Participatory vs Expert-led Evaluation: competing factors in guideline implementation and evaluation

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#deRx2018
Learning Objectives

• Apply phases of drug evaluation to phases of guideline evaluation.

• Explain a complex context where deprescribing guidelines are used.

• Prioritize phases to create a research agenda.

Session resources available at deprescribing.org/TBD
Expert Approach: Analogy with Drug Evaluation

- In vitro studies of mechanism: *algorithm of a guideline*
- Preclinical studies of toxicity: *push-back from target users*
- Phase 0: pharmacokinetics in humans: *speed, fidelity of uptake*
- Phase 1: dosing trials in healthy volunteers: *concise vs detailed*
- Phase 2: efficacy trials in patients: *hospital implementation trial*
- Phase 3: effectiveness trials in select patient populations: *pragmatic trial of guidelines in real-world community care*
- Phase 4: post-market surveillance of actual use in the general population: *deprescribing program rapid cycle evaluation*
Imagine an RCT of Impacts: an Efficacy Trial

Evidence-based guideline for deprescribing one antipsychotic in Alzheimer’s patients. + Training on nondrug methods.

Evidence-based guideline for deprescribing one antipsychotic in Alzheimer’s patients. No training.

Train-the-trainer on nondrug methods. No deprescribing guideline.

No intervention. Just monitoring of deprescribing.
Participatory Approach: Call for Less Antipsychotics in Residential Care (CLeAR)

- Train the trainer in non-drug methods of care for agitated patients
- Were guidelines used in training? What was said about deprescribing?
- How influential or problematic was the deprescribing advice?
- Intervention was by nurses. How were prescribers involved?
- Did the prescribers feel any need for guidance, such as guidelines?
- Among those who felt need, when did they want to check guidelines?
- Did they just want tapering advice? Did they care about source?
- Waves of institutional participation, starting with early adopters
- Need enthusiasm among clinicians. Need simple evaluation methods.
- Quality improvement methods: monthly monitoring of success rates
CLeAR results: trends. Also compare Early vs Delayed

**FAIR HAVEN BURNABY**

**% OF RESIDENTS ON ANTIPSYCHOTIC (ALL)**

**FAIR HAVEN UNITED CHURCH HOMES IN BURNABY, BC**, initiated conversations between nurses and physicians and involved their recreation department in developing programs for residents. The team was able to reduce their usage from 35% to 26%.

**PERCENT OF RESIDENTS PRESCRIBED TO RECEIVE ANY ANTIPSYCHOTIC**

**Provincial Aggregate**

**PROVINCIAL ANY:** % of residents prescribed an antipsychotic within participating facilities submitting reports and is calculated by counting the total number of residents prescribed any type of antipsychotic divided by the total number of residents.
If Effectiveness Trial shows low impact... Why?

Usability of guidelines. Protocol deviations in applying nondrug methods of handling agitated patients.

Subgroup analysis: what types of patients can be deprescribed antipsychotics?

Frequency of rebound among patients who were deprescribed antipsychotics without tapering.

Interviews with clinicians about need for guidelines.
Revised hierarchy of evidence quality:
From expert methods to participatory methods

• IMPACTS
  • Double-blind RCT of selected, unrepresentative population
  • Pragmatic RCT of real-world patients and clinicians
  • Controlled time-series analysis of impacts on population trends
  • Before-after observational study of trends
  • Case-series (clinical experience) and anecdotes about failures

• PROCESS
  • Comprehensive program evaluation (macro level: whole system)
  • Narrative of what happened in one institution (meso level)
  • Watching individual clinicians using individual tools (micro level)
  • Interviews of perceptions of users in retrospect
MedStopper is a deprescribing resource for healthcare professionals and their patients.

1. Frail elderly? 
2. Generic or Brand Name: 
   pioglitazone
3. Select Condition Treated: 
<table>
<thead>
<tr>
<th>Generic Name</th>
<th>Brand Name</th>
<th>Condition Treated</th>
<th>Add to MedStopper</th>
</tr>
</thead>
<tbody>
<tr>
<td>pioglitazone</td>
<td>Actos</td>
<td>type 2 diabetes</td>
<td>ADD</td>
</tr>
</tbody>
</table>

MedStopper Plan

Arrange medications by: Stopping Priority

CLEAR ALL MEDICATIONS

PRINT PLAN
**Concise Guide for Polypharmacy Risk Reduction**

<table>
<thead>
<tr>
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<tbody>
<tr>
<td>RED=Highest</td>
<td>pioglitazone (Actos) / Glitazone / type 2 diabetes</td>
<td>☹</td>
<td>☹</td>
<td>☹</td>
<td>Tapering not required</td>
<td>symptoms of increased thirst/ increased urination, re-measure A1c in 3 months, measure blood glucose only if high glucose symptoms occur/return</td>
<td>None</td>
</tr>
<tr>
<td>GREEN=Lowest</td>
<td>olanzapine (Zyprexa) / Second generation antipsychotic / agitation in dementia</td>
<td>☺</td>
<td>☹</td>
<td>☹</td>
<td>If used daily for more than 3-4 weeks. Reduce dose by 25% every week (i.e. week 1-75%, week 2-50%, week 3-25%) and this can be extended or decreased (10% dose reductions) if needed. If intolerable withdrawal symptoms occur (usually 1-3 days after a dose change), go back to the previously tolerated dose until symptoms resolve and plan for a more gradual taper with the patient. Dose reduction may need to slow down as one gets to smaller doses (i.e. 25% of the original dose). Overall, the rate of discontinuation needs to be controlled by the person taking the medication.</td>
<td>agitation, activation, insomnia, rebound psychosis, withdrawal-emergent abnormal movements, nausea, feeling of discomfort, sweating, vomiting, insomnia these symptoms vary somewhat depending on the specific antipsychotic</td>
<td></td>
</tr>
<tr>
<td></td>
<td>rabeprazole (Aciphex, Pantol) / Proton pump inhibitor / heartburn/ GERD</td>
<td>☺</td>
<td>☺</td>
<td>☹</td>
<td>If used daily for more than 3-4 weeks. Reduce dose by 50% every 1 to 2 weeks. Once at 25% of the original dose and no withdrawal symptoms have been seen, stop the drug. If any withdrawal symptoms occur, go back to approximately 75% of the previously tolerated dose.</td>
<td>return of symptoms, heartburn, reflux</td>
<td>Details</td>
</tr>
</tbody>
</table>
MOUNT ST. MARY HOSPITAL
Medical QI & Interdisciplinary Team
Medication Review Preparation Form

Date of Review: _____________

Last GP Visit: _______________

**NURSE TO COMPLETE:**
Are there any recent marked changes to the resident’s health status?  YES / NO  Specify:

Referral to Geripsychiatrist at current facility?  YES / NO

Is patient a fall risk?  YES / NO
Scott Score: ________
Date: ____________
Number of falls in past 6 months or since last review: ______________
Stands?  YES / NO
Walks?  YES / NO

Are there any PRN’s that are being used frequently that could be ordered regularly?

Are there any PRN’s that have not been used in the past 60 days?  Specify:

Are there any Nursing concerns about medications?  See MAR & TAR & identify: ______________

<table>
<thead>
<tr>
<th>VITAL SIGNS</th>
<th>LATEST VALUE</th>
<th>PREVIOUS VALUE (as needed)</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Value</td>
<td>Date</td>
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<tr>
<td>BP - Blood Pressure (mmHg):</td>
<td></td>
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<tr>
<td>P - Pulse (BPM) If &lt; 50 list previous:</td>
<td></td>
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<tr>
<td>W – Weight (kg)</td>
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<td></td>
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<tr>
<td>BMI</td>
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</table>

Nurses Signatures: ____________________
<table>
<thead>
<tr>
<th>NURSE select:</th>
<th>Cognitv Issues</th>
<th>Phys Issues</th>
<th>Function</th>
<th>Goals</th>
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<tbody>
<tr>
<td>a</td>
<td>Dizzy, Balance</td>
<td>j</td>
<td>s</td>
<td>y</td>
</tr>
<tr>
<td>b</td>
<td>Cognition</td>
<td>k</td>
<td>t</td>
<td>z</td>
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<tr>
<td>c</td>
<td>Memory Loss</td>
<td>l Dry Mouth</td>
<td>u</td>
<td>a’</td>
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<tr>
<td>d</td>
<td>Naus, Anorexia</td>
<td>m Urine Freq</td>
<td>v</td>
<td>b’</td>
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<tr>
<td>e</td>
<td>Depression</td>
<td>n Constipation</td>
<td>w</td>
<td>c’</td>
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<tr>
<td>f</td>
<td>Confusion</td>
<td>o Immobility</td>
<td>x</td>
<td>d’</td>
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<tr>
<td>g</td>
<td>Delirium</td>
<td>p Leg Pain</td>
<td></td>
<td></td>
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<tr>
<td>h</td>
<td>Agitation</td>
<td>q General Weak</td>
<td></td>
<td></td>
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<tr>
<td>i</td>
<td>Insomnia</td>
<td>r Anemia</td>
<td></td>
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Printout: Med Rev Prep Form

Memory Loss: ____________________________
Dizzy, Balance: ____________________________
Dry Mouth: ____________________________
General Weakness: ____________________________
**Printout:** Med Rev Prep Form

<table>
<thead>
<tr>
<th>Numb of Factors</th>
<th>Indication (Dx)</th>
<th>Meds and Reasons (Hist)</th>
<th>Other agents</th>
<th>Actions</th>
<th>Contributes to…</th>
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<tbody>
<tr>
<td>3</td>
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<td>Amitriptyline</td>
<td>Taper:D/C</td>
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<tr>
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<td>Quetiapine</td>
<td>Taper:D/C</td>
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<td>Furosemide</td>
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<td>Reduce</td>
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<td>Digoxin</td>
<td></td>
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<td>NTG patch</td>
<td>D/C</td>
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<tr>
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<td>ASA</td>
<td>D/C</td>
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<td>D/C</td>
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<td>D/C</td>
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<td></td>
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<tr>
<td>8</td>
<td>DM</td>
<td>Metformin</td>
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<tr>
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<td>Ur Incont</td>
<td>Ditropan XL</td>
<td>Taper:D/C</td>
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<tr>
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<td>Esomeprazole</td>
<td>Taper D/C</td>
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<td>Alendronate</td>
<td>D/C</td>
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<td>Osteoporosis</td>
<td>Ca</td>
<td>D/C</td>
<td></td>
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<tr>
<td>2</td>
<td>Osteoporosis</td>
<td>Vit D</td>
<td>D/C</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Pain Legs</td>
<td>Tylenol</td>
<td></td>
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</tbody>
</table>

**Actions:**
- d) Nausea
- q) Weak
- c) Mem
- n) Const
- m) Urine Freq
- d) Naus
- q) Weak: Anemia
- q) Weak: Anemia
- p) Leg Pain:
- q) Weak
- q) Weak
- l) Dry
- q) Weak
- n) Const
Med Reviews in BC’s ‘Residential Care Initiative’

- Residential Care
  - CEO
  - Mg
  - Mg
  - MD
  - RN
  - MD
  - RN
- Nurse
  - Mg
  - Mg
  - RN
  - RN
  - RN
  - RN
- Nursing Home Corporation
- Pharmacist
  - Mg
  - Mg
  - Ph
  - Ph
  - Ph
  - Ph
- Pharmacy Chain
- Care Conference
- Family
- Division of Family Practice
Conclusions

• Like real-world studies of the use of meds, real-world studies of the use of guidelines might be important for the design of future guidelines.

• Participatory approaches to process evaluation of implementations in complex systems might be as important as rigorous effectiveness trials by experts.
Expert Approach: Analogy with Drug Evaluation

- In vitro studies of mechanism: *algorithm of a guideline*
- Preclinical studies of toxicity: *push-back from target users*
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