

WELCOME TO THE NEW THETA QUARTERLY

Editorial

Early HTA: What does it offer?

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The phrase “early HTA” describes efforts to bring HTA methods and processes to bear earlier in the product development cycle, to facilitate the design and adoption of more effective, cost effective and useful health innovations. There is growing interest in early HTA internationally, though it takes different forms in different contexts.

In Ontario, work in early HTA has been pioneered by the MaRS Excellence in Clinical Innovation and Technology Evaluation (EXCITE) initiative, led by Dr Les Levin. THETA is one of the methods centres involved with this initiative, and with Dr. Murray Krahn’s recent success in the Canada Foundation for Innovation New Initiatives Fund, THETA is positioned to establish the Centre for the Evaluation of Technological Innovation (CETI) and become a leading international methods and policy centre for early HTA.

Early HTA appeals to many players. Policy makers and practitioners seeking practical benefits, and researchers in search of methodological innovation, find much of interest. Because of the policy and values issues it raises, early HTA also has implications for the field as a whole.

Critical social science and humanities research has been especially influential in the development of “early” HTA approaches, thus the sub-field offers ways of expanding and enriching efforts to integrate these approaches. Further, because the practice of early HTA promises to expand and complicate the role of HTA as an instrument of public policy, developments in early HTA encourage more active attention to the sometimes-competing policy goals that HTA may serve.

Though the phrase “early HTA” is new, efforts to bring HTA thinking further “upstream” date from at least the mid-1980s.

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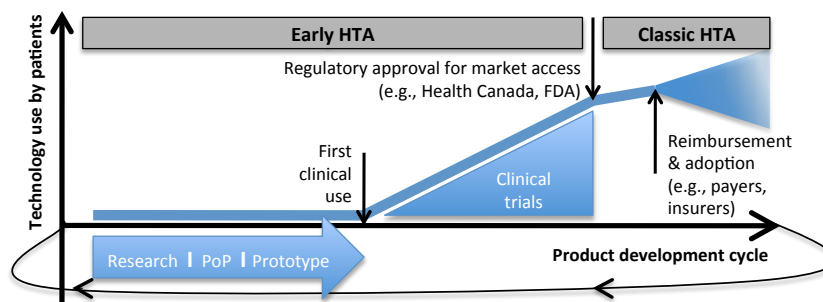
THETA EVENTS

4th Annual KT to Policy Day
6th Annual THETA Symposium
May 29 & 30 at Casa Loma

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Early HTA models offer potential to integrate social values into HTA processes while adding value for payers and technology developers

Illustration adapted from Ijzerman MJ, Steuten LMG. Early assessment of medical technologies to inform product development and market access. *Applied Health Economics & Health Policy* 2011;9(5):331-47.



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While many current early HTA efforts are being led by economists – who are advancing theory and methods in interesting and valuable ways – early efforts were led by critical social scientists, who used a “constructivist” approach to challenge assumptions about the static and manifest nature of technologies, the linear nature of innovation, and the appropriateness of the limited participation systems that dominate contemporary innovation policies and processes.

Researchers working within the tradition of “constructivist technology assessment” or “real time technology assessment” offer new ways of thinking about user and citizen engagement, and new strategies for interrogating the social values that become embedded within health technologies. This work reminds us that the goal of comprehensive technology assessment is not solely to identify and account for the ethical conundrums or social values conflicts that arise in the adoption of technologies, but to ask why they got there in the first place.

Early HTA brings still more philosophical questions into focus by seeking to serve two masters -

payers (governments) and developers (industry). No doubt, payers and developers may share important interests. Early HTA initiatives like the Green Park Collaborative, for example, seek to provide industry with greater clarity about the evidentiary requirements of payers. If clinical studies are designed to generate the evidence HTA groups need to justify collective payment, rather than just the evidentiary requirements of regulators who govern access to the market, the interests of all parties in timely and efficient technology assessment processes may be served.

Yet aligned interests between payers and developers, among developer groups (i.e., pharma, biotech, medical device), or among the groups for whom payers pay (ie, underserved diseases, big ticket diseases) cannot be assured. Early HTA can be a strategy for maximizing profit and market share, helping industry to rationalize “go/no-go” decisions and clarify disease or population targets. Payers may benefit from the efficiencies created, but may also find prices set at the maximum cost per QALY gained.

Early HTA can be a strategy for harnessing the demand side as a lever

for incenting health innovation. Yet payers may use this strategy in very different ways - to incent value (value based payment), to incent domestic innovation and local economic benefits, or to incent innovation that addresses the needs of underserved populations. In one form or other, these complex policy questions have always faced the health technology assessment enterprise, but early HTA makes them harder to ignore.

Early HTA has started to take root in Ontario, and THETA members are closely involved.

This May 29th, we'll be exploring some of the promises and challenges of early HTA at THETA's Annual Knowledge Translation to Policy day.

With international guests and local policy leaders and researchers in the emerging field of early HTA, we'll begin to address the complex and important questions introduced in Dr. Miller's editorial. Please see the back page for more details.

Cancer costs in B.C. and Ontario

Research Team: Murray Krahn, Jeff Hoch, Stuart Peacock, Claire de Oliveira, Karen Bremner, Kelvin Chan, Reka Pataky, Winson Cheung, Paulos Teckle, Mahbul Haq

THETA Collaborative and University Health Network (UHN) are undertaking a large-scale project that seeks to estimate the costs of cancer care for twenty-one cancer sites in British Columbia and Ontario using linked administrative health care data. In particular, researchers are examining the costs of chemotherapy, radiation therapy, hospitalization, same-day surgery, emergency room visits, physician services, outpatient drugs, diagnostic testing, home care, continuing care and long-term care, as well as mean total costs.

The objectives of this work are to estimate pre-diagnosis and first year post-diagnosis costs for each cancer site; understand temporal trends in patterns of care and costs for the first year post-diagnosis for a few cancer sites; and calculate net cancer costs by phase of case, 5-year costs and lifetime costs of cancer care. These estimates can help inform policy-makers' decisions regarding resource allocation for cancer prevention and control, and can serve as important inputs for economic evaluations.

In a recently published study in *CMAJ Open*, researchers provided estimate costs for the twenty-one most common cancers in Ontario in the three-month period before and the first year after diagnosis. In particular, researchers found that higher pre-diagnosis costs (> \$3000) were associated with liver and pancreatic cancers, and multiple myeloma, which are often diagnosed at an advanced stage or during hospital

admission. Among the patients who died within one year, cancers affecting mostly younger patients, such as testicular cancer and leukemia, and commonly treated more aggressively than other cancers, presented the highest costs. Among the patients who survived beyond one year, cancers with low five-year relative survival, such as esophageal and pancreatic cancers, and multiple myeloma, involved the highest post-diagnosis costs. The highest costs for both the pre- and post-diagnosis periods occurred among patients who died within one year after diagnosis and who had cancers with low survival rates.

Stroke Unit Care in Ontario

Research Team: Murray Krahn, Mark Bayley, Moira Kapral, Valeria Rac, Luciano Teraci, Gabrielle van der Velde, Ruth Hall, Linda Kelloway, Iris Fan

Every year in Ontario, 20,000 stroke patients go to the emergency department and 15,350 are admitted for in-hospital care. It has been reported that patients admitted to a stroke unit (SU) with organized inpatient stroke care and inpatient rehabilitation are more likely to survive. Furthermore, organized care in SUs and early supported discharge services have led to higher survival rates.

Our study objective will be to evaluate the cost-effectiveness of SU care in Ontario and the amount of comprehensive care patients receive. This study is the first of its kind in closely identifying and analyzing the characteristics and cost-effectiveness of currently structured Ontario SUs. This study will help to improve patient survival outcomes across SUs in Ontario. Currently, twenty-nine SU hospitals have been identified in Ontario. A portion of SU managers have already been interviewed, while REB approval is still pending for other locations.

Wound Interdisciplinary Teams (WIT)

Research Team: Murray Krahn, Anita Stern (left July 2012), Gina Trubiani (left June 2012), Valeria Rac, Kevin Woo, Shabbir Alibhai, Eva Haratsidis, Paul Grootendorst, Nicholas Mitsakakis, Mike Paulden, Ba Pham, David Urbach, Walter Wodchis, Merrick Zwarenstein, Josephine Wong

Chronic wounds have huge social and economic impact on both the individual and the healthcare system. Few clinical trials have explored the role of multidisciplinary wound care teams in the management of chronic wounds. In 2008, acting on the findings of a systematic review, the Ontario Health Technology Advisory Committee (OHTAC) recommended further research to evaluate the effectiveness of existing models of intermediate care for chronic wounds.

The purpose of this study is to evaluate the clinical effectiveness and cost effectiveness of systematic referral to specialized multidisciplinary wound care teams (MDWCTs) in conjunction with comprehensive primary care delivery (intervention) versus usual care (control) for the treatment of community-based clients with chronic wounds in the Greater Toronto Area. The study is a community-based 2-arm pragmatic randomized controlled trial. Participants were recruited from Toronto Central Community Care Access Centre. The target sample size is 450 and the primary outcome is the time to healing. Quantitative analysis will commence in June 2013. Currently, qualitative interviews of participants and clinicians are in progress.

Research Grants and Awards

Dr. Murray Krahn awarded Canada Foundation for Innovation funding to establish early HTA centre

Dr. Murray Krahn, Director of the Toronto Health Economics and Technology Assessment Collaborative (THETA), has been awarded a five-year, \$3-million grant by the Canada Foundation for Innovation (CFI) New Initiatives Fund.

One of the greatest challenges facing the Canadian healthcare system is sustainability in the face of increasing costs. Technology figures prominently in sustainability discussions. While technological innovations save lives and drive growth and employment, new technologies also contribute to the ever-increasing cost of healthcare. Similarly, the development of new, more effective drugs is expensive and requires a considerable investment of time without any guarantee that the drugs will ever come to market.

This CFI New Initiatives Fund award will allow Dr. Krahn to establish the Centre for the Evaluation of Technological Innovation (CETI).

The centre will be one of only a few in the world pioneering an early HTA model that simultaneously addresses innovation and healthcare system sustainability

CETI will draw together the University of Toronto's resources to become a leading international methods and policy centre for Early Health Technology Assessment.

Health Technology Assessment involves evaluating the clinical evidence, cost effectiveness, and broader social and ethical issues associated with technology. Early Health Technology Assessment is a new model in which scientists, payers, and innovators work together early in the development process to ensure that the clinical evidence will meet the needs of payers (e.g., Ministries of Health) and regulators (e.g., Health Canada) when new technologies and innovations are brought to market.

This new paradigm that Early Health Technology Assessment introduces – bringing the private sector and government together early in the development process – holds great promise for the future development of drugs and health technologies.

CETI will be distinctive in North America, and one of only a few centres in the world to pioneer a comprehensive model of Early HTA that addresses the twin challenges of innovation and sustainability.

Working with both the private sector and the government earlier in the development process, CETI will bring drug and non-drug technologies to market faster.

This type of collaboration will ultimately lead to an improved



Dr. Murray Krahn, Director of THETA

pipeline, shaping how products and innovations get into the system, become licensed, and are eventually purchased and incorporated into the healthcare system. By working with the pharmaceutical industry early in the development process, CETI will identify product shortcomings sooner, build better and more mature evidence portfolios to be brought to provincial drug plans for consideration faster, and encourage good drugs to come to market more rapidly.

In the end, CETI will bring together more than 50 investigators and students; it will produce tangible benefits, including facilitating the development of new drugs and technology, generating new policy-relevant knowledge, training, and enhancing decision support for public policy decision makers.

Research Grants and Awards

The Ontario Drug Policy Research Network (ODPRN)

Ministry of Health and Long-Term Care, Health System Research Fund (HSRF): \$4,700,000 (Feb. 2013-Jan. 2016)

PIs: Muhammad Mamdani and David Juurlink.

Co-Investigators: Laupacis A, Holbrook A, Coyle D, Henry D, Gomes T, Bhattacharyya O, Evans M, Garg A, Evans G, Paterson M, Austin P, Dhalla I, Straus S, Weir M.

Health System Performance Research Network

Ontario MOHLTC: \$4,654,109 (2013 – 2016)

PI: Walter P. Wodchis

Co-Investigators: Anderson G, Baker GR, Barnsley J, Berta W, Bierman A, Bronskill S, Cohen E, Cott C, Durbin J, Gruneir A, Guttman A, Josette Koné AJ, Kuluski K, Laporte A, Lin E, Lum J, Maxwell C, Manuel D, McKillop I, Morisano D, Tanuseputro P, Lyons R, Ungar W, Williams P.

Centre for the Evaluation of Technological Innovation (CETI)

Canada Foundation for Innovation New Initiatives Fund: \$3,000,000

PI: Murray Krahn

Co-Investigators: Alibhai A, Bayoumi A, Cadarette S, Coyte P, Grootendorst P, Miller F, Ungar WJ, Wijeyesundera W, Zwarenstein M.

Integrated GE3LS study: Health technology assessment of genetic testing in ASD diagnosis

Genome Canada, Large Scale Applied Research Project Competition: \$359,271 (Apr 2013-Mar 2017)

Project lead: Wendy J. Ungar

Project team: Smith I, Elsabbagh M, Ray P, Stavropoulos J, Speevak M, Szatmari P, Scherer S.

Project C3 within Autism Spectrum Disorders: Genome to Outcomes. Scherer S (PI), Szatmari P (co-PI), Ungar WJ and 22 others. \$10,039,870.

A Pilot Study to Ascertain the Use of Intensive Care Units (ICU's) as an Option for the Surveillance of Severe Respiratory Illness (SRI) in Canada

Public Health Agency of Canada: \$197,068.59 (2013-2014)

Primary Investigator: Robert Fowler

A National Comparison of Intensity of End-of-Life Care in Canada: Defining Changing Patterns, Risk Factors and Targets for Intervention

\$196,187 (2013-2015)

Primary investigator: Robert Fowler

Co-Investigators: Kozac J-F, Rockwood K, Andrea Hill, Wunsch H, Skinner J, Rubenfeld G, Scales D, Heyland D, Stukel T.

A cost analysis comparing alternative genetic testing approaches in the diagnosis of autism spectrum disorders

The Hospital for Sick Children Centre for Genetic Medicine: \$195,000

Sept 2012-Aug 2015

WJ. Ungar (PI), S. Scherer, C. Carew.

Shining a Light on End-of-Life Care in Canada: Investigating Barriers, Testing Interventions, and Disseminating Integrated Solutions for Patients, Families and Healthcare Professionals

\$187,900. University of Toronto Integrating Challenge Grant (2013-2015).

Primary Investigator: Robert Fowler

Co-investigators: Dev S, Berry S, Downar J, Gandhi S, La Delfa I, Laupacis A, Myers J, Ross H, Rubenfeld G, Scales D, Sinha S, Stukel T, Zimmermann C. Collaborators: Gallagher R, Heyland D, Kryworuchko J, Skinner J, You J, Wunsch H.

Sex Differences in Admission to Intensive Care Units: The Role of Social Support Factors

Technology Evaluation in the Elderly National Centre of Excellence (NCE): \$125,807 (2013-2015)

Primary Investigators: A. Garland, C. Ramsey

Co-investigators: Dodek P, Fowler R, Doupe M, Fransoo R, Wong H, Kozak J.

Regional and temporal variations in incidence, prevalence and outcomes of critical illness among pregnant and post-partum women and newborns in Canada

CIHR: \$41,325 (2012-2014)

Primary Investigator: Robert Fowler

Co-Investigators: Damon Scales, Stephen Lapinsky, Joel Ray, Ruxandra Pinto, Kazu Aoyama

In the Spotlight

CETI initiative recognized by Dean of Pharmacy in latest faculty magazine

Dr. Murray Krahn was recognized in the latest issue of *RXcellence*, the University of Toronto Faculty of Pharmacy's alumni magazine, for his contribution to the faculty's reputation for excellence. In his Dean's message, Dr. Henry J. Mann noted that Dr. Krahn has recently been awarded a significant amount of funding to establish a new Centre for Early Technological Innovation (CETI). Dr. Mann notes in his message that the CETI initiative has contributed to the faculty being ranked among the top in the world.

Introducing the new and improved PEDE Database!



The Paediatric Economic Database Evaluation (PEDE) database is a searchable repository that houses detailed information on over 2,300 paediatric economic evaluations published since 1980. The PEDE database is a valuable HTA tool used by researchers and decision-makers around the globe. Recent upgrades to the database now allow PEDE users to search a collection of over 1,200 health state utility weights from pediatric cost utility analyses.

Visit our new and improved website today at:
<http://pede.ccb.sickkids.ca/pede/>

Congratulations to Dr. Wendy Ungar on her Genome Canada Award!

Dr. Unger is Project Lead of Project C3 within "Autism Spectrum Disorders: Genome to Outcomes" (PI: Dr. S. Scherer). Project C3 is a \$359,271, integrated GE3LS study pertaining to health technology assessment of genetic testing in autism spectrum disorder diagnosis.

The four-year, \$10,039,870 Genome to Outcomes project will be funded through Genome Canada's Large Scale Applied Research Project Competition Award.

Congratulations to Dr. Unger and the Project C3 team of I. Smith, M. Elsabbagh, P. Ray, J. Stavropoulos, M. Speevak, P. Szatmari, and S. Scherer!

35th Annual Meeting of the Society for Medical Decision Making

October 20-23, 2013
Hilton Baltimore
Baltimore, Maryland

"Bench, Bedside and Beyond: Medical Decision Making and Public Policy"

Deadline for abstracts: May 17
Early registration closes: September 26

www.smdm.org

THETA Staff



Welcome, Petros!

Petros Pechlivanoglou has recently joined THETA as a post-doctoral fellow. He holds an M.Sc. in Econometrics and a PhD in Pharmacoeconomics from the University of Groningen, The Netherlands. His PhD was primarily focused on bridging network meta-analysis and decision-analytic modeling, as well as on the application and extension of mixed-effects models in evidence synthesis.

In addition, his interest expands to other econometrical and statistical applications in health policy and health economics. Petros has worked on health technology assessment projects for the Health Council of the Netherlands and as a consultant on various projects from the academic, public and private sector.

THETA Events

4th Annual THETA Knowledge Translation to Policy Day

Early Health Technology Assessment

May 29, 2013

6th Annual THETA Symposium

End of Life Care

May 30, 2013

Both events will be held at
Casa Loma
1 Austin Terrace
Toronto

Agendas will be circulated soon.

Academic Rounds

All rounds take place in the
Leslie Dan Pharmacy Building,
Room 850, at 1 p.m.

April 5: Pascale Lehoux
"The interactions between business
models and health technology design:
a comparative analysis of three
academic spin-offs"

April 19: Kamran Khan

May 3: Jeremy Goldhaber-Fiebert

May 17: Scott Grosse

May 31: Andy Willan
"Value and Uncertainty in pricing new
health care interventions"

Many thanks to past presenters:

- Onil Battacharya
- Sarah Bermingham
- Antoine Boivin
- Stirling Bryan
- Joseph Cafazzo
- Michael Iskedjian
- Laurie Lambert
- Joel Lexchin
- Muhammad Mamdani
- Craig Mitton
- Hai Nguyen
- Mike Paulden
- Ba' Pham
- Walter Wodchis

THETA's Health Technology Assessment Institute 2013

June 26-28, 2013
Health Sciences Building
University of Toronto

Three days of intensive sessions focused on assessing clinical
evidence, economic evidence, and social and ethical issues.

For more information, visit: theta.utoronto.ca



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