Regional versus Centralised HTA: Implications for the assessment of cancer drugs

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ISPOR Meeting, Milan 2015

Overview

- The concept of VALUE and HTA approach
- Methods
- Results
- Conclusions
- … next steps

Value based - HTA model

How do jurisdictions estimate the VALUE of new cancer drugs?

- Notion of VALUE for the payer?
- How to estimate the VALUE of a drug?
- Concept of VALUE for guiding reimbursement and/or pricing decisions?

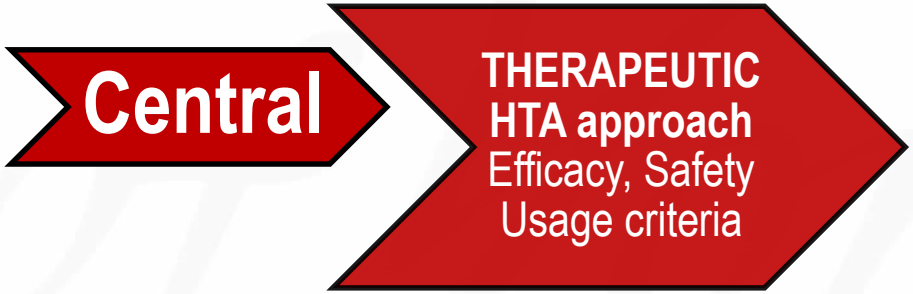
Potential models for HTA:

- Cost per QALY approach
- THERAPEUTIC value approach

NICE approach

- **CENTRALISED** model with **EXPLICIT** analytical framework:
  - A single generic measure of **VALUE: QALYs to MAXIMISE health**
  - Cost-effectiveness (**ICER**): additional cost per QALY gained
  - **NICE threshold** is used to judge if the estimated cost per QALY represents good **value for money for the NHS**
- Technology Appraisals recommendations are based on a review of clinical and economic evidence (RCTs / models)
- **Independent** academic assessment group **reviews** the evidence submission presented by the manufacturer. An Independent Appraisal Committee reaches a consensus.
- **NHS obligation** to fund NICE positive recommendations.

HTA system in Spain



Bodies: Spanish Drug Agency, DF MoH, CCAA (*overlap of activities*)
Coordination group (2012) to conduct Therapeutic Positioning Reports (IPTs).
Pricing and reimbursement advise.
Methods: Lack of transparency or standardised methods.
Mandatory for Regional level

Decentralised model

Bodies: Spanish Society Hospital Pharmacy (**GENESIS, 2004**) gather regional and hospital pharmacy units (agreements to avoid duplication !?)
Methods: Transparent (MADRE model) SR clinical and economic evidence **Basic CEA & budget impact.** Conducted by Regions (And and Cata) and local hospitals.
Not mandatory: hospitals do follow recommendations.

Methods

- We compared NICE technology appraisals from January 2008 to July 2015 with Spanish assessments both at a central (IPT reports) and at a regional level (GENESIS reports).
- Data collected: availability of an HTA report, indication(s), comparator(s), and reimbursement recommendation: recommended, restricted, not recommended.
- Regions of Andalucia (GFTDA) and Cataluña (CAMDHA) use the same HTA methodology, hence selected for the comparision.

Results 1

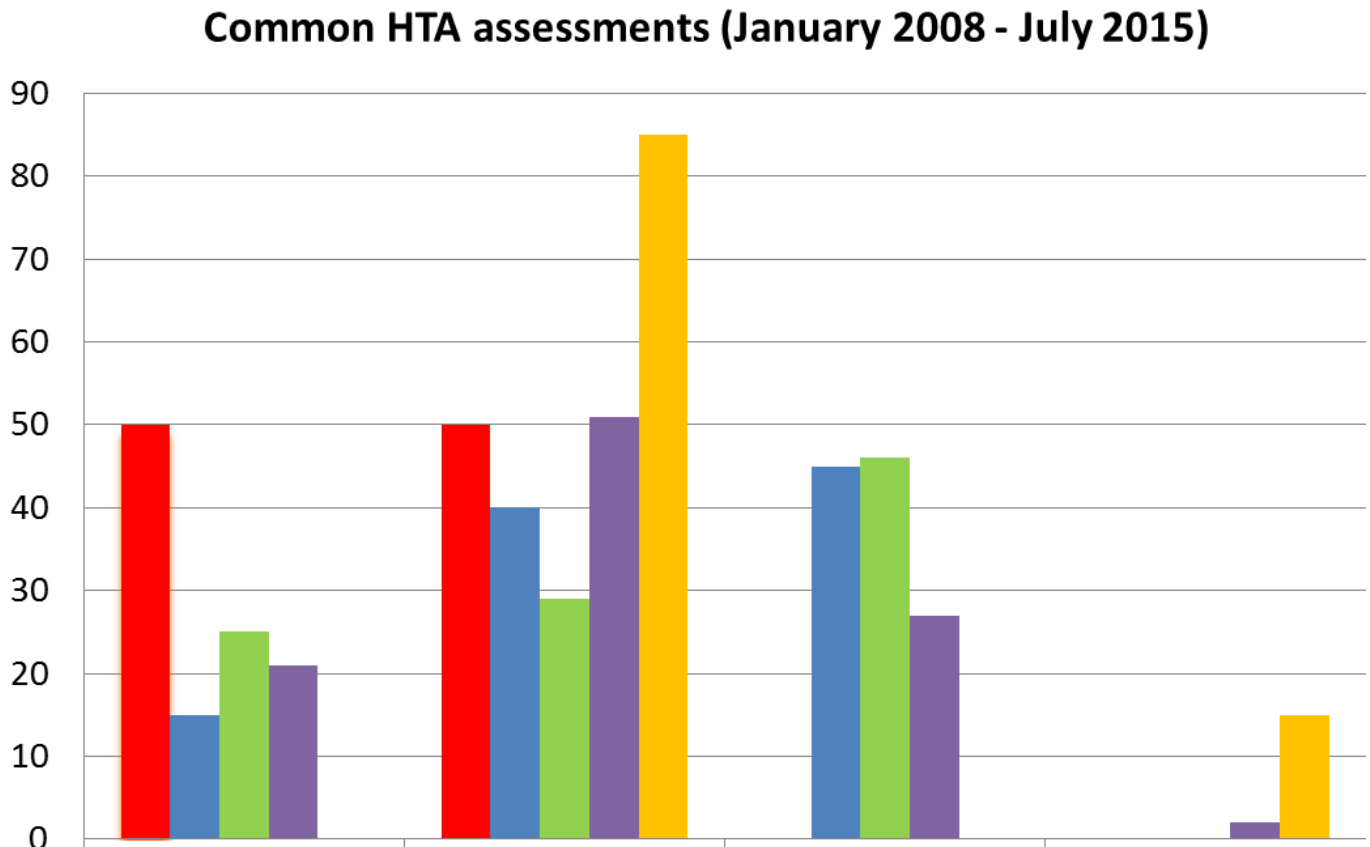
NICE appraisals
67 drug/pairing indications
Recommended: 13%
Restricted: 45%
Not recommended: 42%

Central IPT reports
17 drug/pairing indications
Recommended: 41%
Restricted: 53%
Not recommended: 6%

GENESIS reports
79 drug/pairing indications
Recommended: 13%
Restricted: 65%
Not recommended:16%
Exceptional use: 6%

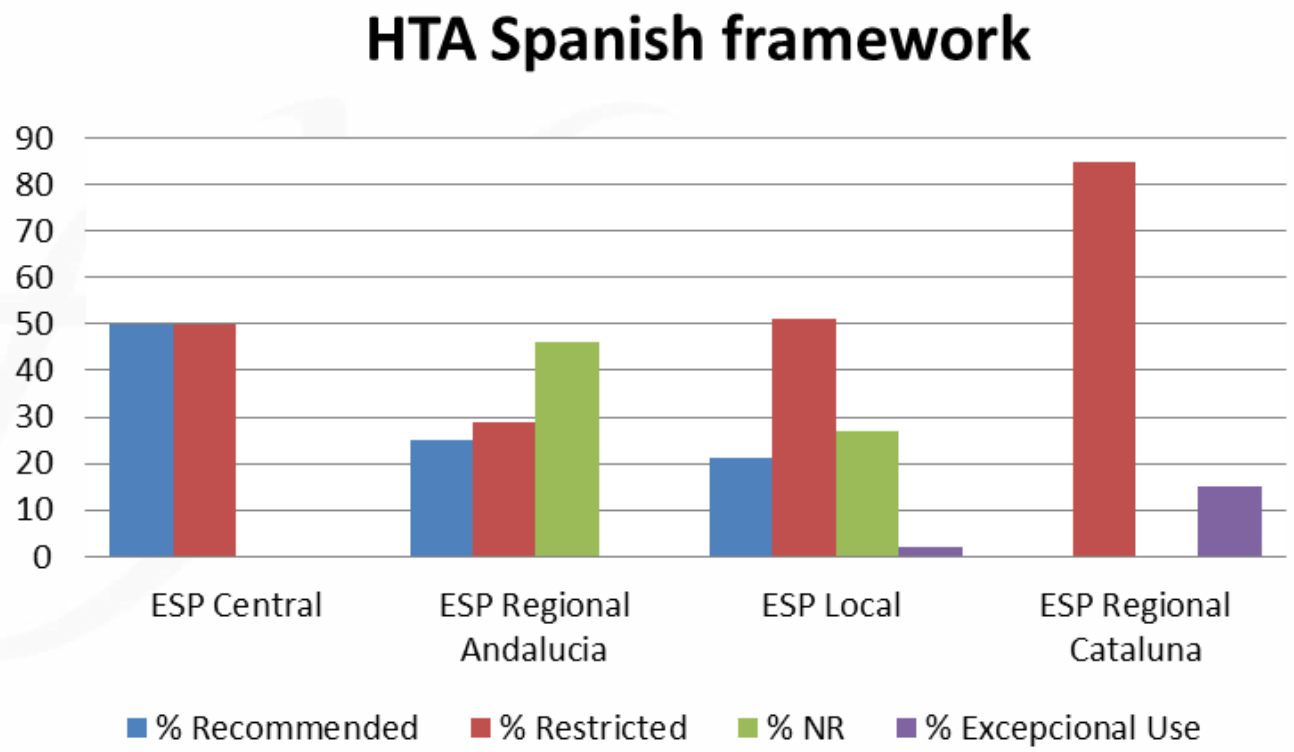
Common assessments in both settings
53 drug/pairing indications

Results 2



	% Recommended	% Restricted	% NR	% Excepcional Use
ESP Central	50	50	0	0
NICE	15	40	45	0
ESP Regional Andalucia	25	29	46	0
ESP Local	21	51	27	2
ESP Regional Cataluna	0	85	0	15

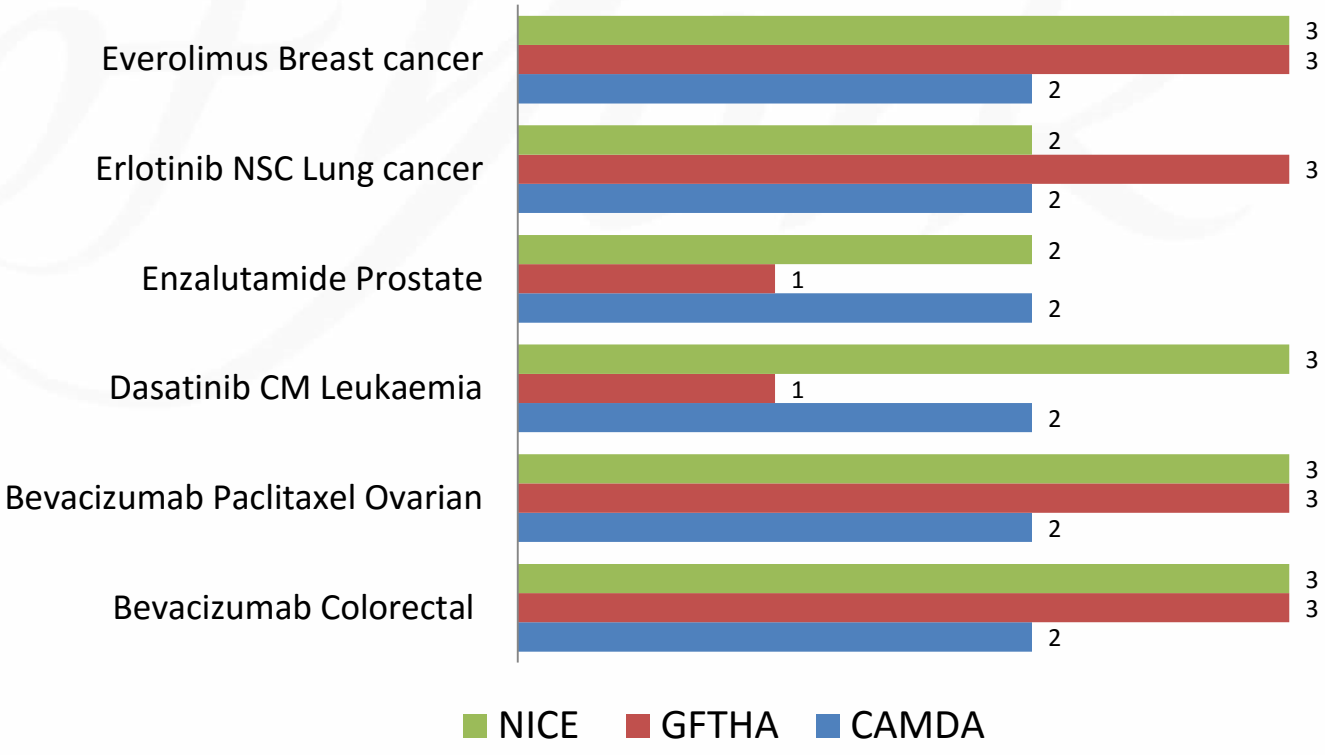
Results 3



		HTA approach - Effect on ACCESS				
Drug	**Indication**	**UK NICE**	**ESP Central**	**ESP REGIONAL**	**ESP LOCAL**	**Used in practice?**
Aflibercept	Colorectal cancer	**NR**	**Non available report**	**Restricted** CAMHDA **NR (C2)** GENESIS	**Rcommended** Hosp Henares	**Restricted** Cataluna Andalucia

Results 4

Duplicated reports by Catalonia (CAMDA) and Andalusia (GTFDA); (n=13). Different recommendations for 46% (n=6)



Recommended (1); Restricted (2); NR (3)

NICE is used as a reference for the Regional HTA system in Spain

Naïve Cost-effectiveness

GENESIS report (MADRE methodology) for Cost-effectiveness

E,G. Trastuzumab emtansine (TDM1) for HER2-positive breast cancer

Coste Eficacia Incremental (CEI) Variables continuas							
Referencia	Tipo de resultado	VARIABLE evaluada	Eficacia de T-DM1	Eficacia Lap/Cap	Diferencia de eficacia (IC95%)	Coste incremental	CEI (IC95%)
Sunil Verma, MD et. Al.	Primaria	SG (mediana)	30,9 meses	25,1 meses	0,48 años (5,8 meses)	56.575,95 €	117.053,7 €/AVG

- T-DM1 = 9.6 m x 0.78 + 21.3m x 0.5 = 18,2 meses ajustados por QoL
- Lapa + Cape = 6.4 m x 0.74 + 18.7m x 0.5 = 14,1 meses ajustados por QoL

Median Survival converted into QALYS using utilities from NICE report (TAG350)

Coste Eficacia Incremental (CEI) AVAC							
Referencia	Tipo de resultado	VARIABLE evaluada	Eficacia de T-DM1	Eficacia Lap/Cap	Diferencia de eficacia (IC95%)	Coste incremental	CEI (IC95%)
Sunil Verma, MD et. Al.	Primaria	AVAC	18,2 meses	14,1 meses	4.1 meses	56.575,95 €	165.588,1 €/AVG

ICER: 180,000 eur/QALY
NICE report (TAG350)

End of Life Criteria

GENESIS report (MADRE methodology) for Cost-effectiveness

E.g. Trastuzumab emtansine (TDM1) for HER2-positive breast cancer

Cost per QALY estimation = EUR 165,000 per QALY

- The use of CEA is not mandatory in Spain hence there is no explicit threshold, although a first reference by PINTO et al was set at 30,000eur/QALY in 2002.
- The most common threshold accepted for cancer drugs ranges between 30,000-50,000 eur/QALY. According to published evidence 32% of Spanish oncologists think that 100,0000 eur/QALY might be considered as an acceptable threshold for cancer drugs assessed in the Spanish setting.
- NICE appraisal was used to justify that TDM1 fulfils **EoL criteria** (despite published evidence supporting higher preferences for QoL in this setting).
- The price is the key factor for cost-effectiveness. The authors state that a 45% reduction in price would be required in order for TDM1 to be cost-effective (at 50,000 eur/QALY). (e.g. Risk Sharing agreements / PAS). Hence recommendation restricted according to clinical criteria

Conclusions 1

- The complex organisation of HTA system at the national and regional level in Spain made the assessments difficult to compare.
- Most of the Spanish (ESP) assessments were accepted either as recommended or on a restricted basis – in Catalonia none were not recommended. In contrast, for NICE 45% were not recommended.
- In Spain, regions cannot (very difficult) deny a drug that has been approved by the Spanish Drug Agency (or IPT).Therefore a filtering system is used to restrict according to clinical criteria or exceptional use.
- Despite the efforts to coordinate HTA assessments for new drugs, there is still overlapping of functions between the central and regional levels in Spain, which produce a delay in access. In the UK the NHS has the obligation to fund positive recommendations within 3 months following NICE guidance.

Conclusions 2

- A transparent and explicit analytic framework is in place only at a regional level in Spain, where cost-effectiveness plays a more important role. Furthermore NICE appraisals are used as a reference for the HTA regions in Spain. This influence is greater in Andalucia.
- Regions only provide isolated data (cost-effectiveness) for national IPT reports, however it is not clear to what extent this data is integrated or taken into account for central decisions.

Further steps

- The UK HTA approach is more consistent and organised, and prescribing might be limited by the guidance given by NICE. The Spanish decentralised HTA approach is complex but it might be more efficient to take into account local practice.

Next step for this study is to explore drug usage in both settings in order to analyse what type of recommendations - locally (Spain) or central (NICE) – (i) are more likely to be followed, (ii) helps to reduce inequalities, (iii) offer the greater value for money given the budget constraints.

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