Criteria for Listing of Non-Prescription Medications on the Canadian Forces Drug Benefit List

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Outline

• **Background**
  – The Canadian Armed Forces Drug Benefit Plan
  – Issues related to provision of OTCs

• **Development of DND’s Proposed OTC Criteria**
  – Literature Review
  – Project Goals and Activities
  – Results

• **Next Steps and Future Directions**
Background
Background

The CAF and its Drug Benefit Plan:

- A publicly funded federal program
- Drug therapy for Canadian military personnel:
  - 72,000 individuals with comprehensive coverage
  - 40,000 individuals with other levels of coverage
- Not representative of Canadian population:
  - Compulsory retirement age = 60 years
  - 15% of CAF personnel are women
  - High geographic mobility
  - Generally healthy – highly engaged in maintaining health
Non-Prescription Medications (OTCs):

- Categorization is based primarily on safe use
  - Health Canada determines Rx meds (Prescription Drug List)
  - NAPRA schedules specify conditions of sale
- Products address a wide range of health needs
- Supporting literature is variable in quality
  - Different regulations for some products (e.g., NHPs)
- Access to OTCs depends on reasonable use
  - Self-selection → “behind-the-counter” → Rx required
Background

Access to OTCs for CAF Personnel

- Often perceived as “overly generous”:
  - Coverage of OTCs is well-publicized.
  - Few quantity limits are built into the system.
  - Mechanisms exist to allow direct reimbursement for OTCs obtained at civilian pharmacies.
  - Prescription generally not required to obtain OTCs from military pharmacies.
  - Various health personnel who “prescribe” OTCs.
Background

Our Challenge:
• Delisting of OTCs is frequently identified as a potential cost-savings measure
• Concerns abound:
  – May eliminate/reduce access to first-line treatment…
    E.G., acetaminophen for osteoarthritis
  – Could prompt use of products with different risk profiles…
    E.G., misoprostol/diclofenac (Arthrotec®) vs. topical diclofenac
  – May shift costs to Pr drug alternatives, thus no savings!
    E.G., celecoxib vs. ibuprofen
  – May introduce new costs
    E.G., out-of-pocket expenses for patients, system inefficiencies
Development of DND’s OTC Criteria
Literature Review

- Few drug plans specifically cover OTCs.
- Literature search performed:
  - Ovid MEDLINE® (65 studies), Embase (428 Studies)
  - MESH Search terms: Dietary Supplements, Self Medication, Nonprescription Drugs, Health Benefit Plans, Employee/, Insurance, Pharmaceutical Services/
  - Keywords: over the counter medications.mp
- All titles and abstracts reviewed to locate studies evaluating:
  - Effect of drug plan coverage on OTC usage
  - Impacts of delisting OTCs or other categories.
  - Prescription-to-OTC status switches.
### Coverage’s Effects on Usage

<table>
<thead>
<tr>
<th>Leibowitz, 1989: Multi-center, randomized, controlled trial</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Population</strong></td>
</tr>
<tr>
<td><strong>Intervention/Event</strong></td>
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<tr>
<td><strong>Outcome</strong></td>
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Impact of Delisting

Republic of Ireland, General Medical Services (Ferrando, 1987)
- Decreased utilization of delisted substances.
- Substitutions eliminated any cost savings.

New Jersey Medicaid Program (Soumerai, 1990)
- Delisting of drugs of questionable efficacy
- Both desirable and unimproved therapeutic substitutions.
- Total Medicaid drug expenses \( \uparrow \)3.2%.

Oregon Medicaid Program (Zechnich, 1998)
- Delisting of OTC coverage.
- Decrease in overall program costs.
- No increase in substitution except hematinics

Turkish Governmental Drug Plan (Ali, 2011)
- Substitutions & zero net effect on cost savings.
Summary of Evidence

- Substitutions may occur with product delisting.
- There may be unforeseen cost increases or delisting will be cost-neutral.
- Few studies investigate:
  - Costs to patient
  - Physician visits
  - Hospitalization
  - Clinical outcomes.
- Out-of-pocket expenses are often transferred to patients.
Project Goal

To develop a framework to standardize the review process for OTCs being considered for inclusion on the CAF Drug Benefit List.
OTC Framework for Review

Desired Process Characteristics:
• Rational & systematic (evidence-based)
• Easy to use (by different decision-makers)
• Application to current & future products (validity)

Desired Output:
• Recommendation for formulary listing
• Recommendation Options:
  – List
  – Do Not List
  – Consider Listing
Project Activities

1. Draft criteria for assessment of OTCs
   • Address issues of interest/concern to stakeholders
   • Generate useful listing recommendations

2. Validate the utility of the criteria
   • Applicable to different OTC medications
   • Useable among different reviewers, with consistent outputs
Step 1: Drafting Criteria
Criteria Development

• Identify key considerations for listing decisions
• Starting point: factors for considering therapeutic alternatives
  – Efficacy, Safety, Convenience, Cost
• Replicate tone of Spectrum of Care Committee Terms of Reference
  – i.e. mandate of CAF Health Services
• Score and rank the factors to generate a listing recommendation
Final Version

• Four criteria:
  – Purpose
  – Efficacy
  – Safety
  – Cost/Convenience

• 10 separate considerations to be made

• Final scoring based on combination of criteria
<table>
<thead>
<tr>
<th>Purpose (Fulfills one of the following)</th>
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<tr>
<td>• To treat symptoms for a condition that prevents a member from functioning optimally in his or her occupation.</td>
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<td>• To cure a disease that is not self-limiting and that may worsen to cause significant morbidity or mortality if left untreated.</td>
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<td>• Part of established clinical protocols without high quality evidence demonstrating lack of efficacy.</td>
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<td>• Serious and unpredictable adverse effects are rare.</td>
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<td>• Benefits of use outweigh the risks.</td>
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<td>• Potential for misuse, abuse, or diversion is low.</td>
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<td>• Other treatments would result in significantly more costs or inconvenience.</td>
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OTC Criteria: Purpose

Fulfills one of the following considerations:

- To treat symptoms for a condition that prevents a member from functioning optimally in his or her occupation.
- To cure a disease that is not self-limiting and that may worsen to cause significant morbidity or mortality if left untreated.
- To prevent transmission of a communicable disease.
OTC Criteria: Efficacy

Fulfills one of the following considerations:

- High quality evidence demonstrates clinically important efficacy.

- Moderate quality evidence demonstrates clinically important efficacy, and also recommended as treatment in recent clinical practice guidelines.

- Part of established clinical protocols without high quality evidence demonstrating lack of efficacy.
**OTC Criteria: Safety**

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Fulfills the following consideration:

- Other treatments would result in significantly more costs or inconvenience.
Application of the Criteria

- All 4 Criteria → List
- Purpose Criterion and Meets 2/3 other Criteria → Consider Listing
- Does not fulfill Purpose Criterion or Meets < 3 Criteria overall → Do not List
Step 2: Testing the Criteria on Different Drugs (Validation, Part 1)
## Validation

<table>
<thead>
<tr>
<th>Minoxidil (Rogaine®)</th>
<th>Negative control</th>
</tr>
</thead>
<tbody>
<tr>
<td>Loratadine (Claritin®)</td>
<td>Positive control</td>
</tr>
</tbody>
</table>
**Positive Control: Loratadine**

<table>
<thead>
<tr>
<th>Purpose (One of the category)</th>
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<td>YES: Allergic rhinitis ↓ quality of life, lost workdays, ↓ productivity.</td>
</tr>
</tbody>
</table>

<table>
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<tr>
<th>Efficacy (One of the category)</th>
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<tr>
<td>YES: well established &amp; included in practice guidelines</td>
</tr>
</tbody>
</table>

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<th>Safety (All of the category)</th>
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<td>YES: Well tolerated; no potential for abuse.</td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>Cost and Inconvenience (One of the category)</th>
</tr>
</thead>
<tbody>
<tr>
<td>YES: Compared to first generation antihistamines and many intranasal corticosteroids, less costly and more convenient</td>
</tr>
</tbody>
</table>

**Score: 4/4**
<table>
<thead>
<tr>
<th>Purpose (One of the category)</th>
<th>NO: Alopecia androgenetica = cosmetic concern.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Efficacy (One of the category)</td>
<td>YES: established efficacy with RCTs showing superiority to placebo.</td>
</tr>
<tr>
<td>Safety (All of the category)</td>
<td>YES: mostly dermatological adverse effects; no potential for abuse.</td>
</tr>
<tr>
<td>Cost and Inconvenience (One of the category)</td>
<td>NO: Alternative: finasteride less costly, and more convenient</td>
</tr>
</tbody>
</table>

Score: 2/4  DO NOT LIST
<table>
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<tr>
<th>Application to Recently Reviewed Products</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Recommended Listing, after applying OTC Criteria</strong></td>
</tr>
<tr>
<td>Docosanol (Abreva®)</td>
</tr>
<tr>
<td>Docusate sodium (Colace®)</td>
</tr>
<tr>
<td>Topical diclofenac (Voltaren Emugel®)</td>
</tr>
<tr>
<td>Dextromethorphan</td>
</tr>
<tr>
<td>Tylenol #1® (codeine 8 mg, caffeine, acetaminophen)</td>
</tr>
</tbody>
</table>
Step 2: Testing with Two Different Reviewers (Validation, Part 2)
## Application by Independent Reviewers

<table>
<thead>
<tr>
<th>Medicine</th>
<th>Reviewer 1</th>
<th>Reviewer 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fluconazole</td>
<td></td>
<td>List</td>
</tr>
<tr>
<td>Diphenhydramine</td>
<td></td>
<td>Do not list</td>
</tr>
<tr>
<td>Clemastine</td>
<td></td>
<td>Do not list</td>
</tr>
<tr>
<td>Chlorpheniramine</td>
<td></td>
<td>Do not list</td>
</tr>
<tr>
<td>Bismuth Salicylate</td>
<td></td>
<td>Consider listing</td>
</tr>
<tr>
<td>Calcium Carbonate</td>
<td>Do not list</td>
<td>List</td>
</tr>
<tr>
<td>Vitamin D</td>
<td>Do not list</td>
<td>List</td>
</tr>
<tr>
<td>Scopolamine patch</td>
<td>Do not list</td>
<td>List</td>
</tr>
<tr>
<td>Cetirizine</td>
<td>Do not list</td>
<td>Consider listing</td>
</tr>
<tr>
<td>Cromolyn eye drops</td>
<td>Do not list</td>
<td>Consider listing</td>
</tr>
</tbody>
</table>

**Interrater reliability analysis:**

Final listing decision: Kappa = 0.28 (p<0.04).  
Each criterion of the tool: Kappa = 0.58 (p<0.001).
Summary of Results

• Criteria-based assessment tool was developed which captures all key considerations when reviewing OTCs for formulary inclusion.

• Listing recommendations generated by the new tool were consistent with decisions made previously on the selected drugs.

BUT…

• Tool is not robust enough to be used by a single reviewer – differences in interpretation of the literature would need to be resolved.
Next Steps
Modification of OTC Review Process

Current Procedure:

• CF Pharmacy and Therapeutics Committee reviews all health products, including OTCs
• Recommendations made re: formulary status (including criteria for access) based on:
  – available scientific evidence on risks/benefits
  – knowledge of system constraints
  – anticipated patient needs
• Minimal consideration re: OTC status per se!
Modification of OTC Review Process

- Proposal to create separate subcommittee to review OTC medications
  - Membership to include health care providers who prescribe or administer OTCs as a key part of their scope of practice
  - Application of criteria by 2 members of this sub-committee, with final recommendation following discussion
  - Final recommendation reported back to CF P&T Committee
Future Directions

• OTC Criteria will be applied to the remaining products on the Drug Benefit List

• New review procedures will be applied to all non-prescription medications entering the market, which are eligible for coverage via the CF Drug Benefit Program

• Information shared with other federal drug programs
Our thanks to:

Commander Sylvain Grenier

Captain Chris Bedard
Captain Andrew Hulleman

Dr. Edwin Ng
References


Soumerai SB, Ross-Degnan D, Gortmaker S, Avorn J. Withdrawing payment for nonscientific drug therapy: intended and unexpected effects of a large-scale natural experiment. JAMA 1990;
