An EXCITE-ing Process for Evaluating Medical Devices:
The Case of Glucose Sensors (CGM) for the Sensor Augmented Insulin Pump, Type 1 Diabetes (Ontario)

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Meet the Presenters

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Disclosures

The work presented today was conducted through the MaRS EXCITE initiative, with funding from Medtronic to cover research and knowledge translation costs.
Agenda

• EXCITE Process Overview

• Case Example: CGM in Type 1 Diabetes
  Key Ingredients to Successful Collaboration

• Potential Challenges in Collaborative Models

• Conclusions and Future Directions of EXCITE
The Adoption Problem
Why Don’t We Adopt Innovation Faster?

- medtech requires training
- procurement
- ownership structure of IP
- lack of competition
- innovators don’t know government priorities
- culture of government led direction
- clinical trial time
- culture of risk aversion
- limited funding opportunities for high cost trials
- innovators can’t navigate all players
- resistance to change in behaviour
- organization of health system
- reimbursement unavailable
- complex system
- heavy regulation
- death by pilot
- lack of insight into needs
- misalignment of evidentiary interests
Clinical Trial:
• Industry, Academia, CROs, Experts

Protocol focuses on regulatory approval

Industry Results

Regulator → Coverage HTA/ Comparative Effectiveness

Adoption

Rejection (50-95%)

Clinical Trial:
• Industry, Academia, CROs, Experts
• Protocol

Results

PROBLEMS WITH THE STATUS QUO:

Studies required **escalating costs & uncertainty**

Evidence polices **adoption**

Uncertainty how to **prioritize selection**

Innovators **moving to countries** with earlier adoption, hindering Ontario’s innovation economy
**EXCITE Overview**

- **Pre-adoption Partnership** formed November 2011 between government, HQO/OHTAC, the health system, regulators, academia, clinicians and industry in selection by the health system and protocol design by all.

- Streamlines path to adoption of disruptive technologies through a single harmonized process that meets regulatory and reimbursement requirements.

- Executed by 8 Methodology Centres working with 24 Research Hospitals and 30+ community health organizations.

- Evidence package is funded by industry.
Collaboration Partnerships in Action

Expert End-Users ➔ SELECTION ➔ Payers & Health Systems

Industry ➔ EVALUATION DESIGN ➔ Patients

Payers/Health Systems ➔ EVALUATION DESIGN ➔ Experts

Regulators ➔ EVALUATION DESIGN ➔ IMPLEMENTATION NAVIGATION & MARKET ACCESS ➔ EVIDENCE GENERATION
EXCITE Process Snapshot

01 APPLICATION PHASE

02 CONSULTATION & DESIGN PHASE

03 EVALUATION PHASE

04 ADOPTION PHASE
Value of EXCITE

Health Tech Companies
- Mitigated risk
- Access to payers, expert clinicians and scientific methodologists
- Exploration of conditions related to successful adoption
- Early socialization of technology
- Coordinated and harmonized

Payer/Health System
- Expedited access to world-class innovative technologies
- Upstream identification of breakthrough health technologies
- Early awareness of innovative technologies
- Articulate endpoints of relevance
- Active participant

Patients
- Timely access to impactful health technologies

Evidence Generators
- Reduced siloes between stakeholders
- Enhanced quality of data generation
- Provides pathway from research group to policymaker
The Case of Continuous Glucose Monitoring Sensors for SAP in Type 1 Diabetes, Ontario
Medtronic Continuous Glucose Monitor Sensors for SAP

Type 1 Diabetes

Glucose Sensors for Medtronic 630G Sensor Augmented Insulin Pump

Objective

- Generation of contextual evidence and information to support the funding decision
- Identify the barriers to adoption and diffusion

Key Results

- Budget Impact Analysis from the Ontario MOHLTC Perspective
- Consideration of the implementation model (patient training and ongoing technical support)
  - Eg. Adoption of 30% of T1D patients maximum at year 5

Outcomes

- EXCITE Management Board recommended consideration for adoption of technology by MOHLTC
- Contextual Evidence and Conditions of Adoption Report outlining implementation considerations
EXCITE is a compelling evaluation model for Medtronic, simply because there was no other channel for the company to bring this new technology to the attention of decision makers.

- Neil Fraser, President, Medtronic Canada
Consultation & Design Phase

Contextual Evidence Matters

- **Systemic Review:**
  Understand clinical benefits/harms

- **Qualitative Evaluation:**
  Role of CGM technology in T1D management and of current reimbursement practices for this device

- **Budget Impact Analysis:**
  Examine the costs of adding sensors to activate the LGS feature over a five year time period

- **Conditions of Adoption Report:**
  Key insights and findings & implementation considerations
Key Ingredients to Successful Collaboration

- Managing Expectations and Relationships
- Entering the Decision-arena Together
Evaluation Phase

Managing Expectations and Relationships

Open Communication
Transparency
Ongoing Dialogue
Entering the Decision Arena Together

Adoption Phase

- Harnessing Convening Power
- Coherent Synthesis of Results
- Incorporating Frontline Perspectives
OBJECTIVES

- Identify barriers and opportunities of uptake
- Understand key stakeholders that impact path to market
- Provide a proposed pathway for uptake should the EXCITE evidence bundle support recommendation

FORMAT

- 3 meetings held as a parallel process with evidence generation
EXCITE board members are composed of key stakeholders from across the health system. Together, these representatives from industry, government, health care providers, and research provide cover the spectrum of perspectives relevant to health technology commercialization and uptake.
Potential Challenges of Collaboration

**Defining the line**
- **Methodologists:**
  - Stakeholder involvement in the research process.
    - Holding firm while permitting opportunities for flexibility

- **EXCITE:**
  - Sharing information between stakeholder groups as the intermediary party
  - Connecting with policy/decision makers at the opportune time

- **Industry:**
  - Managing proprietary information

**Time Commitment**
- Meaningful collaboration takes time
Conclusions and Future Directions

- Collaborator Impressions of the EXCITE Process
- Vision and Future Direction of EXCITE
The EXCITE Difference
Parallel Process for Evidence Generation & Implementation Navigation

**EVALUATION DESIGN & EVIDENCE GENERATION**

1. Methodology Centre Match
2. Evaluation Design
3. EXCITE Management Board Approval
4. Evidence Generation
5. Evaluation Report
6. EXCITE Board Recommendation to MOHLTC for Adoption

**IMPLEMENTATION NAVIGATION**

1. Implementation Working Group
2. Implementation Planning Workshops
3. Infrastructure Planning
4. Conditions of Adoption Report Generation
5. MOHLTC receives report for their consideration

Technology prioritized by EXCITE Management Board
Inform
### EXCITE Process Evolution

#### Modular Service Offerings

<table>
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<tr>
<th>Technology Appraisal</th>
<th>Evaluation Design &amp; Evidence Generation</th>
<th>Implementation Navigation</th>
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<tr>
<td>✓ Application &amp; Intake ✓ Assessment ✓ Selection Decision</td>
<td>✓ Co-design of Trial &amp; Economic Evaluation ✓ Trial Execution ✓ Evidence Generation</td>
<td>✓ Identification of System Barriers &amp; Opportunities via Collaborative Working Groups</td>
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#### Players

- Ministry of Health (MOH)
- HTA Sub-Committee
- EXCITE
- MaRS Due Diligence
- MOH
- Industry
- EXCITE
- HTA-SC
- Scientific Collaborative
- Methodology Centre
- MOH
- Clinical Experts
- Industry
- EXCITE
- Key system stakeholders
- Methodology Centre

#### Outputs

- Notice of Selection
- Evaluation Report
- Market Access Report
- Evaluation Report
- Market Access Report
- Notice of Selection

- Clinical Evaluation
- Economic Analysis
- Systematic Review
- Human Factors Review
- Risks/Opportunities and value to the health system
- Market access plan with potential implementation pathways in Ontario
- An opportunity to present to the EXCITE Management Board
Questions

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