PODIUM SESSION I

HEALTH CARE DECISION-MAKER'S CASE STUDIES I

CASE 1

AN INTEGRATED PILOT PROJECT UTILIZING AN INTERNAL HTA PROCESS TO SET MEDICAL AND PAYMENT POLICY IN A U.S. COMMERCIAL HEALTH PLAN

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Organization: Premera Blue Cross is a 1.6 million member regional commercial health plan in the Pacific Northwest.

Problem or Issue Addressed: Need to perform more rigorous assessments of new medical technologies that present budgetary and utilization management challenges to our health plan.

Goals: (1) Develop and demonstrate a health technology assessment process for non-pharmacologic new medical technologies, utilizing plan medical and pharmacy staff, students and contractors as reviewers, including economic evaluations where data are available. (2) Apply these assessments to inform development of specific medical necessity policies and payment policies and implement the policy changes at Premera.

Outcomes items used in the decision: Clinical efficacy/safety, clinical utility and cost-effectiveness/cost-utility (when sufficient data were available).

Implementation Strategy: A cross-functional strategic planning group of Premera staff, with advice from University of Washington faculty, designed a comprehensive process to assess the value of new medical technologies (medical devices, diagnostics and novel procedures using existing devices) and apply the results to policy development. To strengthen our business case, we conducted a pilot implementation beginning in September 2006. The process involves pipeline surveillance, technology assessment, review by an independent panel of clinical experts, policy development and approval by an internal committee, and policy implementation. Since Premera has a high quality Pharmacy and Therapeutics Committee that meets the above description, we utilized this group as an external review committee, adding one such technology review to each meeting agenda.

Results: Between September 2006 and January 2008, 8 new medical technologies were evaluated using this process and one review was underway at the end of this period. Subjects of the completed reviews consisted of 2 diagnostic scanning modalities, 2 genetic diagnostic tests, 1 other diagnostic modality, 1 robotic-assisted surgical procedure and 2 image-guided radiotherapy procedures. Strength of evidence was generally unimpressive with only 1 case having good evidence, 2 fair and 5 poor. Medical policies were impacted by 6 reviews: medically necessary without prior authorization (1), medically necessary with prior authorization (1), investigational with certain exceptions (2) and investigational without exceptions (2). Payment policies were established by 2 reviews, in each case determining that the new procedure would be reimbursed at the same rate as its comparator, since the published studies had failed to demonstrate additional incremental value.

Lessons Learned: Regional private payers can establish a rigorous health technology assessment process incorporating cost-effectiveness analysis, with modest assistance from health outcomes faculty at a nearby university. These clinical and economic evidence assessments are useful to create medical and payment policies and to refine existing policies. Having a rigorous and transparent process strengthens credibility with providers and other external stakeholders. In addition, standardizing processes for assessing value for medical products informs manufacturers with regard to evidence expectations. Methodology developed for reviewing pharmaceuticals can be adapted to review non-pharmacologic entities, but lack of good quality evidence from clinical trials is a serious limitation. Medical innovations delivering sufficient high-quality evidence require a comprehensive format to optimize opportunities for scientific communication among payers, industry, and academia. Efforts to establish higher evidence standards for devices and diagnostics should be encouraged.

CASE 2

DRUG ELUTING STENTS—AN EXAMPLE OF THE TRANSITION FROM EVIDENCE TO POLICY THROUGH THE ONTARIO COMPREHENSIVE APPROACH TO THE DIFFUSION OF HEALTH TECHNOLOGIES

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Problem or Issue Addressed: In 2002, the Ontario Ministry of Health and Long-Term Care (MOHLTC) was advised that drug eluting stent (DES) would present a diffusion pressure since approximately 10,000 stents were being used per year and the differential cost between bare metal stents (BMS) and DES was $2200–$3840 per stent. An initial review of the literature by the Medical Advisory Secretariat (MAS) found that in low-risk patients the restenosis rates for BMS were 20–30% compared to 0–5% for DES. However, issues of generalisability to the Ontario health system were raised in the MAS analysis, and a concern that there would be creep to off-label use in high-risk patients.

Goals: Establish through a pragmatic study whether results published from randomized controlled trials on DES are generalisable to Ontario and to use this as a basis for long-term funding decision.
Outcomes items used in the decision: One year restenosis and mortality rates according to whether the stents used were bare metal or drug eluting.

Implementation Strategy: A Conditionally Funded Field Evaluation (CFFE) approach to diffusion was adopted. MOHLTC conditionally provided $12 million annually for DES to be used exclusively within a pragmatic study conducted by the Program for the Assessment of Technologies in Health (PATH) Research Institute with the goal to assess the cost-effectiveness of DES in the Ontario context. Using a large registry of over 20,000 patients, the PATH Research Institute collected information on the number and type of stents, rates of revascularization procedures and mortality over a 1-year follow-up period. PATH reported back the findings from the study in early 2007 to the Ontario Health Technology Advisory Committee (OHTAC) whose advice to MOHLTC was used to make a long-term funding decision.

Results: It was found that the effectiveness of DES varied widely across patients with different risk factors and that DES were not cost-effective in a number of patients. The results of the cost-effectiveness study, which have not been previously published, were used by OHTAC to make a recommendation for DES funding in high-risk patients only which, compared to a more open diffusion policy, resulted in an estimated $22 million annual savings to the health care system. These results differed from efficacy data from published RCTs. Reasons for this discrepancy cannot be provided with certainty but possibilities include differences in the use of anti-platelet drugs and the use of a more current bare metal stent.

Lessons Learned: This example of a pragmatic effectiveness study used to inform decision making demonstrates how an evidence-based approach to health technology assessment can, and should, influence policy decision making when faced with concerns of generalizability and decision uncertainty.

CASE 3

REVIEWING AND ADAPTING A LOCAL HEALTH TECHNOLOGY ASSESSMENT PROGRAM TO DEPARTMENTS WITHIN A CANADIAN HEALTH REGION

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Problem or Issue Addressed: Many local decision-makers do not have a consistent and transparent mechanism in place to capture, integrate, and report on the clinical, administrative, and financial aspects of introducing a new health technology into their local environment. To address this need, we first developed a draft Local Health Technology Assessment (HTA) program in conjunction with the Department of Surgery and Surgical Services within the Calgary Health Region. The project described in the present report includes piloting, reviewing, and adapting the Local HTA program to other clinical departments to meet the needs of these local decision-makers.

Goals: The main objectives of our project were: 1) to develop a process for reviewing and adapting the Department of Surgery and Surgical Services Local HTA program to other departments within the Calgary Health Region, 2) to create first and second revisions of the Local HTA program based on key comments and recommendations from the stakeholders, and 3) to identify outstanding issues that need to be addressed by future working groups. The next phase of the project is a trial of the revised program during 2008.

Outcomes items used in the decision: Since the overall goal of this project is to develop a decision-making tool, the outcomes of interest were: 1) a clear process and documents by which the program can be fully utilized and evaluated, 2) synthesis of key comments from participating departments to create a first and second revision of the Local HTA documents, and 3) a list of outstanding issues that are presently not addressed in the Local HTA program but that need to be considered.

Implementation Strategy: A six-step process was developed for reviewing and adapting the Department of Surgery and Surgical Services Local HTA program to other departments within the Calgary Health Region. These steps were: 1) development of a Local HTA Program Review Manual; 2) selection, assessment of readiness, and education of participating departments; 3) review of the Local HTA program by individual departments; 4) gathering of feedback and joint review; 5) synthesis of feedback; and 6) revision of the Local HTA program. Additionally, steps 3-6 were repeated to yield a second revision of the program documents.

Results: 1) Documents for the Review Manual and first and second revisions of the Local HTA program were produced. Participants acknowledged that the program has good face validity and contain the key elements that need to be addressed to introduce a new technology in a safe, effective and comprehensive manner; 2) A major change in the revised Local HTA program was the creation of two major pathways for evaluating new technology: a) Technology Request Pathway, which provides a rapid method for requesting new technology and ensures that safety, cost, and legal and contractual issues are considered (minor change of practice), and b) Local HTA Pathway, which is used when there are uncertainties about the technology’s clinical safety and effectiveness and/or its impact on finances or resources (significant change of practice); and 3) Several issues inadequately addressed by the Local HTA program were identified as follows: a) Clear guidelines are needed to determine when a technology needs to be evaluated by the Local HTA Pathway rather than the Technology Request Pathway; b) Special situations for technology requests were identified including urgent/emergent requests, one-off requests and compassionate requests. A special process to deal with these requests is being developed and will include an after-the-fact critical review to ensure adequate accountability for these requests; c) Approval of many similar technologies can lead to too many choices and patient safety issues. There should be an annual “Clinical Expert Review” of all similar technologies to reduce the numbers of options available; and d) Often replacement of old technology is delayed until the situation is critical, then all review processes are skipped. A process is needed to avoid this.

Lessons Learned: The unique feature of this initiative is the development of HTA capacity at the local level—from the “bottom up.” Users are empowered to adapt and change the program according to their local context. Other elements critical to the success of this project include education of participants (often one-on-one), appointment of HTA leaders in each department, provision of starting documents, and a process (retreats and interviews) to gather feedback for revision to the documents. Challenges included slow buy-in time (approvals needed from various levels of management), finding common meeting times, resistance to change, and ensuring follow-through.