An Overview of Changes in Managing Innovations

Geneviève Plamondon, M.Sc.
genevieve.plamondon@inesss.qc.ca
An Overview of Changes in Managing Innovations

A few definitions

Innovation

- The result of a process of translating an idea or invention into a good or service that has *value*.
- To be called an innovation, an idea must be replicable at an economical cost and must satisfy a specific need. Innovation includes all processes by which new ideas are generated and converted into useful products.  
  [Picard R. *et al.*, 2015], [Business dictionary].

Pertinent innovation

- An appropriate response to a well defined need. Pertinent innovations must provide an incontestable solution for all stakeholders.  
  [Brunet F. *et al.*, 2015].
An Overview of Changes in Managing Innovations

A few definitions

Value

“Value should always be defined around the customer, and in a well-functioning health care system, the creation of value for patients should determine the rewards for all other actors in the system. Since value depends on results, not inputs, value in health care is measured by the outcomes achieved, not the volume of services delivered, and shifting focus from volume to value is a central challenge. Nor is value measured by the process of care used; process measurement and improvement are important tactics but are no substitutes for measuring outcomes and costs.”

Source: Michael E. Porter, Ph.D.
An Overview of Changes in Managing Innovations

THE TRIPLE “E” OF HTA*

Efficacy
Does it work in clinical trials?

Effectiveness
Does it work in clinical practice?

Efficiency
Does it contribute to more efficient use of resources?

* Source: Dr. Leeza Osipenko Senior Scientific Adviser, NICE

Abbreviation: HTA: Health technology assessment
An Overview of Changes in Managing Innovations

Challenges, Issues, Effervescence

- Significant transformation of the health system
- Many technological developments, very short life cycle
- Natural tendency to want to accelerate the innovation process
  - rapid transition from idea to implementation derailing the demonstration of proof of value
  - and/or quick transition to adoption without considering the challenges of implementation
- Classic HTA model often caught in a “too early, too late” syndrome
- Integration of innovative technologies via multiple sources
  - no formal evaluation process for non-pharmaceutical technologies
- Perception of delayed patient access to promising and effective innovative technologies

Abbreviation: HTA: Health technology assessment
An Overview of Changes in Managing Innovations

Current process for evaluating non pharmaceutical health technologies

- **Health Canada** → **Marketing authorization**
- **Non-standardized process**
  - **Designed case by case**
  - **Evaluation by INESSS**
  - **Evaluation by a UETMIS**
  - **No formal evaluation**
- **Patient access/network**

**Institutions**

Abbreviation: CSEMI: Comité scientifique d’évaluation des médicaments aux fins d’inscription, RAMQ: Régie d’assurance maladie du Québec, RGAM: Régime général d’assurance médicaments, SEVAB: Service d’évaluation des analyses biologiques
An Overview of Changes in Managing Innovations

Proposed process for evaluating innovative health technologies

MANUFACTURER

Health Canada

Marketing authorization

Leading-edge or disruptive technologies

Prioritization

INESSS POÉTIS:
- Integration without reserve
- Evaluation in the real context of care
- Conditional integration
- Refusal

Minister MSSS Agreements / Decision

INSTITUTIONS Decision

WHEN RELEVANT
- Post implementation surveillance
- Real world evidence
- Optimal use

Patient access / network (before)

Patient access / network (after)
An Overview of Changes in Managing Innovations

- Optimized process for evaluating innovative health technologies

1. Phase of research and development
2. Pre implementation phase
3. Limited implementation phase
4. Post implementation phase
An Overview of Changes in Managing Innovations

- Optimized process for evaluating innovative health technologies

### Phase of research and development

1. **Evaluation of value proposal**
   - Early dialogue between stakeholders

### VALUE PROPOSAL

What is the expected *added* value of the technology to patients and the health system, and what conditions are needed for this value to be verified?
- Added value/promise
- Alignment with patient/system needs
- Plausibility

### EARLY DIALOGUE

- Identification of all relevant stakeholders
- Anticipation of implementation challenges
- Anticipation of evaluation criteria

Evaluation of the potential for impact and implementation
An Overview of Changes in Managing Innovations

Optimized process for evaluating innovative health technologies

- Evaluation of value proposal
- Early dialogue between stakeholders

Phase of research and development

Pre implementation phase

- Evaluation of value proposal
- Dialogue between stakeholders

VALUE PROPOSAL
The value proposal is based on more robust data.

EARLY DIALOGUE
Relevant stakeholders should all be identified and means should be in place to address the implementation challenges

Recommendations for implementation:
- Implementation without reserve
- Evaluation in the real context of care
- Conditional integration
- Refusal
An Overview of Changes in Managing Innovations

- Optimized process for evaluating innovative health technologies

1. Phase of research and development
   - Evaluation of value proposal
   - Early dialogue between stakeholders

2. Pre implementation phase
   - Evaluation of value proposal
   - Dialogue between stakeholders

3. Limited implementation phase
   - Development of contextualized evidence
     - Collaboration between stakeholders
     - Capture of issues related to implementation

Recommendations about large scale implementation using contextualized real world evidence
An Overview of Changes in Managing Innovations

- Optimized process for evaluating innovative health technologies

- Phase of research and development
  - Evaluation of value proposal
  - Early dialogue between stakeholders

- Pre implementation phase
  - Evaluation of value proposal
  - Dialogue between stakeholders

- Post implementation phase
  - Real world evidence
  - Capture long term effects and population variations

- Limited implementation phase
  - Development of contextualized evidence
  - Capture of issues related to implementation

Techno vigilance

Evaluation of real benefit and optimal use

* Source: Real-World Evidence Studies: Methodology Options for Optimal Research Oct 12, 2015 Mark Cziraky, Michael Pollock
An Overview of Changes in Managing Innovations

- Evaluation in pace with the innovation process

<table>
<thead>
<tr>
<th>Time</th>
<th>Utilization</th>
</tr>
</thead>
<tbody>
<tr>
<td>Research and development</td>
<td>Pre implementation</td>
</tr>
</tbody>
</table>

- Evaluation of value proposal and early dialogue
- Evaluation in the real context of care
- Evaluation of large scale benefit and optimal use
- Evaluation of obsolete technologies

Source: Adapted from the life cycle of innovative technologies, Forum évaluation et technologies innovantes (ETI)_guide_du_participant, prepared by INESSS, 2013;
Abbreviation: HTA: Health technology assessment.
An Overview of Changes in Managing Innovations

- Formalization and systematization of a rigorous evaluation process for innovative health technologies in line with the innovation process

- Risk mitigation for:
  - the patients
  - the health system
  - other actors...

Research and development

Pre implementation

Limited implementation

Post-implementation

Uncertainty is inherent to technological innovation
Thank you