¿Necesita España un NICE?

Does Spain need a HTA National Agency

Jose-Manuel Freire

¿Necesita España un NICE, además de un NIPPE?  
Does Spain need a HTA National Agency in addition to a NIPPE*

Jose-Manuel Freire

*NIPPE (National Institute of Public Policy Excellence)
Points

1. Health Technology Assessment (HTA) and its institutional environment;
2. On the Governance in the Spanish National Health System (NHS);
3. The current situation of HTA Agencies in Spain;
4. HTA and the Rajoy health reforms;
5. Future perspectives: more questions than answers

Decisions where HTA input is needed

• Market approval of a technology (medicines, devices, procedures, etc.)
• NHS Coverage of technologies
• Public Health measures (vaccinations, screening, PH programs)
• Policy/organization/management decisions
Potential users of HTA evidence

- Politicians and policy makers at national, regional, local level;
- Clinicians
- The public: informed and active citizens and their organizations;
- Patient organizations;
- Healthcare professional organizations;
- Civil servants and technical experts in national, regional local authorities;
- Managers, of hospitals, PHC, health services, funding agencies, etc.;
- The Media

Institutional environment and HTA

- Political and social institutions are key determinants of a country’s functioning;
- HTA is meant to improve the health policy making process by providing an input of expert-scientific evidence;
- HTA is just one of the many relevant inputs to decision making and to the regulatory processes
- HTA can only fulfill its promise in an institutional environment of good public governance;
- HTA has also a role in building an open forum to exchange views on health policy;

HTA can only thrive in an political, cultural and social environment of good public governance (transparency, accountability, and true democratic values and practice)
## The Spanish NHS vs Swedish & UK-NHS

<table>
<thead>
<tr>
<th>Sweden / UK</th>
<th>Spain</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tax financing; Universal, equal, public health coverage as a citizen right;</td>
<td>Tax Financing; &quot;De facto&quot; near-universal coverage and dual system (2.3 mill people special coverage)</td>
</tr>
<tr>
<td>Public provision doesn’t imply civil service status (civil service)</td>
<td>Publicly provided health services part of public administration (civil service-like regulations)</td>
</tr>
<tr>
<td>Longer democratic tradition of public accountability; health high in the political agenda; frequent reforms;</td>
<td>Low culture of public accountability and evaluation; Health low in the political agenda; low pressure for reforms.</td>
</tr>
<tr>
<td>Health professions well regulated an with strong organizations; health trade unions with a cooperative culture;</td>
<td>Weak health professional organizations; Many competing trade unions; industrial relations more confrontational than cooperative.</td>
</tr>
<tr>
<td>Governance boards; arms-length organizations; Professional non-political management</td>
<td>Managers political appointees; Command and control management structures; no governing bodies;</td>
</tr>
<tr>
<td>Culture of evaluation and explicit expert-advice input into public policy decision making.</td>
<td>Low culture of evaluation and small room for expert advice input in policy making.</td>
</tr>
</tbody>
</table>
Health Policy Response

CENTRAL GOVERNMENT
• May 2010: Spain’s crisis acknowledged
• 2010-12: Pharma policy
• 2010: NHS Council Agreement (March)
• 2012: Rajoy health reforms (24Apr)

Cuadro 3.3.5 Cambio en la estructura del gasto por funciones

<table>
<thead>
<tr>
<th>ADMINISTRACIONES PUBLICAS (S.13)</th>
<th>Peso gasto 2010 PIB</th>
<th>Peso gasto 2015 PIB</th>
<th>Variación %</th>
</tr>
</thead>
<tbody>
<tr>
<td>01 Servicios públicos generales</td>
<td>5,2</td>
<td>5,4</td>
<td>3,9</td>
</tr>
<tr>
<td>02 Defensa</td>
<td>1,1</td>
<td>0,8</td>
<td>-30,4</td>
</tr>
<tr>
<td>03 Orden público y seguridad</td>
<td>2,1</td>
<td>1,5</td>
<td>-28,9</td>
</tr>
<tr>
<td>04 Asuntos económicos</td>
<td>5,2</td>
<td>2,4</td>
<td>-53,0</td>
</tr>
<tr>
<td>05 Protección del medio ambiente</td>
<td>0,9</td>
<td>0,5</td>
<td>-43,9</td>
</tr>
<tr>
<td>06 Vivienda y servicios comunitarios</td>
<td>1,2</td>
<td>0,5</td>
<td>-61,0</td>
</tr>
<tr>
<td>07 Salud</td>
<td>6,5</td>
<td>5,1</td>
<td>-21,5</td>
</tr>
<tr>
<td>08 Actividades recreativas, cultura y religión</td>
<td>1,6</td>
<td>0,8</td>
<td>-48,3</td>
</tr>
<tr>
<td>09 Educación</td>
<td>4,9</td>
<td>3,9</td>
<td>-21,3</td>
</tr>
<tr>
<td>10 Protección social</td>
<td>16,9</td>
<td>16,1</td>
<td>-5,0</td>
</tr>
<tr>
<td><strong>Gasto total</strong></td>
<td><strong>45,6</strong></td>
<td><strong>37,0</strong></td>
<td><strong>-19,0</strong></td>
</tr>
</tbody>
</table>

Fuentes: INE y Ministerios de Economía y Competitividad y Hacienda y AAPP

(May 2012)
ACTUALIZACIÓN DEL PROGRAMA DE ESTABILIDAD REINO DE ESPAÑA 2012-2015: Página 49;
March 2010 NHS-Council Agreement

- A 1,500 m€ cut in pharma expenditure,
- NHS-wide common criteria for paying personnel,
- A new central purchasing scheme,
- Consideration for increasing health earmarked funding to Autonomous Communities.

Autonomous Communities’ Policy Response

1. Budget cuts (all): 2011 overall budget -4.62%
2. Cuts in personnel expenditure
   - Direct income reduction (Catalonia, Valencia)
   - Indirect (Madrid)
3. Pharma policies:
   - Galicia (positive list)
   - Andalusia (story of comprehensive pharma policy)
   - Auction of medicines
   - E-prescription & dispensing
   - Compulsory prescription by INN (Int. Non-proprietary Names)
4. Reorganization of provision
   - Catalonia: public provision network > public corporation
   - Valencia and Madrid: further privatization
5. Activity cuts
   - Closure of surgical theatres (Catalonia)
   - Beds suppression (Catalonia)
5. Strategic reforms
   - Basque Country ***: global policy for chronic patients; proactive health policy
   - Andalusia**
   - Other Regions with varying scope policies and commitment...
Central Government health policies

- **Expenditure cuts:**
  - €bn 18,349 in 2012
- **Salary cuts 5%**
  - for all public employees RD Ley 8/2010 (20may)

• **Pharma policies:**
  - RD Ley 4/2010 (26mar):
    - Drug price reductions;
    - Shift of high price drugs to hospital dispensing (RD Ley 9/2011 (19ago))
  - Prescription (ICD not trade mark)
  - New reference price
  - Delivering the cheaper drug
  - A “Committee on Cost-Effectiveness of Pharmaceutical & Medical Products”

Rajoy Emergency health legislation

[Image of the BOLETÍN OFICIAL DEL ESTADO]

I. DISPOSICIONES GENERALES

JEFATURA DEL ESTADO

5403

Real Decreto-ley 16/2012, de 20 de abril, de medidas urgentes para garantizar la sostenibilidad del Sistema Nacional de Salud y mejorar la calidad y seguridad de sus prestaciones.

[Link to BOE article]

Rajoy Health reform RD Ley 16/2012

- Redefinition of entitlements: from citizens to insured
- Redefinition of the NHS Benefits package:
  - New copayment for pensioners (by income-groups)
  - Increase in current copayments (by income-groups)
  - Spanish Network of HTA Agencies
- Centralization of benefits definition, economic control, and pharmaceutical regulation policies
- A complex set of non urgent regulations

NHS Benefits coverage after Rajoy health reform (RD Ley 16/2012)

- Basic Health Benefits: No cost sharing in medical services
- Supplementary benefits:
  - Prescriptions of drugs
  - No emergency transp.
  - Prosthesis & appliances
  - Dietetics
  - Cost sharing
- Accessory benefits:
  - Not well defined (yet)
  - Cost sharing
- Autonomous Communities Benefits:
  - With Region’s funds and if financial equilibrium met

COPAYMENT MONTHLY CAPS

- Very poor people: Total exemption
- For some drugs (chronic conditions) 10% or top amount of copayment
- 10% Pensioner
- 50% “People” income:
  - > 18,000 € YEAR
  - < 100,000 € YEAR
- 60% “Rich people”:
  - > 100,000 € YEAR
- 40% “Poor people”:
  - < 18,000 € Año
- < 18,000 €: 8 €
- 18,000 - 100,000 €: 18 €
- > 100,000 €: 60 €
Impact in the Spanish NHS

- **Values**: downplay of solidarity through
  - Exclusion of coverage of non-documentated immigrants
  - Move backwards: from universalist to insurance entitlements
  - Important new copayments and increase in the existing ones

- **Selective recentralization**: Pharma policy, Benefits, Coverage
  - Fiscal equilibrium requirement
  - ... but regional freedom for risky experiments (Valencia, Madrid)

- **Cuts without reform plan**: no strategic reforms for improving healthcare or disinvest in ineffective care
  - Only Basque Country (chronics) and Andalucía (guidelines and clinical management) play another non-cost-containment strategies

New law: role of the Spanish HTA Network in assessing the Common Benefits package

**[NHS Common Benefits Package]**
In developing such content it will be considered the efficacy, efficiency, effectiveness, safety and therapeutic utility, as well as advantages and alternatives, the care of less protected or risk groups, and the social needs, as well as its economic and organizational impact.

In assessing the provisions above shall participate the **Spanish Network of Agencies for Health Technology Assessment and Benefits Evaluation**.
New law: role of the Spanish HTA Network in assessing the Common Benefits package

- In any case, it will not be included in the common benefits package those techniques, technologies and procedures whose effective contribution to the prevention, diagnosis, treatment, rehabilitation and cure of diseases, conservation or improvement of life expectancy, autonomy and elimination or decrease in pain and suffering is not sufficiently proven.

- The new techniques, technologies or procedures shall be subject to evaluation by Spanish Network of Agencies of Health Technologies and Benefits Evaluation as mandatory and prior to its use in the NHS.

Spain’s NHS new Advisory Committee of Pharmaceutical Benefits (RDL 18/2012)

- The Spanish HTA Network will not deal the medicines;
- This is the tasks of a new “NHS Advisory Committee of Pharmaceutical Benefits” [Comité Asesor de la Prestación Farmacéutica del Sistema Nacional de Salud]
- …Previously the RDLe 9/2011 had established the “Committee on Cost-Effectiveness of Pharmaceutical & Medical Products” [Comité de Coste-Efectividad de los Medicamentos y Productos Sanitarios]

1. ...is the scientific-technical collegiate body, assigned to the ministerial unit with competence in pharmaceutical benefits of the MoH, charged with providing advice, evaluation and consultation on the relevance, improving and monitoring the economic evaluation necessary to support the decisions of the Interministerial Commission on Drug Prices.

2. The NHS Advisory Committee of Pharmaceutical Benefits will consist of a maximum of 7 members appointed by the head of the MoH among prestigious professionals with proven experience and track record in evaluation pharmacoeconomic.

4. In any case, the creation and operation of the Advisory Committee Pharmaceutical Service will be supported by the personnel, technical and budgetary resources allocated to the body to which it belongs.
Spain: HTA Agencies

<table>
<thead>
<tr>
<th>Government Territory</th>
<th>Name of the Agency</th>
<th>Year creation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spain’s Central Govt.</td>
<td>AETS</td>
<td>1994</td>
</tr>
<tr>
<td>Basque Country</td>
<td>OSTEB (now</td>
<td>1992</td>
</tr>
<tr>
<td>Catalonian</td>
<td>AATRM &gt; AIAQS (now</td>
<td>1995</td>
</tr>
<tr>
<td>Andalusia</td>
<td>AETS (now</td>
<td>1996</td>
</tr>
<tr>
<td>Galicia</td>
<td>AVALIA</td>
<td>1999</td>
</tr>
<tr>
<td>Madrid</td>
<td>Ag. Lain Entralgo (*)</td>
<td>2003</td>
</tr>
<tr>
<td>Aragon</td>
<td>IACS</td>
<td>2003</td>
</tr>
</tbody>
</table>

(*) To be scrapped 1st Jan 2013

Projects financed by “Plan Nacional de Calidad” (end 2009)

1. Priority according to effectiveness
2. Disinvesting in lack of value intervention
3. **HISPA-NICE**
4. Clinical priorities in waiting list and transparency
5. Change unfair and obsolete copayments for drugs
6. Modulate salaries according to health results and achievements
7. Allocation to centres for promoting effectiveness and integration of care
8. More and better Public Health
9. Stronger and more entrepreneurial primary care
10. Focus shift toward chronic, frail, and terminal patients
11. Opening boundaries and cooperation amongst medical specialties
12. Agency for cooperative governing of the NHS
13. Less civil servant style and more professionalism
14. Professionalization of managers and Good Governance
15. Transparency and open access to all information of healthcare services and providers
16. Assess PFI
17. Prevent conflicts of interest, and enhance honesty and exemplarity

AES: It’s urgent to set up an HispaNICE

3. **AN URGENT SET UP OF AN "HISPA-NICE."**

“To be credible the step towards a selective coverage of benefits, diagnostic tests and drugs based on scientific evidence, it requires a structural change in the procedure and criteria for funding, setting and review of prices, following the example of the British National Institute for Health and Clinical Excellence (NICE).”

...(cont.) “It is needed to create a statewide Evaluation Agency, with autonomy and at arms length of the central and regional governments, which would aim to inform decisions of funding, divestment and reinvestment: defining / delimiting the medical indications based on criteria of efficacy, safety, and cost-effectiveness; establishing the frequency and duration of certain operations, also in light of the same criteria-, and proposing programs in which the financing of certain benefits be temporary, depending on whether or no scientific evidence is collected about its effectiveness in a reasonable period.”
What NICE does

- Providing guidance to ensure quality and value for money
- **NICE guidance** supports healthcare professionals and others to make sure that the care they provide is of the best possible quality and offers the best value for money.
- NICE provide independent, authoritative and evidence-based guidance on the most effective ways to prevent, diagnose and treat disease and ill health, reducing inequalities and variation
- **NICE guidance** is for the NHS, local authorities, charities, and anyone with a responsibility for commissioning or providing healthcare, public health or social care services. We also support these groups in putting our guidance into practice.

How NICE works

- NICE develops guidance and other products by working with experts from the NHS, local authorities, and others in the public, private and voluntary sectors - including patients and the public.

NICE recommendations are based on the best available evidence of the most effective care.

- **NICE guidance** is produced openly and transparently, and we make sure that those that use our guidance, as well as those it affects, are involved every step of the way.
There are other HTA agencies to look at and to learn from.
Swedish Council on Health Technology Assessment (SBU)

- SBU was established in 1987 by the Swedish Government to answer these and similar questions on behalf of the healthcare sector. Initially, SBU was an agency under the Swedish Government Offices.

- In 1992, SBU was commissioned as an independent public authority for the critical evaluation of methods used to prevent, diagnose, and treat health problems.

- Which treatment options are most effective?
- How can we diagnose problems most accurately?
- How can we use healthcare resources to achieve optimum benefits?
It does what?

- Evaluation of benefits, harms, and economic implications of interventions to contribute quality and efficiency of health care in Germany.
- Assessment of benefits & costs by comparing competing health technologies; additional costs have to be related to additional therapeutic benefits.
- Development of the independent scientific capacity to answer the research questions, to evaluate medical issues and to investigate research requirements relevant to patients’ needs.
- Evaluation to assist the GKV-Spitzenverband in setting the appropriate maximum reimbursable price of medicines on behalf of the Statutory Health Insurance (SHI).
- Production of reports on specific topics requested by the G-BA or the BMG or initiated by the Institute to enhance health care knowledge in specific areas.

For whom?

- Federal MoH (Bundesministerium für Gesundheit, BMG),
- Federal Joint Committee (Gemeinsamer Bundesausschuss, G-BA)
- National Association of Statutory Health Insurance Funds (Spitzenverband der Gesetzlichen Krankenversicherung, GKV-Spitzenverband)
- The Public (society)

The IQWiG is set up in 2004 as a private foundation.

http://www.scottishmedicines.org.uk/About_SMC/What_we_do/index
Membership

SMC is a consortium of stakeholders from Area Drug and Therapeutic Committees (ADTCs) and representation is derived from ADTCs across NHS Scotland.

SMC also has two representatives from the Association of British Pharmaceutical Industry (ABPI) on the consortium. Recruitment of these members is facilitated through ABPI who advertise through ABPI channels and review and short-list all nominations before making a formal appointment.

Members of the New Drugs Committee, which is a sub committee of SMC, are also elected from nominations received from ADTCs.

Recruitment of public partners is via advertising through the SMC website and other relevant bodies, i.e. NHS Quality Improvement Scotland, Scottish Health Council, Voluntary Health Scotland and Directors of Public Involvement within Health Boards.

- SMC Executive Membership
- SMC Membership
- New Drugs Committee Membership
- Patient and Public Involvement Group (PAPIG)
- SMC User Group Forum

Minutes

This section contains the Minutes from the SMC monthly meetings.

2012

- Tuesday 01 May 2012
- Tuesday 03 April 2012
- Tuesday 06 March 2012
- Tuesday 07 February 2012
- Tuesday 10 January 2012

2011

- Tuesday 06 December 2011
- Tuesday 01 November 2011
- Tuesday 04 October 2011
- Tuesday 06 September 2011
- Tuesday 02 August 2011
- Tuesday 05 July 2011
- Tuesday 07 June 2011
- Tuesday 03 May 2011
- Tuesday 05 April 2011
- Tuesday 01 March 2011
- Tuesday 01 February 2011
- Tuesday 11 January 2011

2010

- Tuesday 14 December 2010
- Tuesday 02 November 2010
- Tuesday 05 October 2010
Future perspectives: more questions than answers

• Political commitment to a true HTA Agency or Network of Agencies, requires:
  – Independent, autonomous status for such Agency/Network
  – A governing Board,
  – Professional authority in its leadership
  – A properly selected Scientific Advisory body
  – Presence in all Autonomous Communities;
  – Commitment to good practices of accountability, transparency, etc.
  – Its input be mandatory for certainin decissions

Future perspectives: more questions than answers

• The main challenge is an effective UTILIZACION of the technical-expert input provided by the HTA community in Spanish health policy decision-making;

• For that to happen, a stronger culture of good governance is a necessary condition

• Meanwhile, the existing HTA Agencies should be supported and strengthened.
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