HTA IN BRASIL: IMPACTS AND NEW DIRECTIONS

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Capital: Brasilia
Area: 8,514,876 Km²
Official Language: Portuguese
Population (2010): 190.7 millions
GDP (2010 est.): $ 2,172 trillion (PPP Int.)
Human Development Index (2010): 0.699 (high, 73rd)
Life Expectancy at Birth (2007): 72.5 years
Child Mortality Rate (2007): 20.00
27 States; 5,565 municipalities
Per Capita Government Expenditure on Health (2007):
$ 348 (PPP Int.)
Brazil: Two-Tiered Healthcare System

Publicly Funded
Unified Health System (SUS)

Taxes and Social Contributions

Public Healthcare Providers

Universal Coverage

25% of the Population
Access dependent on:
• Ability to pay
• Labour market (companies)

Out-of-pocket
Pre-paid

Private

Private Healthcare Providers

Health Insurance Companies

Secretariat of Science, Technology and Strategic Inputs
Ministry of Health
Unified Health System - SUS

• Universal healthcare system, adopted in 1988
• All Brazilian citizens have the right to free medical care access, from primary healthcare to high-cost/highly complex procedures.
• The SUS is one of the largest public health systems in the world
  – Offering coverage to 60-80% of the Brazilian population
  – With 52.2% of the population covered by Family Health Teams, which are present in 95.1% of the municipalities
  – Conducts 3.1 billion walk-in procedures annually, nearly 300 million medical consultations, and 2 million births
  – Includes more complex activities: 20.1 thousand transplants; 281.7 thousand heart surgeries; 9.6 million chemotherapy and radiotherapy procedures; and 11.4 million admittances
  – The quality and impact of some national programs are internationally recognized (immunization, HIV/Aids and tobacco control programs).
HTA in SUS - Legal Frameworks

• **1990** - Law 8,080/90 – Organic Health Law

• **2004** - II CNCTIS – National Conference on Science, Technology and Innovation in Health
  - National Priority Agenda in Health Research (2005)

• **2009** - National Policy on Health Technologies Management (GM-2690/ November 5th, 2009)

• **2011** - Law No. 12,401/2011 - Establish new roles for the incorporation of health technologies into the SUS
Roles of the Main Areas Involved in Health Technology Incorporation

• **Ministry of Health (MoH)**
  - Coordinates the Commission for the Incorporation of Health Technologies (CITEC)
  - Creates lists for incorporation/exclusion of technologies in the SUS.
  - Elaborates/supports HTA studies (drugs are 90% of the demand).
  - Coordinates MoH’s clinical guidelines elaboration group
  - Supports the Essencial Medicines Commission
  - Coordinates the REBRATS – 45 members

• **National Agency for Health Surveillance (Anvisa)**
  - Price-fixing of medicines on the Brazilian market (Drug Market Regulation Council- CMED);
  - Coordinates the editorial center of the Brazilian Bulletin on Health Technology Assessment (BRATS)
## Who is Who in the Brazilian Context

<table>
<thead>
<tr>
<th>Produtores</th>
<th>Incorporadores</th>
</tr>
</thead>
<tbody>
<tr>
<td>Segmentos do complexo industrial da saúde</td>
<td>Prestadores de serviços</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Reguladores / Cerificadores</th>
<th>Financiadores</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Ministério da Saúde – MS</td>
<td>SUS</td>
</tr>
<tr>
<td>• Ministério da Fazenda - MF</td>
<td>Sistema privado</td>
</tr>
<tr>
<td>• Agência Nacional de Vigilância Sanitária – ANVISA</td>
<td>Cidadãos</td>
</tr>
<tr>
<td>• Agência Nacional de Saúde Suplementar – ANS</td>
<td></td>
</tr>
<tr>
<td>• Instituto Nacional de Metrologia, Normalização e</td>
<td>Avaliadores</td>
</tr>
<tr>
<td>Qualidade Industrial – INMETRO</td>
<td>Ministério da Saúde</td>
</tr>
<tr>
<td>• Instituto Nacional de Propriedade Intelectual –</td>
<td>ANVISA</td>
</tr>
<tr>
<td>INPI</td>
<td>Serviços</td>
</tr>
<tr>
<td></td>
<td>Instituições de ensino</td>
</tr>
<tr>
<td></td>
<td>Consultores independentes</td>
</tr>
</tbody>
</table>

**Gestão: MS / Sistema privado**

**Instâncias decisórias**

**Usuários**

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[Logo: Secretariat of Science, Technology and Strategic Inputs]

[Logo: Ministry of Health]
Role of SCTIE/MS

- **DECIIS**
  - Incentives for National Production

- **SCTIE**
  - DECIT
  - Production of ATS Studies

- **HTA Studies**

- **Industrial Production**

- **Decision-making**

- **CITEC**
  - Recommendation For Adoption
Flow for the Incorporation of Technologies in SUS

Petitioner: submits request for incorporation to the MoH

Petitioner: provides information (scientific evidence + economic evaluation) about the technology

Technical area: issues appraisals regarding relevance and pertinence

DECIT/MoH: elaborates/supports HTA studies

CITEC: deliberates based on relevance to and impact on the SUS

MoH: decides on incorporation

CITEC: evaluates the information and takes appropriate steps
How HTA Studies Are Produced by the MoH?

- Workshop to promote interaction among professionals, policy makers and researchers
- Grants for researchers
- Mini HTAs from Decit professionals and external consultants
- Seminars
- Dissemination of HTA reports
- Discussions during the many research stages

DEFINE PRIORITIES

HTA PRODUCTION

PROMOTION OF EVIDENCE USAGE

EXTERNAL MONITORING OF RESEARCH EXECUTION
Demands According to Most Requested Topics (n) 2007-2009

Source: HTA/Department of Science and Technology (DECIT), 2007-2009
# HTA Studies by Type – 2004 to 2010

<table>
<thead>
<tr>
<th>Types</th>
<th>No.</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rapid Response Reports</td>
<td>168</td>
<td>34</td>
</tr>
<tr>
<td>Systematic Reviews</td>
<td>105</td>
<td>21</td>
</tr>
<tr>
<td>Rapid Reviews</td>
<td>91</td>
<td>19</td>
</tr>
<tr>
<td>Economic Evaluations</td>
<td>52</td>
<td>11</td>
</tr>
<tr>
<td>Technology Management</td>
<td>39</td>
<td>08</td>
</tr>
<tr>
<td>Budget Impact Analysis</td>
<td>5</td>
<td>01</td>
</tr>
<tr>
<td>Others</td>
<td>30</td>
<td>06</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td>490</td>
<td>100</td>
</tr>
</tbody>
</table>

US$ 12 million
## Examples of Technologies Adopted in SUS Supported by HTA Studies

<table>
<thead>
<tr>
<th>Health Field</th>
<th>Phototherapy (for patients with psoriasis)</th>
<th>Meningococcal Conjugate C Vaccine</th>
<th>Rituximab</th>
<th>Alteplase</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dermatology</td>
<td>Vaccines</td>
<td>Oncology</td>
<td>Neurology</td>
<td>Neurology</td>
</tr>
<tr>
<td>Indication</td>
<td>Treatment of Chronic Inflammatory Dermatosis</td>
<td>Meningococcal Diseases</td>
<td>Treatment of Diffuse Large B Cell Non-Hodgkin’s Lymphoma</td>
<td>Treatment of Ischemic Cerebral Hemorrhage</td>
</tr>
<tr>
<td>Year of demand</td>
<td>2009</td>
<td>2009</td>
<td>2007</td>
<td>2005</td>
</tr>
<tr>
<td>Applicant</td>
<td>Brazilian Society of Dermatology</td>
<td>Ezequiel Dias Foundation (FUNED)</td>
<td>Roche Pharmaceutical Company</td>
<td>UNIFESP + Boehringer Ingelheim</td>
</tr>
<tr>
<td>Date of adoption</td>
<td>08/02/2010</td>
<td>04/05/2010</td>
<td>12/07/2010</td>
<td>12/07/2010</td>
</tr>
</tbody>
</table>
REBRATS aims to produce and to disseminate priority research and studies in the HTA field, to standardize methodologies, to validate the quality of studies, and to train human resources.

Its activities also include horizon scanning and the monitoring of new educational perspectives in HTA.

All of these measures facilitate the incorporation or exclusion of technologies and assist in the decision-making process when considering whether or not to maintain existing technologies.

The network (44 members) consists of governmental, educational and research institutions, as well as including members from different sectors of society.

Source: Base document www.saude.gov.br/rebrats - Portuguese
REBRATS: Results After Two Years of Operation

• **Elaborating Guidelines:**
  - HTA Appraisals (Rapid Reviews)
  - Economic Evaluations (2009)
  - Systematic Reviews (in elaboration phase)
  - Budget Impact Analysis (DECIT, Anvisa and IATS - in elaboration phase)
  - Methodology for Horizon Scanning;

• **Implementation of 24 HTA Centers in teaching hospitals – 2009**

• **Electronic platform permitting access to abstracts of HTA studies**
HTA Centers (NATS) in Teaching Hospitals (n=24)
International Cooperation

MERCOSUR

INAHTA

HTAi
Some Challenges For The Future

- Overlap of roles and activities in the whole process
- Sustainability and autonomy of REBRATS and NATs
- Continuing education and professional training
- Extend HTA to policy makers at local and state levels
- Establish early warning of new and emerging healthcare technologies in Brazil
- Share research networks and define the areas that are strategic to improving the quality of healthcare
- Expand/integrate HTA activities to the private healthcare system
- Promote the creation of innovations that meet the needs and priorities of the healthcare policy
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