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Conditionally Funded Field Evaluations: PATHs Coverage with Evidence Development Program for Ontario

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Introduction

Faced with escalating health-care costs, in 2003 the Ontario Ministry of Health and Long-Term Care (MOHLTC) decided to embark on a new evidence-based platform for decision-making around medical devices, procedures, and programs. This new venture was predicated on the belief that assessment of technologies using a more systematic and rigorous process could improve efficiencies in the health-care system, potentially control rising health-care costs, and ultimately improve the overall health of Ontarians. In the case where the evidentiary base for a new technology is strong and fairly conclusive, making recommendations about reimbursement, implementation, or uptake of the technology is relatively straightforward. However, what if the evidentiary base is of poor quality, conflicting, not based on "real world" effectiveness studies or there are concerns about implementation and uptake of the technology for a particular jurisdiction? For example, economic evaluation evidence may exist, but because of known differences in unit costs, practice patterns, or patient preferences across jurisdictions, this might affect the transferability of economic evaluation data across jurisdictions. There may even be concerns about the generalizability of clinical evidence from other jurisdictions for local decision-making needs. For example, differences in patient characteristics like demographics or rates of compliance with therapies, or provider characteristics such as level of expertise or training, or health-care system characteristics like payment incentives or available infrastructure, can all affect whether, and to what extent, a technology works in a particular jurisdiction. In these cases, assessing the technology using local context-specific data collection may be necessary.

The Programs for Assessment of Technology in Health (PATH) Research Institute is the longest established group undertaking conditionally funded field evaluations (CFFEs) of health-care technologies in Ontario. CFFEs are safety, efficacy, effectiveness, or cost-effectiveness studies conducted in the "real world" (i.e., more pragmatic) and where funding for the technology or use of the technology is conditional on sites or professionals participating in data collection for evaluation purposes. There are other groups in Ontario conducting CFFEs and each research group not only addresses slightly different levels of decision uncertainty, but each group also approaches and conducts CFFEs in slightly different ways. The CFFE process used by PATH, illustrative examples of completed CFFEs and their impact on policy and reimbursement in the province are discussed. Finally challenges for government and researchers are highlighted with some conclusions for moving forward.

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Ontario's Evidence-Based Health Technology Assessment (HTA) Process

An overview of Ontario's evidence-based HTA process and the role of CFFEs are provided in Figure 1. The process begins when a health-care organization, health-care facility or health-care provider requests that the MOHLTC consider purchasing or reimbursing a new technology in the province. The funding requests for surgical or diagnostic procedures, devices or products, or new programs or services are submitted to a division of the MOHLTC called the Medical Advisory Secretariat (MAS), which conducts an initial scan of the technology and prioritizes using a standardized scoring algorithm. This initial scan and scoring is then presented to the Ontario Health Technology Advisory Committee (OHTAC), which meets once a month to review evidence around technologies and makes recommendations to the Deputy Minister of Health. OHTAC was formed in 2003 to create an evidence-based single point of entry for the uptake and diffusion of health technologies in the province and consists of clinical epidemiologists, clinicians, health economists, health policy analysts, health services researchers, bioethicists, senior hospital administrators, and representatives from the Ontario Hospital Association, the Ontario Medical Association, Medical Device Manufacturing Association, and community-based health-care programs. Based on the initial scan and prioritization, OHTAC may reject the request for review, request more information or may decide that MAS proceed to conduct a Health Technology Policy Analysis (HTPA) around the technology. An HTPA is completed internally by MAS within 16 weeks, where the technology's safety, efficacy, effectiveness, and cost-effectiveness are reviewed. Guided by a rating of the technology using the Grades of Recommendation, Assessment, Development and Evaluation (GRADE), the evidence around the technology is deliberated by OHTAC at which point OHTAC may make a policy recommendation regarding the uptake and diffusion of the technology. OHTAC may also conclude that there is not enough information to make an evidence-based decision, and recommend that a CFFE be undertaken.

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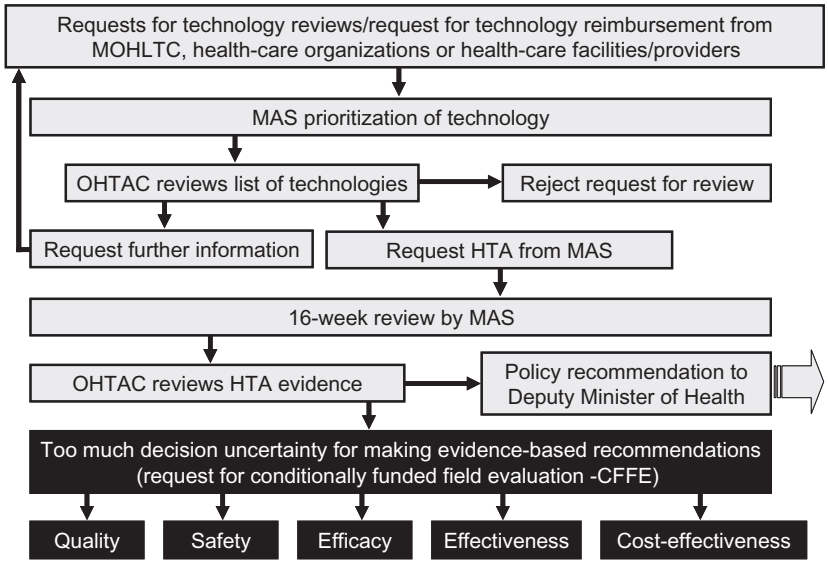

Figure 1 Overview of Ontario's evidence-based HTA process and the role of conditional funded field evaluations. CFFE: Conditionally Funded Field Evaluation, HTA: Health Technology Assessment; MAS: Medical Advisory Secretariat; MOHLTC: Ministry of Health and Long-Term Care; OHTAC: Ontario Health Technology Advisory Committee [1].

Role of CFFEs in Ontario's Evidence-Based Process

As shown in Table 1, OHTAC's decision uncertainty around a technology may be based on a lack of conclusive evidence on quality, safety, efficacy, effectiveness, or cost-effectiveness. These categories of uncertainty are akin to what are referred to as the "hurdles for reimbursement" decision-making for drugs. For example, there may be concerns that the technology may potentially harm patients or health-care providers and, in this case, a CFFE may be conducted to assess safety or develop guidelines or standards of practice for use of the technology. Similarly, there may be concerns about whether the technology could work even under ideal experimental trial conditions and, in this case, a CFFE may be recommended to assess the efficacy of the technology (e.g., an explanatory randomized controlled trial (RCT)). There may also be concerns about whether the technology will work in "real world" practice and it may be recommended that a pragmatic RCT or observational study be undertaken. And finally, there may be concerns over value for money of the technology and it may be recommended that a cost-effectiveness analysis be undertaken where resource use, practice patterns, unit costs, and patient preference information are collected to help reduce uncertainty.

Once a CFFE is commissioned, a study team is put together based on key opinion leaders in the province and a protocol is developed to collect the evidence needed to reduce decision uncertainty. The CFFEs not only vary in the uncertainty being addressed, but also vary considerably in terms of study design, outcomes measured, study duration, sample size, and site participation. To date, CFFEs have ranged in duration from about 1 to 4 years from study initiation to completion.

Examples of PATH's Completed CFFEs

The PATH Research Institute has been in existence since 2003. During the pilot phase of this program, PATH initiated three CFFEs per year and is now initiating four new CFFE per year. Most of the CFFEs conducted by PATH have either been efficacy, effectiveness, or cost-effectiveness evaluations; however, PATH has also been actively involved in developing general disease policy models, which can be used to assess the cost-effectiveness of a number of alternative treatment alternatives at the same time using a common disease modeling platform. For illustrative purposes, examples of two completed CFFEs are presented below, along with their subsequent impact on policy in the province.

Table 1 Attributes of technologies, questions asked, uncertainty faced by decision makers, and type of conditionally funded field evaluations used to reduce decision uncertainty [2]

Attribute of technology	Questions HTAs typically address	Typical uncertainty in decision-making	Types of CFFEs used to address uncertainty
Quality	Is the technology consistent and of high quality?	Lack of quality evidence or inconsistency in quality of the technology	Technology quality assurance assessments
Safety	Does the technology harm patients or health-care professionals?	Safety concerns in general or in context-specific application of the technology	Safety assessments, development of guidelines or standards of practice
Efficacy	Can the technology work under ideal experimental trial conditions?	Poor quality evidence, lack of evidence, or conflicting evidence of efficacy	Explanatory RCTs
Effectiveness	Does the technology work in "real world" practice?	Concerns over generalizability of efficacy evidence or transferability of clinical evidence from another jurisdiction	Pragmatic RCTs, observational studies (e.g., cohort, registries)
Value for money	Is the technology cost-effective Compared with alternative ways of treating patients?	Concerns over transferability of economic and patient preference evidence from another jurisdiction	Effectiveness studies including collection of resource use, practice pattern, unit cost and patient preference information

CFFE, conditionally funded field evaluation; HTA, health technology assessment; RCT, randomized controlled trial.