Governance of effectiveness assessment in France

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French Context

- Bismarck-type system combining compulsory and voluntary complementary insurance
- Rapid growth of health expenditure following a slowdown in the 90s (annual rate of increase 3.5% since 2000)
- Public pharmaceutical expenditure per head is among the highest in OECD (15% public expenditure) and was increasing more rapidly than other countries
- Use of a positive list to define what is paid by public insurance (and complementary insurance)
- Reimbursement rates (for drugs) depend on drug effectiveness and are fixed: 35%, 65%, 100%
- Pharmaceutical industry (production) is very important
Public expenditure on pharmaceuticals /capita, US$ 2000 PPP

French National Authority for Health: HAS

- Set up in 2004 as an independent public body to bring under a single roof a number of activities and institutions to improve the quality of patient care
- Mission includes:
  - Assessment of drugs, medical devices, procedures, health strategies
  - Publication of clinical guidelines
  - Accreditation of healthcare organisations
  - Certification of doctors
- Annual budget of 60m Euros comes from:
  - taxes on promotional spending by drug companies (33%), National Health Insurance (31%), state funding (14%), HCO accreditation fees (14.6%), fees for assessing applications for inclusion on reimbursement lists (7%)
Advisory role for reimbursement decisions

- **Opinion on the clinical effectiveness** *(SMR)* and relative benefit *(ASMR)* of drugs, medical devices, and diagnostic and therapeutic procedures
  - SMR (effectiveness) takes into account clinical impact + importance for public health (four levels: none, low, moderate, important)
  - Determines the reimbursement rates (0, 35%, 65%, 100%)
  - ASMR (improvement in effectiveness/ indirect cost analysis) compares the contribution of the new drug/diagnostic, etc. compared with existing ones
  - Determines the price (levels 1 to 5)

- **Opinion on targeted practice agreements**
  HAS vets all quality targets for practitioners *(ACBUS, CAPI)*, which are set out in agreements between NHI and health professionals, if concern the quality, safety, and efficacy of practice

- **Opinion on chronic (long-term) conditions**
  Definition of conditions that require lengthy and expensive treatment (establishing the eligibility criteria for 100% NHI cover for 30 chronic conditions and the treatments required)

Place of cost-effectiveness analysis

- In 2008 HAS was given a new mission to carry out medico-economic evaluation of health technologies (drugs, procedures, health strategies ...)

- **What is medico-economic evaluation for HAS?**
  - (in best case) A tool for better using available health resources
  - Understand better the global cost implications of health interventions/technologies that have been adopted

- **What it is not?**
  - A tool for rationing health care
  - Establishing criteria for deciding what to include in the health basket

- **Still on shaky ground**
  - Separate from medical effectiveness evaluation
  - Ex post rather than ex ante evaluation
  - Limited analysis of opportunity costs of different strategies
  - Little political power
Key stages in HTA process (Drug reimbursement)

Market share of drugs by their reimbursement rates

<table>
<thead>
<tr>
<th>Market share</th>
<th>Medicaments remboursés à 0%</th>
<th>11 %</th>
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<tbody>
<tr>
<td></td>
<td>Medicaments remboursés à 30%</td>
<td>17 %</td>
</tr>
<tr>
<td></td>
<td>Medicaments remboursés à 65%</td>
<td>70 %</td>
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<tr>
<td></td>
<td>Medicaments remboursés à 100%</td>
<td>2 %</td>
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</tbody>
</table>

Source: Briand et Chambrelaud, 2001
In practice...

- 1999 to 2001 the Transparency Commission evaluated the therapeutic value of 4490 reimbursable specialties
- Recommended that 835 should be removed from the list because their SMR is inadequate
- Only 72 removed, and vigorous contestations from the industry
- HAS asked to re-evaluate these drugs in 2004
- Almost all of the specialties reevaluated by September 2005 were again judged inadequate
- The Minister decided not to reimburse them after March 2006 with the exception of veinotoniques which are reimbursed 15% until 2008

A comparison of molecules reimbursed in three countries: example of benzodiazepines

- Benzodiazepines are used in the treatment of insomnia, anxiety and epilepsy
- They are addictive and susceptible to misuse and abuse (supply is regulated for public health/security reasons in England, France and Germany)
- Of 20 products reimbursed in France (17 at 65%) half are either not reimbursed or not on the market in UK
- In UK only reimbursed in generic form
- In Germany they are all subject to reference pricing (in France only one)
- The reimbursement rates comply with the recommendations of HAS in France (SMR "important" to "moderate")
- Cost in 2002 (per 1000 habitant):
  - more than 2600€ in France; 1200€ in Germany; 1100€ in England
Comparison of drug baskets in three therapeutic classes, 2002

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<td>10</td>
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<td>1</td>
<td>3</td>
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Public expenditure, euros/1000 inhabitants

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<tr>
<td>Anti-obsètes</td>
<td>0</td>
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<td>366</td>
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Concluding remarks

- There is a high margin for improving resource use with CEA
- There are different approaches to “effectiveness assessment”
- Solutions need to fit with system design
- To make CEA programs work, you need political will, stakeholders agreement, incentive scheme …)
- Effectiveness analysis is not forcibly a scientific process
Questions

- How much can we “mutualize” knowledge on effectiveness assessment?
- Is it possible to set a gold standard for conducting effectiveness assessment?