

## HTA OF MEDICAL DEVICES IN SPAIN: COOPERATION BETWEEN HTA AGENCIES AND IMPLICATIONS FOR INDUSTRY

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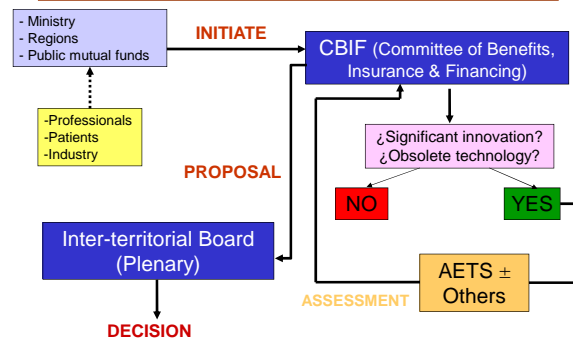
## The Spanish National Health System

- From a hybrid Social Security model to a 17 National Health Services model
- Decentralized decision making (without fiscal responsibility) with variability across regions
- Expansion of primary care, without proper integration with specialized-hospital care
- Standardizing decision making processes (room for improvement in transparency and accountability)
- Not excessive level of expenditures, but accelerated rate of growth, with a significant contribution from private sources
- Unknown quality (as in any other health care system)

## Inter-territorial Board



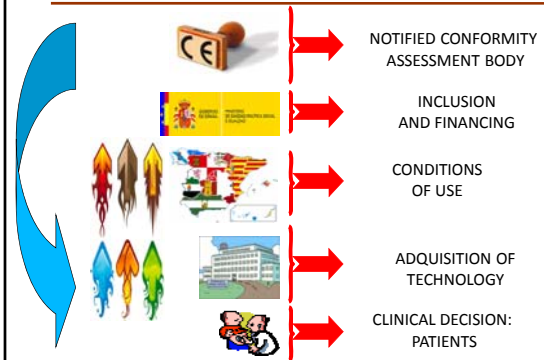
## Updating of the List of Benefits



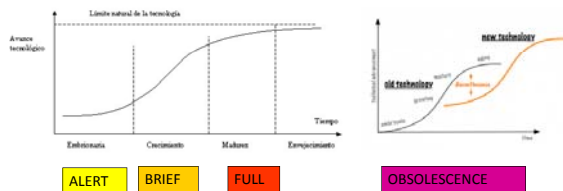
## Content of the assessment

Description of the technology  
 Purpose  
 State of the art regarding safety, efficacy/effectiveness, efficiency  
 Degree of use in Spain and other countries  
 Impact of the technology  
     Patient outcomes  
     Organization of health services delivery  
     Ethical, legal, social implications  
     Economic impact (budget impact)  
 Recommendations

## Different decision-makers, different needs



## Different levels of development, different approaches



<http://aunets.isciii.es>



- Emerging and new technologies
- HTA assessment: effectiveness and cost-effectiveness
- Obsolete technologies
- Coverage with evidence development
- Clinical Practice Guidelines
- Appropriate use of technologies
- Registries

## Domains of the HTA Core Model

1. Health problem and current use of technology
2. Description and technical characteristics
3. Safety
4. Clinical effectiveness
5. Costs and economic evaluation
6. Ethical analysis
7. Organizational aspects
8. Social aspects
9. Legal aspects

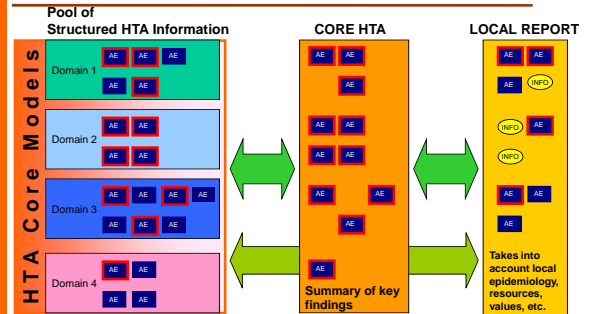
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## The Core HTA Structure

i.e. HTA Core Models and their applications

AE = assessment element  
 AE = Core element  
 AE = Non-core element  
 (NFC) = Locally produced information that does not follow HTA Core model structure



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## Different decision-makers, different answers



## The perspective of HTA

- HTA has to accommodate the needs of different decision-makers/payers:
  - Limiting the growth of health care costs and improving population health
  - Controlling spending ensuring access to effective medical technologies.
- Different decision-makers will have different needs and perspectives
- HTA has to conduct their analysis based on available evidence:
  - The medical technology industry will need to grapple with the requirements of building an evidence-base necessary to satisfy different decision-makers/health-care payers/HTA.

## **Some suggestions for the industry**

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- Providing proven, safe, clinically effective and cost effective new technologies
- Improve existing gaps in information about the cost-effectiveness of technologies.
  - High-quality valid pre-market clinical trials (powered and with clearly defined end points)
  - Post-market continued surveillance (registries allowing full transparency of new and existing products)
- Supported by industry, payers, regulators, biomedical research funds