Potentially Inappropriate Prescribing in Long-Term Care Residents (PIP in LTC): Validation of tools for their future use across Ontario

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Conflicts of interest declaration and sources of funding

- I have no potential conflicts of interest to declare.
- I do not accept any gifts, funding, honoraria, shares or any other forms of payment from manufacturers of medication or medical devices, or from providers of medical services.
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Caveat...
Potentially inappropriate prescribing (PIP):

“The use of medicines whose potential harms to older adults may outweigh the benefits”*

→ Frequent and associated with morbidity and mortality, particularly in LTC residents


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So what is the problem?

Aging population + ↑ vulnerability to medication adverse effects with age

↑ adverse events, morbidity and mortality
↑ health care services use ➔ ↑ costs

People aged 65 years and older:*

➔ 15% of the Canadian population, yet their
➔ 40% of all retail prescription drug sales
➔ 60% of public drug program spending

Potentially inappropriate prescribing (PIP) in seniors – estimates from clinical data (patients with at least one PIP):#

• 22% in the primary care setting
• 35% in the acute care hospital
• 60% in the nursing home setting

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Identifying potentially inappropriate prescribing (PIP)

STOPP/START criteria for potentially inappropriate prescribing in older people: version 2

Denis O’Mahony1,2, David O’Sullivan3, Stephen Byrne3, Marie Noelle O’Connor2, Cristin Ryan4, Paul Gallagher2

American Geriatrics Society Updated Beers Criteria for Potentially Inappropriate Medication Use in Older Adults

The American Geriatrics Society 2012 Beers Criteria Update Expert Panel

JAGS APRIL 2012-VOL. 60, NO. 4

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STPPP/START

- 80 STPP and 34 START criteria
- Published in 2008 by Irish group of geriatricians, GPs, pharmacists, etc.
- Includes:
  - Drugs to avoid in the elderly
  - Drug-drug interactions
  - Drug-disease interactions
  - Drugs that increase risk of falls
  - Duplicate drug class prescriptions

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Appendix 1: STOPP (Screening Tool of Older People’s potentially inappropriate Prescriptions).

The following prescriptions are potentially inappropriate in persons aged ≥ 65 years of age.

A. Cardiovascular System
1. Digoxin at a long-term dose > 125 μg/day with impaired renal function* (increased risk of toxicity).
2. Loop diuretic for dependent ankle edema only: i.e., no clinical signs of heart failure (no evidence of efficacy; compression history usually more appropriate).
3. Loop diuretic as first-line monotherapy for hypertension (safer, more effective alternatives available).
4. Thiazide diuretic with a history of gout (may exacerbate gout).
5. Non-cardioselective beta-blocker with Chronic Obstructive Pulmonary Disease (COPD) (risk of bronchospasm).
7. Use of diuretics or verapamil with NYHA Class III or IV heart failure (may worsen heart failure).
8. Calcium channel blockers with chronic constipation (may exacerbate constipation).
9. Use of aspirin and warfarin in combination without histamine H2 receptor antagonist (except cimetidine because of interaction with warfarin) or proton pump inhibitor (high risk of gastrointestinal bleeding).
10. Dipyridamole as monotherapy for cardiovascular secondary prevention (no evidence for efficacy).
11. Aspirin with a past history of peptic ulcer disease without histamine H2 receptor antagonist or Proton Pump Inhibitor (risk of bleeding).
12. Aspirin at dose > 150 mg/day (increased bleeding risk, no evidence for increased efficacy).
13. Aspirin with no history of coronary, cerebral, or peripheral arterial symptoms or occlusive arterial event (not indicated).
14. Aspirin to treat dizziness not clearly attributable to cerebrovascular disease (not indicated).
15. Warfarin for first uncomplicated deep venous thrombosis for longer than 6 months duration (no proven added benefit).
16. Warfarin for first uncomplicated pulmonary embolus for longer than 12 months duration (no proven benefit).
17. Aspirin, clopidogrel, dipyridamole or warfarin with concurrent bleeding disorder (high risk of bleeding).
* estimated GFR < 50 ml/min.

B. Central Nervous System and Psychotropic Drugs
1. Tricyclic antidepressants (TCA’s) with dementia (risk of worsening cognitive impairment).
2. TCA’s with glaucoma (likely to exacerbate glaucoma).
3. TCA’s with cardiac conduction abnormalities (pro-arrhythmic effects).
4. TCA’s with constipation (likely to worsen constipation).
5. TCA’s with an opiate or calcium channel blocker (risk of severe constipation).
6. TCA’s with prostatism or prior history of urinary retention (risk of urinary retention).
7. Long-term (i.e., > 1 month), long-acting benzodiazepines e.g., chlordiazepoxide, flurazepam, nitrazepam, chlordiazepoxide and its metabolites e.g., diazepam (risk of prolonged sedation, confusion, hypotension, extra-pyramidal side effects, falls).
8. Long-term (i.e., > 1 month) neuroleptics as long-term hypnotics (risk of confusion, hypotension, extra-pyramidal symptoms).
9. Long-term neuroleptics (> 1 month) in those with Parkinson's disease (likely to worsen extra-pyramidal symptoms).
Beers Criteria

- First criteria published; updated in ‘97, ‘03, ‘12

- Criticised based on:
  - Inclusion of obsolete/unavailable medications
  - Not sufficiently inclusive of common instances of PIP
  - Higher scores not associated with ADEs
### Beers Criteria

<table>
<thead>
<tr>
<th>Organ System or Therapeutic Category or Drug</th>
<th>Rationale</th>
<th>Recommendation</th>
<th>Quality of Evidence</th>
<th>Strength of Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Anticholinergics (excludes TCAs)</strong></td>
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<tr>
<td>First-generation antihistamines (as single agent or as part of combination products)</td>
<td>Highly anticholinergic; clearance reduced with advanced age, and tolerance develops when used as hypnotic; greater risk of confusion, dry mouth, constipation, and other anticholinergic effects and toxicity. Use of diphenhydramine in special situations such as acute treatment of severe allergic reaction may be appropriate</td>
<td>Avoid</td>
<td>Hydroxyzine and promethazine: high; All others: moderate</td>
<td>Strong</td>
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<tr>
<td>Brompheniramine</td>
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<tr>
<td>Carbinoxamine</td>
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<tr>
<td>Chlorpheniramine</td>
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<tr>
<td>Clemastine</td>
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<tr>
<td>Cyproheptadine</td>
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<tr>
<td>Dextromethorphan</td>
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<tr>
<td>Diphenhydramine (oral)</td>
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<tr>
<td>Doxylamine</td>
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<tr>
<td>Hydroxyzine</td>
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<td>Promethazine</td>
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<tr>
<td>Triprolidine</td>
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<tr>
<td>Antiparkinson agents</td>
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<tr>
<td>Benztrapine (oral)</td>
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<tr>
<td>Trihexyphenidyl</td>
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<tr>
<td>Antispasmodics</td>
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<tr>
<td>Belladonna alkaloids</td>
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<tr>
<td>Clidinium-bitartrate</td>
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<tr>
<td>Dicyclomine</td>
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<tr>
<td>Hyoscymine</td>
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<tr>
<td>Propantheline</td>
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<tr>
<td>Scopolamine</td>
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<tr>
<td>Antithrombotics</td>
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<tr>
<td>Dipyridamole, oral short acting* (does not apply to extended-release combination with aspirin)</td>
<td>May cause orthostatic hypotension; more-effective alternatives available; intravenous form acceptable for use in cardiac stress testing</td>
<td>Avoid</td>
<td>Moderate</td>
<td>Strong</td>
</tr>
</tbody>
</table>

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85% of prescriptions are written by primary care physicians → Target for interventions

“Transparent evidence, rational use, equitable access”

- Monitoring of prescribing quality and related patient outcomes
- Development of feedback mechanisms for prescribers
- Development of targeted strategies for CME about common and/or costly PIPs
- Point of care access to medication information for all patients (health administrative data)

...requires population-level data

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How well do these criteria perform in Health Admin Data?

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The PIP in Long-Term Care (LTC) study:


Study goal:
To validate medication appropriateness criteria applicable to health administrative data by comparing their performance when applied to clinical data
The PIP in Long-Term Care (LTC) study

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Study Participants

- Recruiting newly admitted residents to LTC, convalescent, or respite care after June 2014 from 6 LTC homes in Ottawa area
  - Individuals providing informed consent
  - Aged 66+
  - OHIP-eligible
## Recruitment to date

<table>
<thead>
<tr>
<th>Month</th>
<th># of new Willingness to be Contacted forms received</th>
<th># of Potential Participants Reached</th>
<th># of Consents Gained</th>
<th># of Refusals*</th>
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<td>4</td>
<td>4</td>
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<tr>
<td>July 14</td>
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<td>September 15</td>
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<tr>
<td>October 15</td>
<td>8</td>
<td>6</td>
<td>5</td>
<td>1</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>186</strong></td>
<td><strong>88</strong></td>
<td><strong>74</strong></td>
<td><strong>14</strong></td>
</tr>
</tbody>
</table>

*7 refusals due to death prior to contact with resident or their substitute decision maker

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Data Collection – Clinical Data

- Charts abstracted by a contracted pharmacist

- Excel-based data collection template created – (available as downloadable file, appendix to protocol)


- Prompts entry of relevant patient data

- Responds to data entry by directing evaluator toward most pertinent PIPs
Snapshot – PIP identified via clinical data

Frequency distribution of PIP by medication assessment tool

- Full STOPP/START 2014
- Subset of STOPP/START clinical data
- Full Beers 2012
- Subset of Beers 2012 clinical data

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### Snapshot – PIP identified via clinical data

<table>
<thead>
<tr>
<th>Data Type</th>
<th>Clinical Data</th>
<th>Health Administrative Data</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td># PIP</td>
<td># PIP/Pt</td>
</tr>
<tr>
<td>Medication Assessment Tools</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Full STOPP/START 2014</td>
<td>237</td>
<td>3.65</td>
</tr>
<tr>
<td>Subset of STOPP/START HA Data</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Subset of STOPP/START clinical data</td>
<td>119</td>
<td>1.83</td>
</tr>
<tr>
<td>Full Beers 2012</td>
<td>106</td>
<td>1.63</td>
</tr>
<tr>
<td>Subset of Beers 2012 HA data</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Subset of Beers 2012 clinical data</td>
<td>103</td>
<td>1.58</td>
</tr>
</tbody>
</table>

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## Snapshot – Most frequent PIP identified via clinical data

<table>
<thead>
<tr>
<th>Criterion</th>
<th>Definition</th>
<th>Prevalence</th>
</tr>
</thead>
<tbody>
<tr>
<td>START E5</td>
<td>Vitamin D supplement in older people who are housebound or experiencing falls or with osteopenia (Bone Mineral Density T-score is &gt; -1.0 but &lt; -2.5 in multiple sites).</td>
<td>40%</td>
</tr>
<tr>
<td>START I2</td>
<td>Pneumococcal vaccine at least once after age 65 according to national guidelines.</td>
<td>31%</td>
</tr>
<tr>
<td>START E3</td>
<td>Vitamin D and calcium supplement in patients with known osteoporosis and/or previous fragility fracture(s) and/or (Bone Mineral Density T-scores more than -2.5 in multiple sites).</td>
<td>28%</td>
</tr>
<tr>
<td>Beers Caut A4</td>
<td>Antipsychotics Carbamazepine Carboplatin Cisplatin Mirtazapine SNRIs SSRIs TCAs Vincristine --&gt; Use with caution</td>
<td>28%</td>
</tr>
<tr>
<td>Beers Diag B3</td>
<td>Dementia and cognitive impairment --&gt; Anticholinergics (see Table 9 in the original guideline document for full list) Benzodiazepines H2-receptor antagonists Zolpidem Antipsychotics, chronic and as-needed use --&gt; Avoid</td>
<td>26%</td>
</tr>
</tbody>
</table>

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### Snapshot – Most frequent PIP identified via clinical data

<table>
<thead>
<tr>
<th>Criterion</th>
<th>Definition</th>
<th>Prevalence</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>START A6</strong></td>
<td>Angiotensin Converting Enzyme (ACE) inhibitor with systolic heart failure and/or documented coronary artery disease.</td>
<td>18%</td>
</tr>
<tr>
<td><strong>Beers Diag B4</strong></td>
<td>History of falls or fractures --&gt; Anticonvulsants Antipsychotics Benzodiazepines Nonbenzodiazepine hypnotics Eszopiclone, Zaleplon, Zolpidem TCAs/SSRIs --&gt; Avoid unless safer alternatives are not available; avoid anticonvulsants except for seizure</td>
<td>18%</td>
</tr>
<tr>
<td><strong>STOPP A1</strong></td>
<td>Any drug prescribed without an evidence-based clinical indication</td>
<td>17%</td>
</tr>
<tr>
<td><strong>START I1</strong></td>
<td>Seasonal trivalent influenza vaccine annually.</td>
<td>17%</td>
</tr>
<tr>
<td><strong>STOPP A2</strong></td>
<td>Any drug prescribed beyond the recommended duration, where treatment duration is well defined.</td>
<td>15%</td>
</tr>
</tbody>
</table>
Data Collection – Administrative Data

• 5 databases accessible to the Institute for Clinical and Evaluative Sciences
  ❖ ODBD – Drug claims
  ❖ DAD – Acute care hospitalizations
  ❖ NACRS – Emergency department visits
  ❖ OHIP – Claims paid by ON health insurance
  ❖ RPDB – Birth and death dates
From clinical criteria to SAS code...

Section B: Cardiovascular System
3. Beta-blocker in combination with verapamil or diltiazem (risk of heart block).

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Next Steps

- Pilot testing and preliminary analysis with ICES data
- Completion of data collection
- Analysis with larger datasets – both patient clinical data with health administrative data

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Questions?

THANK YOU!

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ADDITIONAL SLIDES – PIP STOPP STUDY
The PIP-STOPP study

- Population-based retrospective cohort study using Ontario’s large health administrative and population databases.
- Eligible patients aged 66 years and older who were issued at least one prescription between April 1st 2003 and March 31st 2014, (approximately 2 million patients) will be included.

**Goals:**
To describe the occurrence of PIP in Ontario’s older population, and assess the health outcomes and health system costs associated with it.

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PIP-STOPP study: Next steps

Analyses
- ED visits
- hospitalizations
- death
- adverse drug events

Dissemination

Stakeholder engagement

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