FINAL Comprehensive Research Plan:

Treatment of Attention Deficit Hyperactivity Disorder in Adults

Pharmacoeconomic Unit

April 27th, 2015
Research Questions

RQ1. What is the current evidence for the comparative cost-effectiveness of pharmacological treatments for attention deficit hyperactivity disorder (ADHD)?

RQ2. What is the budget impact of alternative policies for reimbursing pharmacotherapies in the treatment of ADHD?

Methods

Systematic Review of Published Economic Evaluations

To address RQ1 we will conduct a systematic review of the available literature on the cost-effectiveness of pharmacotherapies for the treatment of ADHD in adults (18 years and older). Specifically, pharmacologic treatments will be limited to pharmacological treatments approved for use in Canada (mixed amphetamine salts XR, atomoxetine, bupropion, clonidine, dexamethylphenidate, dextroamphetamine, guanfacine, lisdexamfetamine, methamphetamine, methylphenidate, and modafinil). Cost-effectiveness of stimulants will be compared with each other, with non-stimulants, as well as combination therapy (i.e. stimulants + non-stimulants).

A search of the medical literature will be conducted in MEDLINE (OVID interface, indexed, in-process and other non-indexed citations, 1946 onwards), EMBASE (OVID interface, 1947 onwards), NHS EED, and Tufts CEA registry in order to capture all relevant literature based on the NHS EED recommended search strategy. This literature search will be carried out by coupling a standard search strategy for identifying economic studies with the clinical search terms adopted by the clinical review. Moreover, a search of grey literature sources such as the CADTH and NICE websites, as well as hand-searching of reference lists of retrieved studies will supplement the electronic database search.

Two independent reviewers will screen the titles and abstracts of citations retrieved by the initial literature search, and potentially relevant full-text articles will be obtained and screened for inclusion in the economic appraisal by the same two reviewers. Any disagreements will be resolved by discussion or the involvement of a third reviewer.

Extracted studies will then be further reviewed with studies excluded for lack of context or for not being full economic evaluations.

Critical appraisal of economic evidence will entail identifying common methodological issues within included studies. Each study will be assessed through a three step process: initial assessment for validity, assessment of study quality, and assessment of study’s pertinence to the decision question. Selected comparators will include stimulants in comparison with each other, with non-stimulants, and with combination therapy (i.e. stimulants + non-stimulants) Emphasis will be placed on the strength and quality of evidence addressing the cost-effectiveness of the selected pharmacological treatments for ADHD.

Within the context of the review of economic studies we will also review any publications which examine data linking ADHD, ADHD treatment or response to ADHD treatment to broader societal impacts.
**De Novo Economic Evaluation**
Due to the paucity of data, especially related to utility values in adult ADHD, no de novo cost-effectiveness model will be developed.

**Reimbursement Based Budget Impact Analysis**
The aim of this portion of the pharmacoeconomic review is to develop a budget impact analysis that will facilitate the reimbursement decision-making process. Emphasis will be placed on identifying the budget impact of alternative approaches to the current reimbursement status of pharmacologic treatments for adult patients with ADHD. This will be achieved through a three stage process.

1. **Forecasting of current expenditure for ADHD pharmacotherapies.**
   
   We will obtain data on current usage of stimulants and non-stimulants for treating ADHD from OPDP to allow identification of the number of claims, number of claimants, total costs, and drug unit costs in a given year (broken down quarterly).

2. **Identification of candidate reimbursement strategies**
   
   The second stage will involve identifying alternative approaches to reimbursement of combination therapies. This will rely heavily on strategies identified during the scoping assessment along with further consultation with OPDP. Reimbursement strategies could be general (applied to all products) or specific (targeted at specific products), and consideration may be given to the availability of generics and changes to EAP listing.

3. **Assessment of budget impact of candidate scenarios**
   
   Using the techniques adopted in step 1, we will forecast the budget expenditure on pharmacotherapies for the treatment of ADHD for each alternative reimbursement strategy.

**Deliverables**

We will provide a written report detailing methods adopted, results, discussion and summary policy recommendations. The report will comprise a two-page executive summary followed by a detailed technical report.

**Timelines**

Our work will commence on acceptance of this proposal. The review of economic evidence will be completed within 6 weeks of project onset. Forecasting of drug expenditures will be completed within 12 weeks of commencement. Reanalyses and revisions of the final report will be available 4 weeks after receipt of stakeholder reviews.