Bringing HTA and Commercialization Closer

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Center For the Advancement of Health Innovations
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Why would we want to?

• Reconcile the apparent tension between public interest of creating health and the private interest of creating wealth

• Health system demands effective interventions
  – Clinically
  – Economically

• Identify how we mobilize a way forward

“In the eyes of dialectical philosophy, nothing is established for all times, nothing is absolute or sacred.”

Karl Marx
Objectives

• Define our terms
• Describe why and how the means and ends of HTA and commercialization are confluent, in fact, they are symbiotic
• Describe why and how the two must work closer together
The perfection of means and the confusion of ends seems to be our problem.

Albert Einstein
Commercialization

..... The development segment of the R & D spectrum requires time and money as systems are engineered that will make the product or method a paying commercial proposition...

**NOT TO BE CONFUSED WITH MARKETING OR SALES**

- It is essential to look at many ideas to get one or two products or businesses that can be sustained long-term.
- It is a stage-wise process, and each stage has its own key goals and milestones.
- It is vital to involve key stakeholders early, including customers
Health Technology Assessment

• **Health technology assessment** is a multi-disciplinary field of policy analysis that studies the medical, social, ethical and economic implications of development, diffusion, and use of health technology.
  — INAHTA

• the systematic evaluation of the properties and effects of a health technology, addressing the direct and intended effects of this technology, as well as its indirect and unintended consequences, and aimed mainly at informed decision making regarding health technologies.
  — HTAi

• A multidisciplinary process that summarises information about the medical, social, economic and ethical issues related to the use of a health technology in a **systematic, transparent, unbiased, robust** manner. Its aim is to inform the formulation of safe, effective, health policies that are **patient focused and seek to achieve best value**. Despite its policy goals, must always be firmly rooted in research and the scientific method.
  — EUnetHTA
Putt’s Law

- Technology is dominated by two types of people: those who understand what they do not manage and those who manage what they do not understand
  – Putt’s Law

- "Every technical hierarchy, in time, develops a competence inversion."[3] with incompetence being "flushed out of the lower levels" of a technocratic hierarchy, ensuring that technically competent people remain directly in charge of the actual technology while those without technical competence move into management.
  – Putt's Corollary
HTA and Diffusion of Health Technologies

Use

Time

Research and Development

Experimental Technology

Innovative Technology

General Use

Obsolescence/Replacement

Innovation

Disinvestment

Medical Device Licensing

HTA

HTA

HTA

Obsolescence
Certainty of Evidence and Effectiveness

2. Reassessment

Evidence certain
Not effective

Ineffective
technology

Evidence certain
Effective

Technology to be adopted

3. Access with Evidence Development

Uncertain evidence
Not effective

Promising technology

Uncertain evidence
Effective

4. Innovation

5. Education & Dissemination

1. Assessment & Appraisal
Traditionally HTA and Technology commercialization processes have had competing objectives

**Health Technology Assessment**
- Deliberate and evidenced-based
- Rigorous evaluation of evidence to ensure effectiveness and cost-effectiveness
- Risk averse process to ensure opportunity costs are surpassed

**Technology Commercialization**
- Rapid and market driven
- Decision-making dependent of extending market share and generating shareholder value
- Risk tolerant process to ensure profits are generated
Two central challenges in health technology adoption

Resource scarcity

Health care systems are characterized by a limited supply of resources. Therefore, provision of care is constrained by available budgets.
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Due to misalignment of objectives, successful technology adoption occurs haphazardly when offering matches need. Can this degree of alignment be improved?
HTA and the Health Technology Commercialization process

Buy Side

- HTA
- Public Institutions
- Societal Perspective
- Opportunity Cost
- Expected Gain > Benefit Foregone

Sell Side

- Commercialization
- Private companies
- Shareholder Perspective
- Return on Investment
- Projected revenue > Projected Expenses

DCF

ICER
Integration of HTA into the Technology Commercialization process can improve alignment between health systems and companies, facilitating permeation of new products into health systems.

Mechanism

Product Development Uncertainty

Product Adoption time lag
Can HTA improve the Health Technology Commercialization process?

High Uncertainty associated with Technology Development:


The researchers identified 3 purposes for conducting this evaluation:

1. To manage expectations surrounding innovation
2. Allow benchmarking within organizations to external comparators
3. Allow calculation of future expected benefit from investing in innovation

Commercial success was defined as an innovation that provided an economic benefit to the organization. Specifically, “the money returned is greater than all the money invested in creating that product.”
INNOVATION FUNNEL

IDEATE  DEFINE  DESIGN  DEVELOP

YOU ARE HERE

TOM FISHER BURNE
marketoonist.com
Can HTA improve the Health Technology Commercialization process?

- Raw Ideas (3000)
  - No patent disclosure (2700)
    - (0.90)
  - Patent Disclosure (300)
    - (0.10)
    - Patent Application (150)
      - (0.50)
      - Patent Issued (112)
        - (0.75)
        - Patent w/ value (9)
          - (0.08)
          - Not Crown jewel patent (8)
            - (0.89)
            - Crown Jewel patents (1)
              - (0.11)
      - No Patent Issued (38)
        - (0.25)
        - Patent w/ no value (103)
          - (0.92)
          - (0.0375)
        - (0.0345)
    - (0.50)
  - No Patent Application (150)
    - (0.25)
    - (0.05)
- (0.90)
Can HTA improve the Health Technology Commercialization process?

**Implications for Commercialization**

- The mortality rate of innovation at the raw idea stage is very high (The probability of failure is 99.75%).

- Patent protection does not appear to improve probability of success (with a patent the probability of failure drops to 96.55%).

- The low probability of success results in low expected values for novel medical technologies.

- Low expected values coupled with high R&D costs can promote high pricing strategies from developers to offset the losses from commercially unsuccessful innovations.

- High pricing strategies can result in reduced cost-effectiveness impeding adoption and reimbursement from health systems.
Can HTA improve the Health Technology Commercialization process?

Medical Device Development Life Cycle\(^1\): 

- **Discovery**
- **Prototype**
- **Pre-Clinical**
- **Clinical**
- **Regulatory**
- **Product Launch**
- **Post-market**

**Time:** 2 - 3 years\(^2\)
**Cost:** $10 – $20 Million (US)\(^2\)

**Time:** 3 - 5 years\(^2\)
**Cost:** $10 – $12 Million (US)\(^2\)

Period to Product Launch 5 – 10 Years

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1) Adopted from the FDA - http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHInnovation/ucm242067.htm
Can HTA improve the Health Technology Commercialization process?

Medical Device Adoption Curve (Rogers’ Diffusion Curve):

- Innovators: 2.5%
- Early Adopters: 13.5%
- Early Majority: 34%
- Late Majority: 34%
- Laggards: 16%
Can HTA improve the Health Technology Commercialization process?

Medical Device Adoption Curve (Rogers’ Diffusion Curve):

- **Innovators**: 2.5%
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- **Late Majority**: 34%
- **Laggards**: 16%

Period to full adoption = 15 years
Can HTA improve the Health Technology Commercialization process?

Implications for Commercialization

- Medical technologies have a long development time (5 – 8 years of development prior to product launch).
- Once a product has been launched an additional 10-15 years may be required to achieve full market penetration and product adoption.
- Product development requires a significant initial investment (i.e., $10-15 million) to achieve milestones. However, peak revenues may only be achieved 15 - 20 years after initial investment. This can produce downward pressure on the Net Present Value (NPV) of a medical technology.
- Consequently, the high cost and opportunity cost of medical technology development requires that innovators are very selective in differentiating potential winners from losers early in the development process.
Can HTA improve the Health Technology Commercialization process?

Key Lessons for Commercialization

1) Medical technology development includes a significant amount of uncertainty and very few technologies are successful

2) Medical Technology is costly to develop and takes a long time to get to market

Developer strategy:

Establish high pricing strategies for successful technologies to offset R&D losses from unsuccessful technologies

Consequence of strategy:

Increasing prices place a premium on innovation to health systems. Increasing prices reduces cost-effectiveness of technology and increases opportunity costs.
Can HTA improve the Health Technology Commercialization process?

**Solution:** Integrate HTA early into product development process

Conventional Health Technology Development Process:

- Discovery
- Prototype
- Pre-Clinical
- Clinical
- Regulatory
- **Product Launch**
- Post-market
Can HTA improve the Health Technology Commercialization process?

**Solution:** Integrate HTA early into product development process
Can HTA improve the Health Technology Commercialization process?

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Can HTA improve the Health Technology Commercialization process?

Discovery | HTA | Prototype | Pre-Clinical | Clinical | Regulatory | Product Launch

Step 1:
Systematic Review of the literature

Step 2:
Conduct a Cost-Effectiveness Analysis

Post-market
Implications for decision-making and resource allocation

- All decisions to adopt new health technologies occur within a fixed budget context.
- Given this fixed budget, the sustainability of health care systems requires increasingly more effective outcomes achieved per dollar invested.
- That is, resources should be allocated to interventions where the clinical benefit achieved from adopting a novel intervention is greater than the opportunity cost from removing existing practices.
When the times were a-changing

How the pharmaceutical world is evolving
Feb 15th 2014 | From the print edition

Shooting for the moon


“MEDICINE is for people, not for profits.” So read the caption beneath a photograph of George Merck, boss of a huge American drug company, on the cover of Time magazine in 1952. Of course the choice was a false one, as Merck himself admitted in Time’s article. His company, by devoting itself to making medicines that helped patients, made money too. After the second world war Merck & Co and other big pharmaceutical companies began a golden age in drug development, producing better antibiotics, vaccines and other treatments that transformed patients’ lives.
Invent it, swap it or buy it

Why constant dealmaking among drugmakers is inevitable
Nov 15th 2014 | From the print edition

FEW industries have been shaped more by mergers and takeovers than pharmaceuticals. This is because developing drugs is such a high-risk business. Most potential medicines either fail to reach the market, or fail thereafter to recoup the cost of developing them. If a company does not have enough promising drugs in its research pipeline, its most obvious route to growth is to buy another firm. So, many of the world’s biggest drugmakers, such as Pfizer, Merck and GlaxoSmithKline (GSK), have been built through a succession of deals.

However, something has changed in the nature of drug firms’ dealmaking over the years. It used to be all about achieving sheer scale, and building a broad portfolio of potential treatments for a range of illnesses. Now it is increasingly about drug companies concentrating on what they do best, and getting out of areas in which they are weak. There is evidence that this is a better route to success. A study by Bain & Company, a consulting firm, of the most successful pharma companies over the past 20 years found that the top ten, in terms of shareholder returns, all to some degree used mergers and
Values Surrounding Commercialization: Conflicted or Confluent?

- Patients
- Clinical Settings
- Academia
- Government
- Industry

Health & Wealth
Where Does Innovation Flourish?

Adapted from Steven Johnson
Where Good Ideas Come From 2010

Non-Market/State
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What Lessons Are Relevant To Commercialization and HTA

- Networks and commerce ascendant
- Creative insights of group(s) enrich
- Market incentives matter but not dominant
- Collective invention more efficient than protected
- Open platforms catalyze
- Academia emergent and free flowing
- Creates the adjacent possible
The Adjacent Possible

• The adjacent possible is a kind of shadow future, hovering on the edges of the present state of things, a map of all the ways in which the present can reinvent itself. ...it... captures both the limits and the creative potential of change and innovation... the strange and beautiful truth about the adjacent possible is that its boundaries grow as you explore them. Each new combination opens up the possibility of other new combinations.
  • Steven Johnson
How is the HTA community responding?

“How HTAi should not become instrumentalised for market access issues (helping to ease the pathways to the market) and selling industry politics; instead HTAi should serve [as a place] for honestly discussing appropriate methods for assessing medical technologies, but also overtreatment, over diagnosis and waste of limited health resources. HTAi is an instrument to distinguish between true innovations and me-too, unsafe and unnecessary care.”

BMJ 2014; 349:g5858 doi: 10.1136/bmj.g5850 (Published 24 September 2014
http://www.htai.org/index.php?id=787

HTAi Policy Forum – is exploring adaptive approaches to decision making along with the potential for aligning HTA evidence requirements with those of related decision making processes, particularly licensing.

Carole’s President’s Diary October 2014
Adaptive Approaches to licensing and reimbursement

- Coverage with evidence development or access with evidence development, and managed entry

- Sharing risk between payer and provider by leasing health technologies
  - Richard Edlin, Peter Hall, Elemens Wallner, Christopher McCabe, Value in Health 17 (2014)

- MaRS EXCITE

- Breakthrough designation, Fast track approval

- MIT NEWDIGS
  - [http://cbi.mit.edu/research-overview/newdigshomepage/](http://cbi.mit.edu/research-overview/newdigshomepage/)
MaRS EXCITE

- EXCITE addresses the two largest hurdles in a technology’s path to market: **regulation and reimbursement.** The EXCITE process, which includes feedback from the health system, provides value beyond standard safety and efficacy evaluations.
Strategic Clinical Networks as one approach

Alberta Health Services

- One health care delivery system for an entire Province
- The ‘third way’ in Canada
- Largest health care system in Canada- 3.7 million people
- Budget $12B, 100,000 employees, 7500 doctors
- Formed in 2008, 5 Zones added in 2010, Networks in 2012
- Nine clinical networks launched to date
- Up to six more planned
- We aspire to being the best in Canada
Central Strategy for SCNs

recycling the waste to fund improvements: PRIHS Program

**STEP 1**: Identify Waste
- real dollars to be saved -

**STEP 2**: Project(s) to Eliminate Waste

**STEP 3**: Strategies to Reinvest in Sustainable Improvements

**STEP 4**: Projects to Improve Sustainable Quality + Health

Research and Innovation Supports Whole Cycle
Partnership for Research and Innovation in the Health System (PRIHS I and II)

- **Partnership** between AIHS + AHS + OTHERS (TBD)

- Supports research and innovation aligned with SCNs that target **high impact activities** associated with any part of the continuum of care: primary, community and/or specialty care – to eliminate waste/improve care.

- Must demonstrate **evidence of value for money combined with quality improvements** in AHS

**Level of Funding**: Up to a maximum of $250,000/year

**Term**: Up to 3 years, non-renewable
Improved Outcomes in Health & Wealth

• “One of the great mistakes is to judge policies and programs by their intentions rather than their results.”
  — Milton Friedman
I hope that I have convinced you

- HTA and Commercialization can have a symbiotic relationship
- It can inform and expedite prudent investment, create wealth and improve health
- Provide you with some means to advance the discourse and take action
Acknowledgements

• Ulrich Wolfaardt AHS
• Reg Joseph AIHS