INSTITUTE OF HEALTH ECONOMICS
ALBERTA CANADA

IHE Methodology Forum: *Prioritizing Methodological Research in the Evaluation of Health Technologies in Canada*

Forum Summary

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THE INSTITUTE OF HEALTH ECONOMICS

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FOREWORD

On September 23rd and 24th, 2010, the Institute of Health Economics conducted an Inaugural IHE Methodology Forum: *Prioritizing Methodological Research in Evaluation of Health Technologies.* Delegates from academia, government, industry and other stakeholders involved in the production and use of evidence were brought together to discuss methodological challenges in evaluation of technologies and to identify priorities for research methods development. This document summarizes those deliberations. The presentations from the forum are available at http://www.ihe.ca/research/ihe-inaugural-methodology-forum-1/ .

We would like to express special thanks to Forum Chair, Dr. Michael Drummond from the University of York and to Dr. Deborah Marshall from the University of Calgary for leading development of the program and this summary document. Through the circulation of this report we hope to help inform national discussions on research priorities for the evaluation of health technologies in Canada.

We hope that future IHE Methodology Forums will examine some of the identified topics in more detail, with a view to identifying specific researchable questions and the mechanisms for funding the associated research.

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BACKGROUND

Advancements in methodological approaches in the evaluation of health technologies are important for ensuring that assessments are increasingly able to provide valid and appropriate information for decision makers. Therefore, the Institute of Health Economics has established a Forum series on *Prioritizing Methodological Research in the Evaluation of Health Technologies*, in consultation and partnership with the Canadian Agency for Drugs and Technologies in Health (CADTH), the National Institute for Health and Clinical Excellence (NICE), Alberta Health and Wellness and several industry partners (Pfizer, Merck, Eli Lilly, Astra Zeneca and Glaxo Smith Kline).

The *objective* of the Forum series is to identify and address major methodological challenges in informing policies and decisions around the funding and use of health technologies, in partnership with the stakeholders that are involved in the production of evidence and use of assessment. These include health professionals, health service managers, patients and technology manufacturers. The subject matter of the first Forum was generated as a result of a consultation with Canadian methodologists in 2009, to scope out potential methodological issues relevant to the Canadian Health Care System.

It was proposed that the first Forum would establish priorities for topics that will be pursued in subsequent research studies. IHE recognizes that this is not a 'one-shot' effort, as methodologies are developing continually. The intent was to learn from other organizations (such as NICE) that had gone through similar processes and to engage the various stakeholders, such as government, health technology assessment agencies, the health care sector and industry. However, the focus was on determining research priorities that are particularly important in the Canadian context. In doing so, it was considered important to emphasize that methodology is not just for the methodologists and that the main purpose of discussing methodological developments was to improve the quality of health care decision-making.

This paper reports on the discussions in the inaugural Forum, held in Edmonton from September 23 -24, 2010. This Forum reviewed experience from overseas, explored a range of Canadian policy perspectives on health technology assessment and discussed, in detail, the five methodological challenges identified in the initial consultation. The report also suggests some preliminary research priorities and outlines the key steps to follow.

INTERNATIONAL EXPERIENCE

Methodological debates are taking place continually in the health economics literature. No attempt was made as part of the Forum, to conduct a systematic review of the literature. However, international speakers identified several important topics, such as; the choice of viewpoint for economic evaluation, the methodological issues surrounding quality-adjusted life-years (QALYs) and their alternatives, the methods for making indirect and mixed treatment comparisons, especially where head-to-head clinical trials do not exist, the pros and cons of using surrogates and intermediate outcomes in assessments, and the methods for incorporating equity and other societal considerations into health technology assessment (HTA)

It was felt that there were also several important methodological issues surrounding the wider decision-making processes that economic assessments aim to support, such as; those raised by the recent increase in interest in managed entry schemes (including risk-sharing, or coverage with evidence development) and ways of engaging stakeholders in health technology assessments.

Several international initiatives to advance methodological standards and/or develop research priorities were also discussed. For example, Health Technology Assessment International (HTAi) has seven *interest sub-groups* which support international discussion of important issues in HTA, in some cases producing or disseminating tools and methodological resources. Recent examples include; methodological guidelines for identifying and prioritizing patient/consumer input into HTA systematically, information retrieval and systematic review methodology, guidelines for consideration of ethical issues in HTA, dialogues to refine terminology for conditional coverage arrangements and work to identify current approaches for use of surrogate outcomes in cost-effectiveness models. HTAi also operates a *Policy Forum*, which has held high-level discussions and published papers in areas such as coverage with evidence development, harmonization of evidence requirements for HTA processes for optimizing technology utilization, and managed entry agreements.

In addition, the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) has established several *good research practices task forces* that discuss a range of issues, and propose methodological standards. The topics discussed to date include; decision-analytic modeling, analysis of retrospective databases, economic analysis alongside clinical trials, conducting 'real world' studies, issues surrounding the transferability of economic data, conjoint analysis (discrete choice experiments), and mixed and indirect treatment comparisons.

In the United States, the Effective Health Care Program has been created and the Agency for Healthcare Research and Quality (AHRQ) authorized to conduct and support research with a focus on comparing the outcomes and effectiveness of different treatments and clinical approaches, as well as communicate its findings widely to a variety of audiences including clinicians, consumers, and policymakers. The program has continued to expand since its initiation with specific funding for comparative effectiveness research. The Effective Health Care Program reviews and synthesizes published and unpublished scientific evidence, generates new scientific evidence and analytic tools, and compiles research findings

that are synthesized and/or generated and translates them into useful formats for various audiences. The findings are communicated as research reviews of completed scientific studies, original research reports, or summary guides. A series of methodological research guides have been produced through the Effective Health Care Program including: Principles in Developing and Applying Guidance for Comparing Medical Interventions; Identifying, Selecting and Refining Topics for Comparative Effectiveness Systematic Reviews; Methods Guide for Effectiveness and Comparative Effectiveness Reviews, and Registries for Evaluating Patient Outcomes: A User's Guide.

In Europe, the European Union has funded the EUNeTHTA project, which, building on various earlier informal collaborations between some HTA agencies in European countries, has developed methods and processes for the harmonization of HTAs across different jurisdictions. The most relevant of these include, a 'Core HTA' and a toolkit for assessing the transferability of HTAs.

In the inaugural Forum, a report was presented on the priority setting exercise conducted by NICE and the Medical Research Council (MRC) in the United Kingdom.[1] This involved a wide range of methodologists, stakeholders, and NICE's own staff. In total, 125 topics were identified and categorized into 5 areas: analysis, design and synthesis of effectiveness studies; synthesis of evidence from patients, the public and stakeholders; economic analysis and uncertainty; measurement and valuation of benefits and; decision-making at NICE. The priority setting process involved a workshop and responses to a web-based survey. As a result 10 potential projects were commissioned by the MRC, at a total cost of £2.3 million.

Several important messages emerged from the discussion of international experience. First, 'methodological' research can, and should, include study of decision-making processes (e.g. scoping of assessments, involvement of stakeholders and, perhaps most importantly, ways of factoring issues that are not addressed formally within the economic assessment into appraisal of the assessment and other relevant evidence in the decision making process). Secondly, discussion of priorities should include both a focused phase that involves methodologists and experienced users of HTAs, and a broader consultation involving all stakeholder groups. In particular, decision-makers need to be involved in order to ensure that research help to make assessments more relevant to their needs. Thirdly, it is important to develop a process for converting general ideas for study into researchable questions/topics. Finally, since the ultimate objective is to pursue some of the topics further, it is important to identify potential funding streams at an early stage.

POLICY PERSPECTIVES

In keeping with the notion that the main purpose of methodological developments is to improve the quality of healthcare decision making, a panel discussion took place at the inaugural Forum, involving decision-makers from the Government, HTA agencies, and industry. The focus here was ensuring that

[1] MRC Nice Scoping Project:
http://www.york.ac.uk/media/che/documents/papers/researchpapers/CHE%20Research%20Paper%2051.pdf

whatever priorities for methodological research were discussed, they would have practical application in decision-making.

In general, there was considerable agreement on current 'hot topics', such as; managed entry of health technologies, harmonization of HTA methods and data requirements, and improving stakeholder involvement. It was also pointed out that in some areas there was already extensive knowledge of the various methodological approaches and that the major issues may surround implementation of what were currently known about how to conduct valid and appropriate assessments, as opposed to conducting yet further methodological research.

In addition, it was stressed that often the focus of efforts was exclusively on health technology *assessment* (i.e. should the technology be introduced into the health care system) as opposed to health technology *management* (i.e. how should the technology be used, for which indications and patient groups and how appropriate usage should be reviewed over the technology's lifecycle ad disease patterns and possible alternative treatments may change). There was widespread agreement at the Forum that more emphasis should be placed on health technology management, in order to redress this balance.

Building on the concept of technology management, it was pointed out that the evaluation of health technologies could be viewed as a series of stepwise decisions, namely; investment by the technology developer; licensing; reimbursement and; physician-patient choice from amongst alternative technologies that will develop over the lifetime of a technology. It was necessary to study the issues raised by, and the relationship between, these various steps. For example, it was pointed out that in several jurisdictions, including Canada, it was possible for a health technology to be granted approval to market based on one set of evaluative criteria deemed relevant to market access, but be denied reimbursement based on a set of evaluative criteria deemed relevant to judging need, value for money and/or affordability within the health care system. While these frames of reference necessarily differ, there is a need to debate whether the various criteria could be better harmonized or at least coordinated to arrive at a single evidence package that would satisfy all decision-making needs.

Several participants emphasized that there needed to be a balance between the rigor of HTA methods, and the timeliness and efficiency of HTA processes. That is, we should be striving for methods that are fit for purpose rather than perfect. In the spirit of making HTAs more efficient, there was also discussion of the scope for harmonization of HTA methods and processes. It was felt that while there is considerable scope for more harmonization of methods and processes decisions will always be location, or system specific. However, much of the evidence and analysis involved in them is common across many or even all health systems. Indeed, it would be important to study the implications for cost-effectiveness of different healthcare delivery systems, as well as the individual health technologies themselves.

DETAILED DISCUSSION OF FIVE KEY METHODOLOGICAL CHALLENGES

A major part of the inaugural Forum was the discussion of the five key methodological challenges identified in the initial consultation with Canadian methodologists. This discussion is summarized here, and the resulting research priorities are given in the final section of the report.

Data Quality and the Development of National Costing Panels to Better Utilize Administrative Data

It was acknowledged that administrative data, including those on resource use and cost, were collected for purposes unrelated to the evaluation of health technologies. Therefore, those data often had limitations for HTA and it is important that these limitations are better understood. Thus, the key to better utilizing these data was a clearer understanding of the various types of data required for HTAs and where use of administrative data had a comparative advantage.

It was also stressed that researchers needed to develop appropriate skills for analyzing administrative data and that better communication is required between those who assemble/maintain the databases and those who seek to analyze them.

Several of the practical issues surrounding the use of administrative data were also discussed, such as; the need to maintain confidentiality, and to provide adequate resources for extracting the data. In Alberta, in particular, these were seen as priority issues by researchers. In addition, in the case of cost data, there would be benefits from greater standardization in data capture and better linkage between the various datasets.

Finally, since administrative data are essentially a product of how the health care system is managed, the input of system changes on the quality and availability of data needs to be assessed. For example, it was anticipated that changes in how physicians were reimbursed would have profound effects on the availability of data on physician activity and resource utilization.

Incorporating Routine Patient Reported Outcome Measures

Patient-reported outcome measures (PROMs) are widely used in clinical and economic evaluations of health technologies, but they are rarely applied in routine data collection. Therefore, their use is currently mainly in health technology *assessment*, as opposed to health technology *management.* However, routinely-collected PROs could be useful in informing patients about their rate of recovery, in informing clinical judgments about which patients are experiencing on-going health problems, informing health care managers about which are the high performing clinical teams, and informing health service researchers about the variations in health outcomes across jurisdictions and over-time.

Nevertheless, the routine collection of PROMs raises a number of methodological and practical issues. For example, choices would need to be made about the types of measures collected. In particular, would a series of condition-specific measures need to be collected, or would a single generic measure

be suffice? Among the generic measures, should the choice by a descriptive (or profile) measure (such as SF-36), or a preference-weighted measure (such as the health utilities index in Canada, or the EuroQol-EQ-5D in Europe)?

One important practical issue is whether health professionals would have the appropriate mechanisms to collect PROMs routinely. This suggests that data collection should either be targeted towards informing clinicians about their clinical outcomes, or towards informing health care managers about clinical performance.

How to Incorporate Multi-Criteria Decision Frameworks into Economic Evaluation and Decision-Making

Approaches to aid decision-making, such as Multi-Criteria Decision Analysis (MCDA) and Stated Preference Methods, such as Discrete Choice Experiments (DCEs), have acquired scientific respectability. However, they are still only rarely used in formal decision-making processes for health technologies. Therefore, an important scientific agenda topic would be to assess whether these approaches have decision applicability. Several unresolved questions remain; such as how the decision (or choice) criteria are defined, how they are weighted, and how scores are aggregated, and who should contribute as respondents in these processes.

Since these approaches are rarely used in formal decision-making procedures at present, an important opportunity exists to study their introduction in a systematic way. This was an opportunity missed in the case of QALYs, which were introduced without any study of their impact on decision-making processes or outcomes.

Some of the limited experimentation with MCDA approaches suggests that the process may be more important than the final scores. Since these approaches force decision-makers to consider trade-offs in an explicit fashion, they also offer the potential to increase the transparency of the decision-making process.

Research into the use of stated preference methods demonstrates that patients, physicians, public decision-makers, and the general public may have different preferences. This mirrors some of the evidence concerning QALYs. Therefore, there is a research agenda surrounding whose preferences should be used for different types of healthcare decisions and the role that the different preference sets should play in resource allocation decisions. In particular, the viewpoint of the patient should be considered, as emphasized in recent health policy reports and the Canadian Strategy for Patient Oriented Research. Stated preference methods have been examined by the US Food and Drug Administration as an explicit approach for communicating benefits and risks of new drugs in the post-approval setting.

The application of system modeling is an emerging method within the context of multi-criteria frameworks, although it is well established in other sectors. System dynamics modeling can be used to simulate options for care delivery that balance the multiple goals of access, effectiveness and efficiency

and consider patient and system outcome measures. This is a methodology that could be explored further to support decision making processes oriented towards a broader systems perspective for health technology management.

It was noted at the Forum that decision-making processes for drugs and other health technologies differ across Canada. This might provide a natural laboratory in which to study the use of multi-criteria decision approaches in different decision-making settings.

Approaches to Mitigating Against Methodological Bias in Economic Evaluations

There have been several studies demonstrating methodological deficiencies in economic evaluations, which in turn could lead to sub-optimal decisions. The methodological concerns relate to both internal and external validity. More detailed analysis suggests that, although there are many sources of potential bias, the major sources appear to be in the methods for extrapolating clinical benefits in the long term, the incorporation of economic and clinical data in decision-analytic models, and in the application of study findings to different patient sub-groups.

Decision-makers often have concerns about the transparency of decision models, including the assumptions made in decision-analytic models, both in the incorporation of data and decisions about model structure. Therefore, there is a need for more sharing, validation, and standardization of decision-analytic models. It is common for several new technologies to be developed in parallel for a given health condition (this is particularly true in the case of pharmaceuticals). One problem faced by decision-makers is that although the design of the clinical trials may be similar for the various technologies, there may be differences in the structure of the models developed by manufacturers.

There is also the need to establish which surrogate endpoints are reliable predictors of final outcomes and which are not. It was mentioned earlier that authorities licensing are more likely to accept surrogate endpoints than payers. Therefore, more discussion should take place concerning these differences with a view to harmonizing the various decision-makers' requirements.

Although the methods of systematic review are well-developed, more investigation is required of the applicability of findings to different patient sub-groups, and their extrapolation to patient groups that were not enrolled in the clinical trials forming the basis of the systematic review. However, in an ideal world, it would be preferable if a higher number of clinical trials enrolled patients that are more typical of the patient population for which the technology is to be reimbursed.

Finally, there should be study of the impact that decision-making processes themselves, have on the quality of the analyses presented and the quality of the final decision. For example, it is possible that decision outcomes could be influenced by the quality of the scoping process for the assessment, the thoroughness of the review of manufacturer's submission, and the extent of stakeholder involvement.

How to Incorporate a Broader Health System and Societal Perspective in Evaluation, Including the Value of Innovation

It was noted at the Forum that the methods of economic evaluation most frequently used by decision-makers (cost-effectiveness analysis and cost-utility analysis), were less amenable to the inclusion of broader societal costs and benefits than cost-benefit analysis. Therefore, unless these broader issues were explicitly included in the process by which the economic assessment and other relevant evidence were appraised to arrive at a decision, there was a risk that they would not be adequately considered, particularly if a cost-effectiveness threshold was rigidly applied.

There was divided opinion at the Forum on how economic analysis and HTAs should be framed and, in particular, whether they should adopt a healthcare system or societal perspective. Elected and duly accountable governments and/or politicians ultimately make decisions as to the goals of health care spending and thus the factors that are relevant to assessing the value for money of a technology in relation to those goals. Nevertheless, it was felt that this issue merits more investigation and discussion, particularly in a Canadian decision-making context.

Another possible area for research is the development of methods for valuing the productivity losses from absenteeism and presentation, for situations where these are deemed relevant to a decision. Several studies were reported where the inclusion of productivity gains/losses influenced the conclusion of the study. However, decision-makers still remain skeptical about the reliability of the methods for valuing productivity changes. In addition, there was relatively little study on how patient adherence affects the value of health technologies in routine use.

There was considerable discussion about how best to value innovation and how this should be reflected in decision-making. More clarity is required on what constitutes innovation and whether excessive attention to static, as opposed to, dynamic efficiency reduces the level of innovation and thus the potential extent of health gain in the long-run. In particular, it would be useful to build a more rigorous analytic approach around the current case studies that seek to illustrate how innovation is often a step-wise process, with the implication that the failure to reward small gains in the short term may threaten attainment of larger gains in the longer term from incremental innovation.

Finally, it was again recognized that a decision to adopt a given technology should be made in the understanding of, the costs of implementing the decision and the costs of monitoring the subsequent use of the technology. There may also be costs associated with reversing an initial decision, once a technology had been adopted by the healthcare system, if the longer-term evidence suggests that the technology concerned may not offer good value for money.

DETERMINING PRIORITIES FOR METHODOLOGICAL RESEARCH IN THE EVALATION OF HEALTH TECHNOLOGIES IN CANADA

Priorities for research were discussed in the final session of the Forum. Panelists were asked both to reflect on what they had heard in the previous two days and also to suggest areas for research that had

not been discussed. Based on the panel discussion and other issues raised during the Forum, the following research priorities are proposed.

General Topics

1. Study of the mechanisms (i.e. horizon scanning, initial assessment and appraisal methods, reimbursement strategies, and methods for monitoring uptake and use and reviewing appropriateness) that can be used to ensure the appropriate diffusion and use of health technologies at various times in their lifecycle (e.g. immediately after adoption, during their mature phase, at the end of their useful life).
2. Identifying and removing existing health technologies that are no longer cost-effective.
3. Effective engagement of patients and other stakeholders in health technology assessment/management in order to encourage the sustainable use of technologies in the long term.
4. Exploration of the scope for harmonization and/or coordination of regulators' and payers' requirements for the licensing and reimbursement of health technologies.

Data Quality and the Development of National Costing Panels to Better Utilize Administrative Data

1. Clearer specification of the main uses of administrative data in health technology assessment/management and the challenges in analysing these data.
2. Identification of the actions needed to enhance access to administrative data for research and evaluation purposes. Are there good models in other jurisdictions?
3. Standardization and linkage of health service utilization data with clinical data and patient-reported outcomes including standardized costing panels of health services across Canada.

Incorporating Routine Measurement of Patient Reported Outcomes

1. Pilot studies of the main uses of routinely-collected patient reported outcomes in health technology management.

How to Incorporate Multi-Criteria Decision Frameworks into Economic Evaluation and Decision-Making

1. Studies of the use MCDA to help decision-makers incorporate other factors, alongside cost-effectiveness, in reimbursement decisions.
2. Exploration of the use of DCEs as an alternative to QALYs in reimbursement decision-making.

3. The contribution of systems-based evaluations in health technology management, incorporating the perspectives of patients, payers and other stakeholders and including patient and system level outcomes.

Approaches to Militating Against Methodological Bias in Economic Evaluations

1. Study of the potential and feasibility of developing standardized decision-analytic models for several important disease areas.
2. The predictive ability of surrogate, or intermediate, endpoints in cancer and other major diseases.
3. Exploration of how HTA processes (e.g. scoping assessments, engaging stakeholders) influence decision outcomes. Can different Canadian provinces be compared with each other and with other jurisdictions?
4. Approaches for increasing the transparency of evaluations of health technologies.

How to Incorporate a Broader Health System and Societal Perspective in Evaluation, Including the Value of Innovation

1. Discussion of whether the societal perspective, or a narrower healthcare perspective, is the most appropriate for healthcare evaluations in the various jurisdictions in Canada.
2. Improving the methods used to measure and value productivity gains/losses in economic evaluations.
3. How to develop rigorous methods for assessing the value of incremental innovation in the context of health technology to address a given disease state.
4. Improving methods to capture and quantify the full value of innovation including the development of appropriate definitions of what constitutes innovation.

NEXT STEPS

Through the circulation of this report, IHE seeks to stimulate a national debate on the research priorities for the evaluation of health technologies in Canada. Future IHE Forums will examine some of the topics in more detail, with a view to identifying researchable questions and the mechanisms for funding the associated research.

ORGANIZATIONAL WEBSITES AND SELECTED READING LIST

Organizational Website Links

Agency for Healthcare Research and Quality - http:www.ahrq.gov/

Alberta Health and Wellness - http://www.health.alberta.ca/

Canadian Agency for Drugs and Technologies in Health – http://www.cadth.ca

Drug Safety and Effectiveness Network - http://www.cihr-irsc.gc.ca/e/40269.html

European Network for Health Technology Assessment - http://www.eunethta.net/Public/Home/

Health Technology Assessment International - http://www.htai.org/

International Society for Pharmacoeconomics and Outcomes Research - http://www.ispor.org/

International Network of Agencies for Health Technology Assessment - http://www.inahta.org/

Institute of Health Economics – http://www.ihe.ca

National Institute for Health and Clinical Excellence - http://www.nice.org.uk/

Society for Medical Decision Making - http://www.smdm.org/

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