disease;
- An improvement in overall survival;
- An improvement in the medicine's safety profile; or
- An improvement in patients' quality of life.

Source: IHS Survey, 2012



Γαλλία: Κριτήριο η βαθμονόμηση της καινοτομίας (2.1)

Haute Authorité de Santé (HAS)

Transparency Commission

Assessment / Appraisal

Pricing
Committee
Negotiates price
based on ASRM

ASSESSMENT CRITERIA				
Medical Benefit (SMR)	Improvement in Medical Benefit (ASMR)			
 Product's therapeutic value (SMR) is based on five criteria: Efficacy and Safety Position of the medicine in the therapeutic strategy and the existence or absence of therapeutic alternatives Severity of the disease Type of treatment: preventive, curative or symptomatic Public Health Impact 	 Based on relative efficacy according to randomised clinical trials (RCT) Unless the product is first in its class, the evaluation is done in comparison with products of the same pharmacotherapeutic class that are already enlisted. 			
Rating	Rating			
 4 possible ratings Important Moderate Weak Insufficient Impact on reimbursement rate 	 5 possible ratings I: breakthrough innovation II: Important improvement III: Moderate improvement IV: Minor improvement V: no improvement Impact on price 			

Source: Simon-Kucher & Partners





ΓΑΛΛΙΑ

Primary Institution: HAS

Be well

FRANCE						Equity
TRANGE	Conditional reimbursement	Subgroup data	Real life studies			Patient convenience
	After launch regular revision	Compliance/ convenience	Modelling	Most recently used	WTP	Cost- effectiveness
Mandates Guideline	Ad hoc revision	Quality of Life	Indirect /network analysis	Best possible care	Cost/benefit	Budget impact
Mandates Price	After launch new evidence	Safety	Meta-analysis	Cheapest alternative	CUA with thresholds	Innovation
Mandates Access/Reimb.	After launch new indication	Efficacy surrogate	RCT vs comparator	Most frequent	Cost utility	Disease burden/severity
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Influence	Submission Requirement	Required clinical endpoint	Evidence Required	Comparator	HECON Metrics	HTA Decision Criteria

- Assessment process: based on the therapeutic value rated from "insufficient" to "important"-, and on the improvement in medical benefit rated from "no improvement" to "breakthrough innovation".
- Access: In the near future, HTA evaluation by HAS will be officially binding. If the MoH does not follow HTA evaluation, this should be justified.
- Guidelines: HAS is publishing recommendations on therapeutic strategies (used by national social scheme to review physicians' practices).
- BoD: In 2011, orphan drugs and cancer drugs have been granted a medical benefit of moderate/minor despite the severity of the disease ISD

Γερμανία: Κλινικοί δείκτες από την σκοπιά του ασθενή

Institute for Quality and Efficiency in Health Care

G-BA (Federal Joint Committee) commissions inspection

Assessment

G-BA announces benefit assessment and resolution

CHARACTERISTICS OF THE ASSESSMENT						
Assessment criteria: Added therapeutic benefit	Generating evidences					
 IQWIG was changed under AMNOG in 2011 Manufacturers are to submit a dossier (pre-filing consultation is optional) for approved indications Added therapeutic benefit (based on SPC and clinical studies) is to be evaluated with a scoring system Patient relevant endpoints are accepted, G-BA can ask for new studies Cheapest appropriate comparator is requested (determined by G-BA) Patient groups with meaningful additional benefit should be indicated and sized 	 Morbidity, mortality, QoL are deemed to be patient related endpoint Surrogate endpoints are not patient relevant, relationship of surrogate and hard endpoints might be validated with meta-analysis Individual components of combined endpoints must all be patient relevant Indirect comparisons might be accepted but evidence considered to be lower (vs H2H) Modelling is not accepted (no QALY, CEA, BIM) 					
Scores for Added Therapeutic Value	Impact of assessment: Pricing					
1: Major benefit over comparator 2: Significant added benefit 3: Slight added benefit 4: Unquantifiable added benefit 5: No added benefit 6: Less than comparator	 Added therapeutic benefit of the technology was linked to pharmaceutical pricing Price is function of the comparator, added value score Technologies scoring 1 to 4 qualify for price negotiations, and may obtain price premium over the comparator Technologies scoring 5 to 6 get a price under the reference pricing system or negotiate a price with a maximum at the comparator level 					



FEPMANIA: IQWIG

RMANY						Equity
						Equity
	Conditional reimbursemen	Subgroup data	Real life studies			Cost- effectiveness
	After launch regular revision	Compliance/ convenience	Modelling		WTP	Budget impact
Mandates Guideline	Ad hoc revision	Quality of Life	Indirect/netwo rk analysis	Best possible care	Cost/benefit	Innovation
Mandates Price	After launch new evidence	Mortality	Meta-analysis	Cheapest alternative	CUA with threshold	Patient convenience
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Reporting only	At launch by chemical entity	Safety	Low evidence, Unpublished data	Placebo	Cost minimalization	Disease burden/severit y
Influence	Submission Requirement	Required clinical endpoint	Evidence Required	Comparator	HECON Metrics	HTA Decision Criteria

- •Added therapeutic benefit is to be evaluated with a scoring system from "less than comparator's" to "major benefit over comparator".
- $\bullet \text{Added the rapeutic benefit of the technology was linked to pharmaceutical pricing}. \\$
- •Morbidity, mortality, and quality of life are deemed to be patient related endpoint, surrogate endpoints are not patient relevant, modelling is not accepted (no QALY, CEA, BIM)

Παράδειγμα χώρας που εστιάζει στην κλινική / οικονομική αποτελεσματικότητα: ΑΓΓΛΙΑ

National Institute for Health and Clinical Excellence

Technologies proposed by NICE to Dep. Of Health

Assessment & Appraisal

Recommendations to the NHS

ASSESSMENT PHASE	APPRAISAL PHASE
Topic selection criteria	Factors for considerations
 Burden of disease Resource impact on NHS Clinical & policy importance Inappropriate practice variations Timeliness of recommendation/guidance Expected impact of guidance on public health, QoL reduction in inequalities 	 Nature and quality of the evidence Uncertainty generated by the evidence Effectiveness and AEs in subgroups Risk and benefits from the patient's perspective Technology's position in care pathway Appropriateness of comparators ICER, robustness of the result Clinical and policy priorities Health need and effective use of resources Impact of decision on NHS resources Encouraging innovation on the long-term
Scoping of the project	Multiple vs single appraisal
 Definition of the topic Identification of relevant care settings, delivery systems and providers Question development in policy context (on effectiveness, CE, feasibility, acceptability, etc.) Specification of outcome measures and any comparators 	Multiple technology appraisal (MTA) Single technology appraisal (STA): usual





ΑΓΓΛΙΑ

Equity Cost-Conditional Real life Subgroup effectiveness reimbursemen studies data After launch Compliance/ **Budget impact** Modelling WTP regular convenience revision Indirect Ad hoc Best possible Mandates Innovation Quality of Life Cost/benefit /network revision Guideline care Patient Mandates After launch Mortality Cheapest CUA with Meta-analysis new evidence convenience Price alternative threshold Mandates Comparative After launch RCT vs Most frequent Morbidity Access/Reimb Cost-utility effectiveness new indication comparator Efficacy At launch by Efficacy Cost Active control Advisory **Anv RCT** indication Safety surrogate effectiveness At launch by Low evidence. Disease Reporting Cost Safety Placebo chemical Unpublished burden/severit minimalization only entity data Influence Submission Required clinical **Evidence** Comparator **HTA Decision Effectiveness** Requirement endpoint Required/Used Criteria Metrics Used

- Access: HC organizations in the NHS are obliged to implement NICE recommendations on the evaluated technology.
- Cost-effectiveness: threshold has moved to £30k. A threshold of £50k applies to drugs that meet 'end of life' criteria (usually cancer area).
- Safety: NICE is always interested in safety but looks at it from the perspective of how adverse events might affect cost-effectiveness.
- Innovation: it has been recognized by NICE in a number of decisions; the question is now routinely asked about.



Πρότυπο 1. ΝΙCΕ

Πρότυπο 2.1: HAS

Πρότυπο 2.2: IQWIG



















BELGIUM

CZECH

DENMARK

ESTONIA







ITALY



IRELAND



FINLAND



HUNGARY



NETHERL.





LATVIA







PORTUGAL SCOTLAND







POLAND



SLOVENIA



SWEDEN





AUSTRIA







The Spanish system is under development

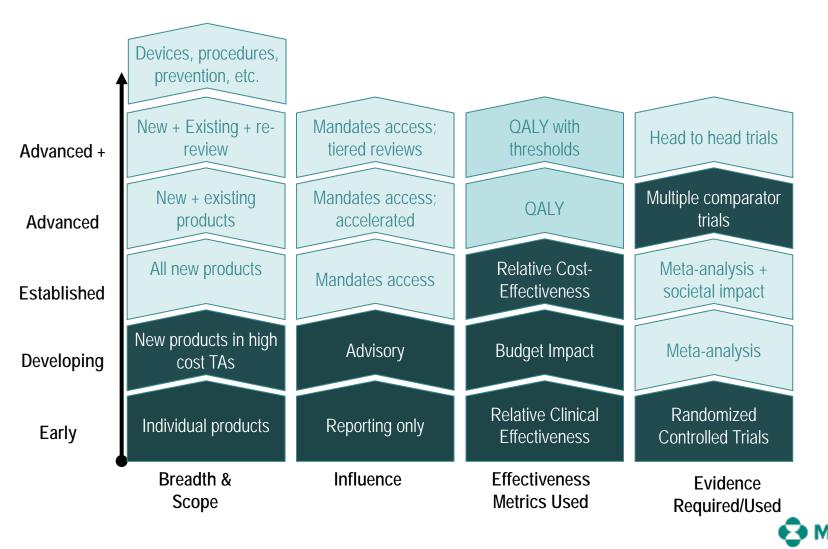


SPAIN

Ερωτήματα για το Ελληνικό Σύστημα Υγείας: 1) Πόσο γρήγορα;



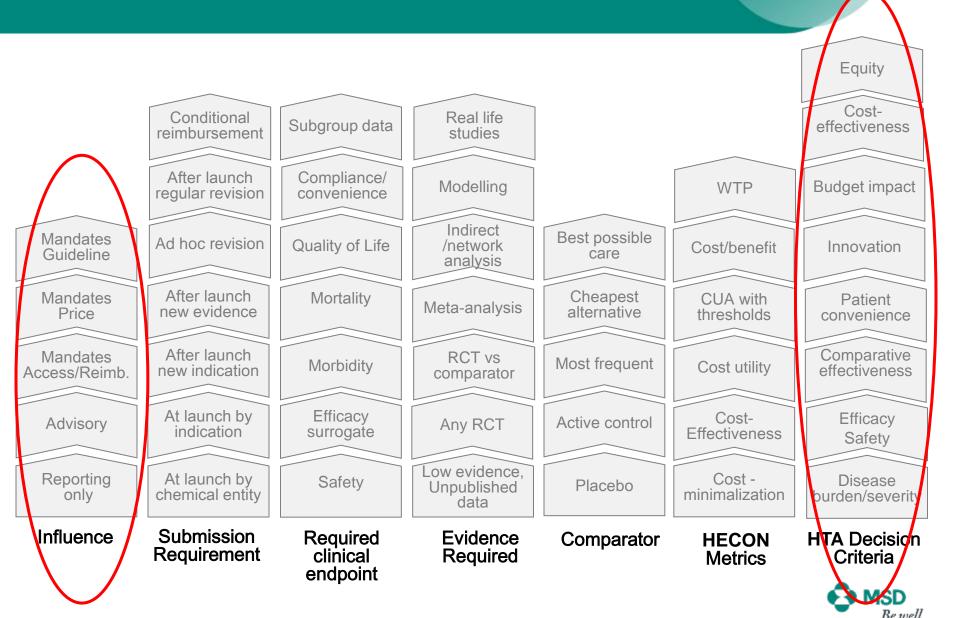
Η ανάπτυξη δεν μπορεί παρά να είναι σταδιακή



Ερωτήματα για το Ελληνικό Σύστημα Υγείας: 2) Ποια τυπολογία θα ακολουθούμε στην αποτίμηση;



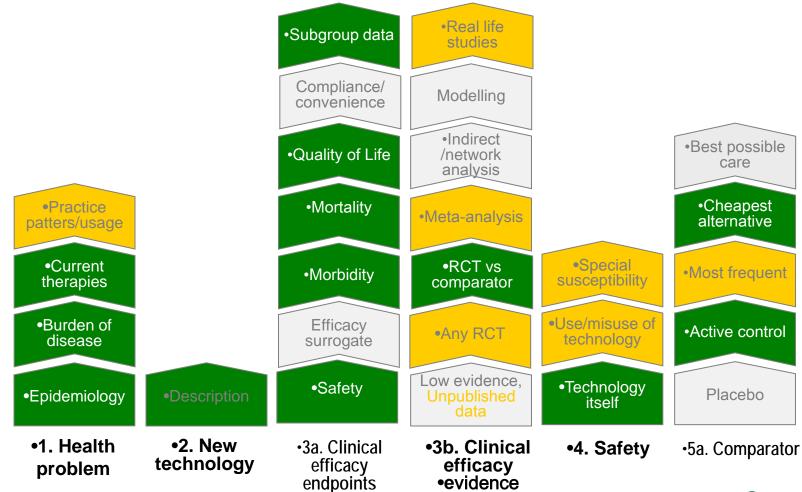
Ποια η επιρροή και ποια τα κριτήρια αποτίμησης του φορέα ΗΤΑ;



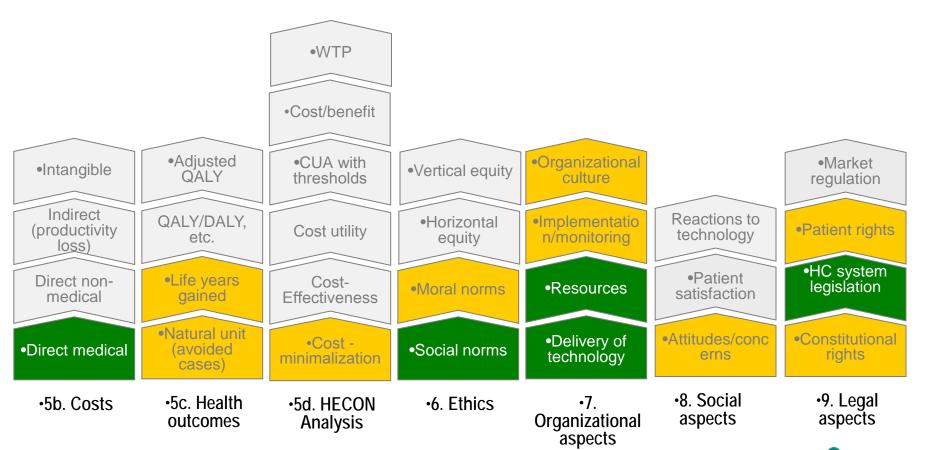
Ερωτήματα για το Ελληνικό Σύστημα Υγείας: 3) Ποια μεθοδολογικά πρότυπα θα ακολουθούνται για την υποβολή φακέλου αξιολόγησης;



Πρότυπο αξιολόγησης σύμφωνα με ΕUNEHTA (1/2)



Πρότυπο αξιολόγησης σύμφωνα με EUNEHTA (2/2)



Ερωτήματα για το Ελληνικό Σύστημα Υγείας: 4) Ποια η θέση του ΗΤΑ στην αρχιτεκτονική του συστήματος;



Πού εντάσσεται ο φορέας αξιολόγησης;

- Στο Υπουργείο Υγείας;
- Στον ΕΟΦ ΙΦΕΤ ΕΚΑΠΤΥ;
- Στην Επιτροπή Αποζημίωσης;
- Στον ΕΟΠΥΥ;
- Τελείως Ανεξάρτητος;
- Ποιες δεξιότητες πρέπει να αναπτύξουμε;



Ερωτήματα για το Ελληνικό Σύστημα Υγείας: 5) Εμείς ή οι άλλοι;



Η συνεργασία μεταξύ των φορέων μπορεί να προσφέρει μια λύση

The timeline of reaching a sustainable and permanent HTA cooperation in Europe





European network for Health Technology Assessment | JA2 2012-2015 | www.eunethta.eu

MSD
Re well

Καθώς οι κατευθύνσεις διαφέρουν από χώρα σε χώρα η τοπική διάσταση θα είναι πάντα απαραίτητη

Table 3.2. Criteria for assessment

Criteria	AT ⁴	BE	CH	DE	FI	FR	NL	NO	SE	UK
Therapeutic benefit	X	×	X	Х	х	×	×	X	х	Х
Patient benefit	X	×	X	X	×	X	×	Х	X	X
CE	×	Х			Х		X	×	X	X
Budget impact		Х			Х	×	X	×		×
Pharmaceutical/innovative characteristics	X	Х				×	Х			×
Availability of therapeutic alternatives	X						×		X	X
Equity considerations								X	X	X
Public health impact						X				
R&D					X					

Source: Adapted from Zentner et al. (2005) and case studies.



Το δίλημμα: Τι σύστημα θέλουμε;

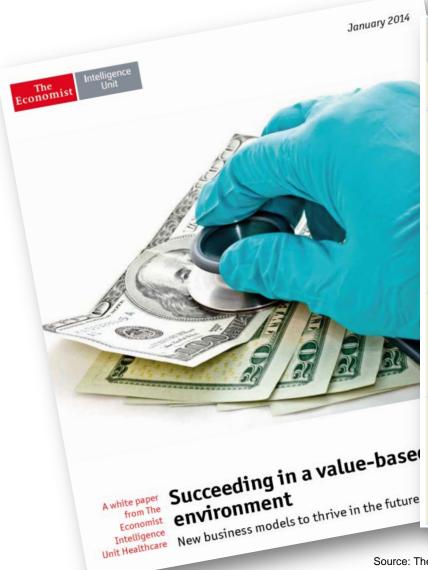


Figure 3		
Reimbursement	Traditional health systems By volume of healthcare activity or product	Value-based health system By patient outcome compared with alternatives
Regulatory approval requirements and process	Demonstrate high quality manufacturing standards, clinical safety and clinical effectiveness, but only against a placebo	Formal systems in US and EU now require clinical effectiveness to be proven against comparative therapies for best outcome over cost
Pricing of supplies	By volume purchased	Relative pricing correlated with health benefit delivered per unit of input
Data and records	Lack of measurement of health outcomes, leading to an inability to purchase or performance manage against this metric	Transparency of input (activity and product volumes) and outcomes
Health system planning	Lack of planning against present and future need	Integrated and collaborative care, budgeted and planned for in accordance with population health needs, access and universal coverage of essential services



Ευχαριστώ πολύ για την προσοχή σας

DOCTORS



What my friends think I do



What my Mom thinks I do



What society thinks I do



What the government thinks I do



What I think I do



What I really do