Researching the Role of Pharmacists in Chronic Disease Management

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The Need for Pharmacy Practice Research

- Threat: With the advent of automation and regulated pharmacy technicians, pharmacy practice must shift away from dispensing to patient-centered care
- Opportunity: to carve out an important role for pharmacists
  - Accessible, public health approach
  - Systematic, proactive
  - Drug therapy expertise
  - Infrastructure already there
VISION FOR PHARMACY

Optimal drug therapy outcomes for Canadians through patient-centred care

In our Vision for Pharmacy

Pharmacists and pharmacy technicians
- practice to the full extent of their knowledge and skills, and are integral to emerging health care models.
- protect the safety, security and integrity of the drug distribution system through the enhanced role of regulated pharmacy technicians and greater automation of dispensing.
- lead the development of and participate in medication safety and quality improvement initiatives.

Pharmacists
- manage drug therapy in collaboration with patients, caregivers and other health care providers.
- identify medication use issues, take responsibility for drug therapy decisions and monitor outcomes.
- initiate, modify and continue drug therapy (e.g., through collaborative agreements, delegated or prescriptive authority), and order tests.
- access and document relevant patient care information in health records, including test results and treatment indications (e.g., in electronic health records).
- empower patients in decision-making about their health, and play a prominent role in health promotion, disease prevention and chronic disease management.
- conduct practice research and contribute to evidence-based health care policy and best practices in patient care.

Pharmacists’ services
- are compensated in a manner that relates to expertise and complexity of care.

To realize the Vision, strategic action is needed in five key areas:

- Pharmacy human resources
- Education and continuing professional development
- Information and communication technology
- Financial viability and sustainability
- Legislation, regulation and liability

www.pharmacists.ca
The Role of Pharmacists in Chronic Disease Management

- Hypertension as a model
- Key success factors
- Unresolved issues and challenges
Hypertension is the most important avoidable risk factor for death (WHO):
- 2/3 of strokes
- ½ of coronary disease

Hypertension

- Prevalence: about 25%
  - 90% will develop hypertension over their lifetime
- Effects of blood pressure lowering:
  - 35-40% reduction in stroke
  - 20-25% reduction in myocardial infarction
  - 50% reduction in heart failure
  - Benefits in just 2-3 years
- Treatment and control are very poor

# Treatment and BP Control in Patients with Diabetes and Hypertension – Systematic Review

<table>
<thead>
<tr>
<th>Definition of “Controlled BP”</th>
<th>Treated *</th>
<th>Controlled *</th>
</tr>
</thead>
<tbody>
<tr>
<td>( \leq 160/90 ) 5 studies n = 11,339</td>
<td>68% (range 53 -97%)</td>
<td>37% (range 31 -60%)</td>
</tr>
<tr>
<td>( \leq 140/90 ) 26 studies n = 66,833</td>
<td>83% (range 32 -100%)</td>
<td>29% (range 5 -59%)</td>
</tr>
<tr>
<td>( \leq 130/85 ) 24 studies n = 49,420</td>
<td>87% (range 53 -100%)</td>
<td>12% (range 6 -30%)</td>
</tr>
</tbody>
</table>

*Weighted average of all subjects with diabetes and hypertension

Current Rates of Treatment and Control of Hypertension

- 65% with diabetes were uncontrolled

Hypertension Challenges

- Finding those with, or at risk of hypertension
- Treatment to target
- Keeping on target
- Opportunity for pharmacists(!)
Improving Blood Pressure Management in Patients with Diabetes

- **Objective:** To determine the effect of a community-based, interdisciplinary care program of identification, assessment, physician referral, and follow-up on blood pressure lowering in patients with diabetes and elevated blood pressure.

- **Methods:**
  - 227 patients with diabetes and not at target BP, identified by community pharmacists.
  - Randomized to interdisciplinary* care (BP measurement, patient education, physician referral, regular follow-up by a nurse and pharmacist team) for 6 months) or usual care.

*interdisciplinary means: nurses and pharmacists acting as a team, utilizing their complementary and synergistic skills, working with the patient and family physician to achieve improved outcomes.

Screening/Eligibility: Contact by pharmacist
Type 1 or 2 diabetes
>18y

Community Pharmacies
Regional diabetes program referrals

Clinic visit #1 (BP measurement)
BP>130/80

Clinic visit #2 (BP measurement)
BP>130/80

CONSENT
RANDOMIZATION
BP<130/80, exclude
BP<130/80, exclude

Usual Care:
BP wallet card
General DM advice, pamphlet

Enhanced Care:
BP wallet card
BP and Tx recommendations to family physician
Opinion leader statements
Patient education: lifestyle, pamphlet
Referral to family physician

Follow-up: 6, 12, 18 weeks

24 weeks: Close out visit
Endpoints: reduction in BP, achievement of target BP, ACEI use
• BP reduced 5.6 mm Hg further in intervention group (p=0.008)
  - BP reduced by 24 mmHg further in those with baseline SBP>160 mmHg
• Extrapolates to a reduction in stroke of 30%, in CHD events by 23%, and in mortality by 13%

SCRIP-HTN Limitations

- No improvement in antihypertensive medication use
- No improvement in ACEI/ARB use in diabetics
- Only 47% achieved target in intervention group (33% in control)
- Could BP reduction have been greater?
- Role of clinical inertia?
- Is there a ceiling effect to pharmacist recommendations?
Next Steps…

• In Alberta, pharmacists have opportunity to further improve management of hypertensive patients by obtaining additional prescribing authority
• Need for a remuneration system to allow patients to access pharmacist care services
rural RxACTION (‘reaction’)
Alberta Clinical Trial In Optimizing hypertension

• **Primary Objective:** To evaluate the effect of enhanced pharmacist care* on systolic BP reduction in patients with poorly controlled hypertension

• **Secondary Objective:** To evaluate the effect of a performance-based remuneration model, compared to a fee for service model on systolic BP reduction

*taking responsibility for hypertension care, including independent prescribing, follow-up visits and laboratory monitoring
Intervention

• Assess patients with regards to cardiovascular risk reduction including
  – reviewing BP control, treatment goals and determining lifestyle modifications

• Review the patient’s current hypertensive therapy regimen
  – options for improvement of BP control (lifestyle modification, increase dose, additional BP medications), and implementation (prescribing) of these strategies

• Encourage adherence to BP medications

• Education
Intervention: Follow-up

• Patients will be seen q4weeks until they reach BP target, then q3months until end of study
• Routine laboratory assessment
• Final visit at 24 weeks
Control Group

• Usual care by pharmacist and physician
• Wallet card for BP readings, pamphlet on BP
• Follow-up at 12 and 24 weeks for BP measurement
Outcomes

• Primary: difference in change in blood pressure between intervention and usual care

• Secondary:
  – Impact of payment for performance on magnitude of BP change
  – Patient satisfaction
  – Health economics
Study Sites
rural RxACTION

• First randomized trial of pharmacist prescribing
• Important health policy implications:
  – Advancing pharmacy practice
  – Advancing patient care
  – Remuneration model evaluation
• Rural, at risk patients
• Improves access
• Improved quality of care?
Key Features

• Pharmacist-initiated, in the community, not dependent upon referral from a GP
  – Yet, interdisciplinary (brings the GP “into the loop”)
• Proactive case-finding
• Intervention is based upon the Canadian Hypertension Education Program (CHEP) guidelines
  – CHEP-CPhA guidelines for pharmacists

www.hypertension.ca
PRACTICE GUIDELINES

2008 Canadian Hypertension Education Program Guidelines for the management of hypertension by pharmacists

www.cpjournal.ca

I. Screening

1. Pharmacists are in a unique position to actively screen individuals for elevated blood pressure
   - Accessible, community-based practitioner
   - Pharmacists should screen patients for hypertension, particularly those at high risk for cardiovascular events

2. This screening should include an assessment of cardiovascular risk using established tools such as the Framingham Risk Calculation

Also: Heart Failure, Respiratory Diseases, Vaccination, Diabetes, Dyslipidemia, Gastroesophageal Reflux
Key Features

• Broad-based Steering Committee:
  – includes clinical experts (opinion leaders) and health policymakers
Study Team/Partnerships

- Dr. Ross Tsuyuki
- Dr. Finlay McAlister
- Dr. Richard Lewanczuk
- Dr. Mike Kolber
- Dr. Norm Campbell
- Dale Cooney
- Meagen Rosenthal
- Sherilyn Houle
- Teri Charrois

- Endorsed by the Alberta College of Pharmacists, Alberta Health and Wellness, Alberta Medical Association, Alberta Health Services
Key Features

- Remuneration included:
  - RCT of payment for performance vs fee for service
Enhanced Pharmacist Care Group

Randomized

Fee for visit n=125

First visit: $150 (est. 60 min)
Each additional visit: $75/visit (est. 30 min)
Visits:
- q4weeks until at target
- q3months once at target
- total 6 months follow-up
Max payment: $600 per patient

Payment for performance n=125

First visit: $150 (est. 60 min)
Each additional visit: $75/visit (est. 30 min)
Visits:
- q4weeks until at target
- q3months once at target
- total 6 months follow-up

Bonus of $125 if reach 50% of target
Bonus of $250 if reach target (bonus dispersed at end of follow-up)
Max payment: $850
Unresolved Issues

- Current state of practice
- Do pharmacists want to change?
- Professional organizations as a barrier
- Funding
What should a reasonable pharmacist do in the following scenario?

A 50 year old new patient approaches you with the following question:

“I took my blood pressure last night at my friend’s place and it was 150/100. What does that mean?”
Objective: To determine current practices of community pharmacists in the management of hypertension

Cross-sectional observational design using unannounced standardized patients

Random, stratified sample of 101 community pharmacies in Edmonton

Scenario: 50y male concerned about BP of 150/100mmHg.

Sponsor/Partner: Alberta College of Pharmacists
Community Pharmacists’ Practices in Hypertension Management

- Knowledge of current BP targets: Although 70% stated a BP target, only 14% asked enough clinical information to determine the target.
- Review of past medical history: 7% asked medical history, 16% asked medication history, ~20% asked family history, previous HTN dx.
- Accuracy of BP reading: ~50% inquired about conditions under which BP was taken, many offered to retake BP themselves.
- Education/Lifestyle: 75% discussed how HTN is diagnosed, half described proper conditions for BP measurement, one third gave educational materials.
- Referral: 83% referred to physician.
- Standardized patients impressed with pharmacist’s empathy and caring.

Why do we need to understand pharmacist’s psyche and culture?

- Barriers to practice change: lack of time, remuneration, patient/physician/pharmacy manager support, need for education
- Premise: Previous strategies to remove these barriers to the implementation of patient-centered care have been largely unsuccessful
- “Culture eats strategy for breakfast”
Pharmacist’s Professional Psyche

- Passive
- Lack confidence/professional identity
- Fear of new responsibilities
- Risk aversion
- Paralysis in the face of ambiguity
- Need for approval, desire to please

"What does a pharmacist do?"

(a) Overall responses, n = 287

(b) First response, n = 100

Rosenthal M, et al. JAPhA, in press
Knowledge Translation and Advocacy for Pharmacy Practice Research

• Background: Practice change requires knowledge translation and advocacy by pharmacy professional organizations

• Objective: To determine the knowledge translation and advocacy activities of Canadian pharmacy professional organizations in relation to a major pharmacy practice study

• Methods:
  – A letter summarizing the findings of a recently published trial, SCRIP-HTN (Arch Intern Med Nov 2008) was sent to all pharmacy professional organizations on December 2008
  – We followed up 6 months later to determine activities arising from the publication and letter

Results:

- Of 22 organizations, 3 performed some KT activities (no advocacy)
- Major reasons cited:
  - Regulatory bodies: “not my job”
  - Advocacy bodies: “not a priority”, “lack of time, resources”, “political issues”

Pharmacillin?

- Highly efficacious in controlled clinical trials
- Poor efficacy in real world:
  - Under utilized
  - Subtherapeutic doses often used
- Poorly marketed
### Pharmacists As Public Health Professionals

**Key ingredients:**
- Highly accessible *in the community*
- Contact with patients more frequently
- Drug therapy experts
- Consistent with our training
- Increasing public demand for services
- Trusted by the public
- Infrastructure already there

**Mechanism of action:**
- **Proactive** identification of patients at risk
- Interventions *(care)* (education, medication adjustments, adherence evaluation, involvement of other healthcare professionals such as physicians, regular follow-up, etc)
- Taking **responsibility** for patient outcomes
Pharmacist Care in Hypertension: Systematic Review

- Meta analysis of 13 controlled trials of pharmacist interventions
- N = 2246
- Reduction of systolic BP of $10.7 \pm 11.6$ mmHg, $p=0.002$.

Proactive Pharmacist Involvement Improves Outcomes in Patients With Heart Failure: A Systematic Review

- Systematic review of pharmacist care in addition to usual clinic care
- Pharmacists provided drug therapy review, recommendations to physician, patient education on medications/self care and follow-up
- 12 studies, 2060 patients

<table>
<thead>
<tr>
<th>Study or sub-category</th>
<th>Treatment n/N</th>
<th>Control n/N</th>
<th>OR (random) 95% CI</th>
<th>Weight %</th>
<th>OR (random) 95% CI</th>
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<tbody>
<tr>
<td>01 Pharmacist directed care</td>
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<tr>
<td>Bouvy 2003</td>
<td>12/74</td>
<td>10/78</td>
<td>7.93 1.32 [0.53, 3.26]</td>
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<tr>
<td>Tsuyuki 2004</td>
<td>37/140</td>
<td>38/136</td>
<td>14.22 0.93 [0.55, 1.57]</td>
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<tr>
<td>Sadik 2005</td>
<td>17/104</td>
<td>26/104</td>
<td>11.18 0.59 [0.30, 1.16]</td>
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<tr>
<td>Lopez Cabezás 2006</td>
<td>17/70</td>
<td>22/64</td>
<td>10.05 0.61 [0.29, 1.30]</td>
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<td></td>
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<tr>
<td>Holland 2007</td>
<td>33/149</td>
<td>26/144</td>
<td>13.27 1.29 [0.73, 2.29]</td>
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<td></td>
</tr>
<tr>
<td>Murray 2007</td>
<td>11/122</td>
<td>21/192</td>
<td>9.80 0.81 [0.37, 1.74]</td>
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<td></td>
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<tr>
<td><strong>Subtotal (95% CI)</strong></td>
<td><strong>659</strong></td>
<td><strong>718</strong></td>
<td><strong>66.45 0.89 [0.68, 1.17]</strong></td>
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<tr>
<td>Total events: 127 (Treatment), 143 (Control)</td>
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<tr>
<td>Test for heterogeneity: Chi² = 4.80, df = 5 (P = 0.44), I² = 0%</td>
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<tr>
<td>Test for overall effect: Z = 0.82 (P = 0.41)</td>
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| 02 Pharmacist collaborative care |
| Stewart 1998       | 12/49         | 18/48       | 8.32 0.54 [0.23, 1.30] |
| Gattis 1999        | 1/90          | 11/91       | 2.07 0.08 [0.01, 0.65] |
| Rainville 1999     | 4/17          | 10/17       | 3.75 0.22 [0.05, 0.95] |
| Gwadry-Sridhar 2005 | 7/67         | 17/67       | 7.37 0.34 [0.13, 0.89] |
| Triller 2005       | 32/77         | 39/77       | 12.04 0.69 [0.37, 1.31] |
| **Subtotal (95% CI)** | **300**       | **330**     | **33.55 0.42 [0.24, 0.74]** |
| Total events: 56 (Treatment), 95 (Control) |
| Test for heterogeneity: Chi² = 5.86, df = 4 (P = 0.21), I² = 31.7% |
| Test for overall effect: Z = 3.03 (P = 0.002) |

**Total (95% CI)**

<table>
<thead>
<tr>
<th>Total (Treatment)</th>
<th>959</th>
<th>1018</th>
</tr>
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<tbody>
<tr>
<td>Test for heterogeneity: Chi² = 16.70, df = 10 (P = 0.08), I² = 40.1%</td>
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<tr>
<td>Test for overall effect: Z = 2.32 (P = 0.02)</td>
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Significance: 2nd most common reason for hospitalization, 75% of HF costs

Objective: To develop and economic model based upon SCRIP-HTN to predict costs and health resource savings

Methods:
- Economic model based upon 5.6 mmHg systolic BP reduction
- Included physician visits, hospitalizations for HTN, stroke, myocardial infarction, heart failure
- Data sources: Canadian Community Health Survey, CIHI, Alberta Schedule of Medical Benefits and BP Trialists Collaboration

Results: Cost savings of $1927 /patient/y
- Extrapolated to 1/4 of uncontrolled HTN: cost savings of $1B/y

Houle S, Chuck A, McAlister FA, Tsuyuki RT
Can J Cardiol 2010; 26(Suppl D): 125D (abs)
Conclusions

• The evidence for enhanced pharmacist care and improved patient outcomes is strong
  – Opportunity is there (if we want it...)
• The evidence for usual ("traditional") pharmacist care and outcomes does not exist and likely has no impact
• The future:
  – Continue building the evidence
  – Continue to study how to apply this evidence
  – Leadership needed