Aligning Regulatory + HTA Non-Drug Technologies, Local Perspective

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How can we realize our full potential?

Regulatory + HTA + Decision-Maker interaction
Regulatory – HTA Interactions

I. The Present
II. The Future
III. How to get There
Health Technology is Changing Health Care

- Exoskeletons
- Ingestible sensors
- 3D printed organs
- 3D printed drugs
- Physiologic simulation
- Self-regulating artificial heart
- Tissue regeneration
- Synthetic blood
- Neuroprosthetics
- Myoelectric prosthesis
- Auditory vision substitution
- Hybrid assisted limbs
- Epidermal sensors
- Non-invasive glucose sensors
- Rapid gene sequencing
- Open health records
- Question answering computing systems
- App-driven diagnostics
- Stem-cell treatments
- Prenatal gene mapping
- Personal medicine
- 3D-printed drugs
Doctors replace 75 percent of patient’s skull with 3-D-printed polymer implant

Oxford Performance Materials, a Connecticut-based company, analyzed an unidentified American patient’s head, then printed out a 3-D object, layer by layer.

BY CAROL KURUVILLA / NEW YORK DAILY NEWS / Saturday, March 9, 2013, 5:38 PM

Printed from stem cells
Meet Rex (Artificial Man)
The “lost in translation” problem

0.8 x 0.8 x 0.8 x 0.8 = 33%
Techno Hype Cycle

- Peak of Inflated Expectations
- Plateau of Productivity
- Slope of Enlightenment
- Trough of Disillusionment

Axes:
- Visibility
- Technology Trigger
- Time
Dark side
Top 10 Technology Hazards

www.ecri.org/hazards

• Alarm hazards
• Infusion pump medication errors
• CT radiation exposure in pediatric patients
• Data integrity failures in EHRs and other health IT systems
• Occupational radiation hazards in hybrid ORs
• Inadequate reprocessing of endoscopes and surgical instruments
• Neglecting change management for networked devices and systems
• Risks to pediatric patients from “adult” technologies
• Robotic surgery complications due to insufficient training
• Retained devices and unretrieved fragments
Human Factors (Surprise Factor)
Survey: One third of wearable device owners stopped using them within six months

By: Aditi Pai | Apr 3, 2014

A third of consumers who own a wearable device stopped using it within six months, according to consulting firm Endeavour Partners’ September 2013 survey of 500 adults. Additionally, more than half of consumers who own one no longer use it.

The researchers received responses from 6,223 consumers in the United States about whether they owned a “modern activity tracker”, which they described as devices similar to Jawbone, Fitbit, Nike, and Misfit Wearables. And of those, 500 responded that they did own such a device. The age group with the largest percentage of activity trackers owners is the 25-to 34-year-old range (25 percent). After that, 35- to 44-year-olds made up 19 percent of the wearable owning population. Parents, more specifically, are less inclined to own wearable devices; only 10 percent of the age group with children own these devices.
Wearable Devices: Helpful Health Tools or Privacy Nightmare?

Taylor Shechet — March 26, 2014 — Leave a comment
Drugs≠Devices
TECHNO LIFE CYCLE: COMPLEXITY onto COMPLEXITY

ACQUISITION COSTS
Only the *Tip of the iceberg*

**Acquisition Costs ~ 20%**
- Technology Purchase Price
- Shipping
- Installation

**Life Cycle Costs ~ 80%**
- Staffing & Training
- Maintenance
- Consumables & Utilities
- Upgrades
- Software Licenses
- Financing
- Compliance
- Quality Assurance
- De-Installation & Disposal
Many Hurdles from Conception to Innovation

Health Canada
(Drugs & Devices Licensed for Market)

Drugs

Devices & Machines

Procedures

Canadian HTA Agency (CADTH)
Advice on New Drugs from CDEC (non-binding for hosp)

Ontario MOH
Drug Committee (CED)

Ontario MOH
HTA Committee (OHTAC)

Ontario Hospitals
Technology Enters Hospital BEFORE Market
“Local HTA” + “arms-length HTA” + Regulatory Assessment

- Evidence-based (can it work?)
- Reality-based (does it work?)
- Local data about tradeoffs (is it worth it?)
- Collaborative (together with end-users)
- Contextualized (real questions, not theoretical)
- Fast-paced, in “decision-making time”
- Accountable to “predictions” (did it work?)
- Decision impact is “felt” very quickly (measureable opportunity costs)
# Regulatory Assessment vs HTA

## Key Questions

<table>
<thead>
<tr>
<th>Key Questions</th>
<th>Published Evidence</th>
<th>Contextualized Evidence</th>
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<tbody>
<tr>
<td>Can it work</td>
<td>...in the ideal setting?</td>
<td>...here?</td>
</tr>
<tr>
<td>Does it work</td>
<td>...in real world settings?</td>
<td>...here?</td>
</tr>
<tr>
<td>Is it worth it</td>
<td>...for whom?</td>
<td>...here?</td>
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</table>
It’s always too soon, until it’s too late!

Buxton’s Law
What Decision-Makers Want

What Decision-Makers Want and What They Have Been Getting

Maurice McGregor, MD
McGill University Health Center, Royal Victoria Hospital, Montréal, QC, Canada

Introduction

I believe we would all agree that the only reason we produce health technology assessments (HTAs) is to inform health policy decisions, and when they fail to do so they are a waste of time and effort. Nevertheless, at the present time it seems that HTAs often have little impact [1–4]. My first objective will be to consider some of the factors that cause HTAs to fail to influence policy. My second will be to report on an ongoing required to follow them. North America is probably too big and regional differences too great for such a solution to be accepted. So we must consider the other option. We must ask why many HTAs lack impact and what we can do about it.

Why Some HTAs May Lack Impact

For HTAs to have impact, they must first of all be understood and be acceptable to those who use them.
Contextualized Evidence throughout the Lifecycle

All Hands on Deck
Regulators + HTA Agencies + Decision-Makers
Contextualized HTA

- B:R
- Evidence Synthesis
- Cost-effectiveness
- SLEEPERs
- Opportunity Cost

KnowGo
What is a SLEEPER?

- Social
- Legal
- Ethical
- Environmental
- Political
- Entrepreneurial-Research-Innov’n
- ‘Stickiness’
Now | Future
Case: TAVI (Investment)
A Tradeoff Between Stroke And Death

“For every 100 patients treated with TAVI instead of medical mgt, there will be 20 additional survivors at 1 year - but at a cost of 6 more stroke/TIAs ...”

↑ 6 strokes/TIAs  
↓ 20 deaths  
↑ 33 symptom-free survival  

↓ 6 stroke/TIA  
↑ 20 deaths  
↓ 33 symptom-free survival  

TAVI  
MM (+/-BAV)
TAVI: Learning Curve & Death at 30d


Regression of Experience on Logit event rate

Within increasing experience, 30-day all-cause mortality declines (p=0.00016)
Imagine...

- Evaluate early
- Evaluate collaboratively
- With fit-for-purpose tools that adapt with time and act as canaries in the coalmine to see what is viable and what is not to take only the promising and worthy forward (utopia, you have arrived!
- Only then will we reach our full potential in technology-enabled health and healthcare
New Tools & New Processes

If not satisfactory comparative trials, then, we need new tools to inform earlier stages, NOT for premature decisions, but for appropriately partnered fostering of meaningful innovation and ‘in time’ redirection

- Coverage with Evidence Development (CED)
- Value of Information Analysis (VOI)
- Bayesian, iterative analysis
- Progressive licensing and decision-making
Demonstrated (EVIDENCE) + Undemonstrated (PROMISE) Value

• the “promise” of a technology and its likely value once fully developed and established in use, as well as current demonstrated
Collaborative + Iterative HTA that spans traditional boundaries

<table>
<thead>
<tr>
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<th>Can it work? (Efficacy)</th>
<th>Does it work? (Effectiveness)</th>
<th>Is it worth it? (Value)</th>
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</thead>
<tbody>
<tr>
<td>Evidence Generation</td>
<td>Clinical Trials</td>
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<tr>
<td>Evidence Synthesis (KS)</td>
<td>MA-SR</td>
<td>HTA &amp; CEA</td>
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<tr>
<td>Decision-Making (KT)</td>
<td>EBDM &amp; Health Policy</td>
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Aligning Evidence Expectations

• EUnetHTA, Green Park Collaborative and EXCiTE are attempting to align expectations and requirements around the core of value: the elements concerned with health outcomes for patients.

• accelerate, focus, and improve coordination of work in this area
Pro imbursement (risk share)

Rather than decision as one-off events (snapshots), treat them as ongoing processes aiming to provide greater certainty and increasing clarity on appropriate use (and price) as real-world evidence is collected and analyzed.

“Progressive health system decision making” of this kind could align well with thinking in the regulatory community on “progressive” or “adaptive” licensing, and build on existing approaches to managed entry or access with evidence development to create a system that better reflects the technology and evidence lifecycle.

Henshall. IJTAHC 2013;29(4)
Relevance to Decision-Makers in the Real World

“However excellent an HTA may be, if it fails to influence the working of the health care system, it is without impact and must be considered without value.”

Jacob A, McGregor M. Int J Health Technol Assess 2005
Waiting until technology enters the market is an inefficient model for “meaningful innovation”
Uptake is difficult. Disinvestment even more so

Breaking up is hard to do!
In Summary.

- Health Technology Assessment recommendations and reimbursement decisions to be made closer to the point of marketing authorisation.
- Traditionally, this has been assumed we will rely on evidence that has been developed mainly to suit regulatory agency needs.
- Instead of status quo, we need to align regulatory + HTA + decision-makers to improve the relevance of regulatory evidence for HTA and coverage decisions.
- Drugs and devices require different tools for assessment.

Iterative and collaborative HTA, where decision-making is a progression, and not a one-time event, and where new fit-for-purpose tools allow for improved timelines and estimates.
Time to Decide
MAKE NO BAD DECISIONS