DESAFIOS NOS SISTEMAS DE SAÚDE DA AMÉRICA LATINA: QUais evidências de mundo real são necessárias para estimar valor de equipamentos médico-assistenciais e testes diagnósticos em um processo de avaliação de tecnologias em saúde?

Cristina Nunes, Pharm MBA
Head Health Economics & Market Access LATAM
Edwards Lifescience

Topics

Medical devices challenges
Value Assessment
Conclusion
Topics

- Medical devices challenges
- Value Assessment
- Conclusion

Medical Devices barriers is it?
## Devices versus Drugs

<table>
<thead>
<tr>
<th></th>
<th>Medical Devices</th>
<th>Drugs</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Properties</strong></td>
<td>Physical</td>
<td>Chemistry</td>
</tr>
<tr>
<td><strong>Complications</strong></td>
<td>Decrease with use</td>
<td>Increase with use</td>
</tr>
<tr>
<td><strong>Life cycle</strong></td>
<td>Rapid release</td>
<td>Long release</td>
</tr>
<tr>
<td><strong>Feasibility of blinding or Placebo control</strong></td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Investment in training</strong></td>
<td>High</td>
<td>Low</td>
</tr>
<tr>
<td><strong>Cost</strong></td>
<td>High expenses</td>
<td>Risk concentrated in pre-Market</td>
</tr>
<tr>
<td><strong>Adherence</strong></td>
<td>Alto</td>
<td>Variable</td>
</tr>
<tr>
<td><strong>Size of patient Population</strong></td>
<td>Low</td>
<td>High</td>
</tr>
<tr>
<td><strong>Realized patient protection</strong></td>
<td>Low</td>
<td>High</td>
</tr>
</tbody>
</table>

Source: Adapted from Klie Leidy et al and from Faulner et al

## The Devices results depend on....

- **Correct indication**
- **Physician / Hospital**
  - Operator skill and Experience level
- **Product Quality**
  - Impacto material

Results effects
Evaluate only the prices

Topics

- Medical devices challenges
- Value Assessment
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1. **STEP**

**Stakeholders often have different, interests and incentives**

- Integrate viewpoints of patients, providers and others before decisions are finalized

<table>
<thead>
<tr>
<th>Payers: historically, want the least the expensive product that “fixes” the basic problem</th>
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<tbody>
<tr>
<td>Physicians: want to be the first to try a new technology</td>
</tr>
<tr>
<td>Patients: generally accept what the physician or payer deems appropriate</td>
</tr>
</tbody>
</table>

- Understand that devices often can be part of sophisticated patient care processes where operator expertise and the care setting can influence outcomes as much as the technology itself

2. **Step**

**Evaluate Epidemiological data...**

- Be creative generate parallel research on external data sources
- Encourage protocol development: “right solution, right patient”
- Same patient characteristics?
  - Same implant local?
  - Operator learning curve?
- Same regulatory submission?
  - FDA / CE / ANVISA / INVIMA / COFEPRIS...
- Size patient number?
  - 80 VS 1,000
3. Step
RWE and other data partnerships are creating new opportunities for value demonstration across lifecycle.

4. Step
Evidences impact in costs....

- Cost assessment should include both costs incurred and those averted.
Summarize

- May shorten the time of a medical device evaluation
- May allow for the design of clinical trials that may produce required outcomes for coverage determinations as RWD
- Increase differentiation in the market
- Evaluation Clinical trial the methods and evidences level
Goals happen when we work together