Advanced Clinical Practice in Primary Care

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Objectives and Outline

• To describe the current state of evidence for an advanced clinical practice
  – Focus on Alberta, Canada
• How to achieve robust evidence for new clinical pharmacy services
Some Definitions

- **Advanced clinical practice:**
  - Case finding
  - Assessment, including physical examination and laboratory tests
  - Prescribing
  - Follow-up
  - Taking responsibility for care

- **Primary care:** first point of contact with the healthcare system (community pharmacists!)

Expanded Scope of Practice for Pharmacists in Canada*

- **Prescribing**
  - Renew/extend prescriptions
  - Change drug dosage/formulation
  - Make therapeutic substitution
  - Prescribe in an emergency
  - Prescribe prescription drugs as part of a common ailment (“minor ailments”) program
  - **Initiate prescription drug therapy**

- Order and interpret laboratory tests
- Administer a drug by injection
- Pharmacy technician regulation

*Scope of practice varies by province and territory
In Canada, we would not have achieved our expanded scope of practice without research that proves the value of pharmacist care.

We must have evidence to prove the benefit of an advanced scope of practice.

- This is why pharmacy practice research is so important to the future of our profession (and for patients!)

Pharmacist Prescribing in Diabetes: RxING Study

- **Background:** glycemic control in patients with type 2 diabetes is very poor (about 50% controlled)
- **Objective:** To determine the effect of a community pharmacist prescribing intervention on glycemic control in patients with poorly controlled type 2 diabetes
- **Methods:**
  - Design: before-after design conducted in 12 community pharmacists in Alberta
  - Patients: 99 patients with poorly controlled type 2 diabetes, HbA1c of 7.5-11.0%
  - Intervention: prescribing by pharmacist (including oral medications and insulin glargine), including titration and follow-up at for 26 weeks

Al Hamameh YNJ et al. BMJ Open 2013: 3:e003154
Pharmacist Prescribing in Hypertension: RxACTION

**Background:** Blood pressure control in the community is poor (30-90% uncontrolled)

**Objective:** To evaluate the effect of pharmacist prescribing on systolic BP reduction in patients with poorly controlled hypertension

**Methods:**
- Randomized trial conducted in 23 pharmacies in Alberta
- Patients: 248 patients with BP >140/90 or 130/80 mmHg recruited by the pharmacist
- Intervention: pharmacist assessment of BP, CV risk, patient education, prescribing, lab monitoring, monthly follow-up according to the Canadian hypertension guidelines (CHEP)
- Control (active): usual pharm and physician care (written educational materials, BP wallet card, physician referral)

**RxACTION Results**

- Adjusted odds of achieving target BP 2.32 (95% CI 1.17, 4.15) in favour of intervention


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**Pharmacist Prescribing in Dyslipidemia: RxACT**

- **Background:** Dyslipidemia is poorly controlled (about 50% are not treated to evidence-based targets)
- **Objective:** To evaluate the effect of pharmacist prescribing on LDL-c reduction patients with poorly controlled dyslipidemia
- **Methods:**
  - Design: randomized, controlled trial in 12 pharmacies
  - Patients: 99 patients with poorly controlled dyslipidemia, identified and recruited by their pharmacist
  - Intervention: pharmacist assessment, prescribing and follow-up for 6 months according to 2009 Canadian guidelines
  - Control: usual pharmacist and physician care

R\textsubscript{x}ACT Results

- Proportion of patients achieving target LDL-c levels after 6 months (p=0.007)
  - Adjusted odds ratio of achieving target: 3.17 (p<0.001)
  - Adjusted change in LDL-c: 0.546mmol/L (SE 0.157, p=0.001)

The Effect of Community Pharmacist Prescribing and Care on Cardiovascular Risk Reduction: The R\textsubscript{x}EACH Multicentre Randomized Controlled Trial

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Background

- Cardiovascular diseases are one of the leading causes of death
  - Most are caused by modifiable risk factors and yet their identification and control is still suboptimal
  - Over 17.5 million deaths per year (WHO)
- Pharmacists are accessible, frontline primary health care providers who see patients with, or at risk for, cardiovascular events frequently
  - In Alberta, Canada, pharmacists can independently prescribe and order laboratory tests
- Numerous trials have demonstrated the benefit of pharmacist care on individual risk factors, but not “all together” in a comprehensive, province-wide program (and not with independent prescribing)

Objectives

Primary objective:
- To evaluate the effect of community pharmacy-based case finding and intervention in patients at high risk for cardiovascular events on reduction in risk for major cardiovascular events.
Methods

- **Design**: Multicentre randomized controlled trial with patients as the unit of randomization

- **Setting**: 56 community pharmacies across Alberta for recruitment and follow-up

Inclusion Criteria

- Adults at high risk for cardiovascular events, including patients with:
  - Diabetes
  - Chronic Kidney Disease (CKD)
  - Established atherosclerotic vascular disease
  - Multiple risk factors and Framingham risk score > 20%

- Patients were eligible if they had at least one uncontrolled risk factor (blood pressure, LDL-cholesterol, HbA1c, or current smoking)
Intervention

A standard Medication Therapy Management consultation:
• Patient assessment (BP, waist circumference, weight and height measurements)
• Lab assessment of HbA1c, lipids and kidney function
• Individualized CVD risk calculation and education about this risk (web-based graphic CV risk calc.)
• Treatment recommendations, prescription adaptation, and prescribing as appropriate to meet treatment targets as per latest Canadian practice guidelines
• Regular follow-up every 3-4 weeks for 3 months

Web-Based Cardiovascular Risk Calculator

• Input demographics:
  • DM (UKPDS Risk), vascular disease (Int’l Risk), CKD (FRS), primary prevention (FRS) risk engine selected
• Graphic risk shown:
  • Sliders for modifiable risk factors
  • Contribution to risk shown
  • Print for patient

Available from www.epicore.ualberta.ca/rxeach
Usual Care

- Usual pharmacy/physician care with no specific interventions or follow-up for 3 months
- At the end of follow-up, patients crossed over to receive intervention
Outcomes

Primary outcome:

- Relative difference (baseline to 3 months) in estimated risk for cardiovascular events between intervention and usual care groups
  - Risk for future cardiovascular events was calculated using validated risk engines (UKPDS, International, Framingham)

- Secondary outcomes: change in individual risk factors

Results: Demographics

Patients: n=723
Age: 62y (SD12)
Male: 58%

Study Qualification:
- 79% uncontrolled HbA1c
- 72% uncontrolled BP
- 58% uncontrolled LDL
- 27% current smokers

- Diabetes (n=573)
  - 263

- Vascular Disease (n=220)
  - 72
  - 85

- CKD (n=290)
  - 153
  - 18
  - 34

Primary Prev (n=53)
CKD Screening

- Of the 720 patients enrolled, 283 patients had CKD:

![Diagram showing CKD screening process]


RxEACH: Change in Risk of Cardiovascular Events

![Graph showing change in CV risk]

21% RRR
(Absolute RR -5.37; 95% CI -6.56 to -4.17, p<0.001)

All differences adjusted for baseline values using ANCOVA
**RxEACH: Individual Risk Factors**

- **Systolic BP (mmHg)**
  - Reduction: -9.37 mmHg (95% CI -11.07, -7.67, p<0.001)
- **LDL-c (mmol/L)**
  - Reduction: -0.2 mmol/L (95% CI -0.31, -0.08, p<0.001)
- **Diastolic BP (mmHg)**
  - Reduction: -2.92 mmHg (95% CI -4.21, -1.62, p<0.001)
- **HbA1c (%)**
  - Reduction: -0.92 % (95% CI -1.12, -0.72, p<0.001)

**RxEACH: Smoking Cessation**

- **Smoking (%)**
  - Reduction: 20.2 % (95% CI 9.9, 30.4, p<0.001)
**R\textsubscript{x}EACH Conclusions**

- Pharmacists using the CKD targeted screening guidelines identified a large number of patients with previously unknown CKD
  - validation of pharmacist ordering of lab tests
- Community pharmacist prescribing and care reduced the estimated risk for cardiovascular events by 21% in 3 months
  - Improvements in all major risk factors


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**Economic Evaluation of Pharmacist-Managed Hypertension**

- Purpose: Evaluate the economic impact of pharmacist care (including prescribing) in patients with hypertension
- Methods:
  - Markov model
  - Perspective: 3\textsuperscript{rd} party payer
  - Effects:
    - SBP reduction from R\textsubscript{x}ACTION and other studies
    - Cardiovascular and renal outcomes
    - Framingham 30y risk equations
  - Costs:
    - Pharmacist costs/visit $\text{CDN} 125/25 (6 in first year, 4/y thereafter)
    - Increased medication costs of +$\text{CDN} 30/mo
  - Sensitivity analyses

Marra C, Johnston K, Santschi V, Tsuyuki RT. Can Pharm J 2017;150:184-197
www.cpjournal.ca
Results

Marra C, Johnston K, Santschi V, Tsuyuki RT. Can Pharm J 2017;150:184-197
www.cpjournal.ca
Economic Evaluation of Pharmacist-Managed Hypertension

Results:

- Economically dominant: $CDN 6,364 cost savings over a lifetime (discounted at 5%/y)
- If applied to ½ of Canadian population, cost savings of $CDN15.7B/30y

Marra C, Johnston K, Santschi V, Tsuyuki RT. Can Pharm J 2017;150:184-197
www.cpjournal.ca

How To?

- Getting to an advanced scope of practice
  - Bringing evidence to healthcare policymakers (e.g., hypertension)
- Proving the benefits of the scope of practice you already have (pharmacists taking responsibility, engaging patients, practicing to full scope)
How To?

• Get involved in clinical practice guidelines (get prominent physicians onside)

How To?

• Whenever possible, randomized designs
• A network of community pharmacists
• Partnership with disease-based organizations and professional organizations
How To?

- Economic analyses
- Registries to help drive practice and further document outcomes
  - Without widespread adoption of these practices, patients cannot benefit

Summary/Conclusions

- Pharmacists have a societal duty to provide patient care and improve health
- With an advanced scope of practice, we can do more for our patients
- What we need:
  - high level of evidence

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Summary/Conclusions

• The missing element: courage
  − To be bold
  − To advocate for patient care

• Pharmacists are primary care providers – expanding scope of practice is important for public health

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Prescribing By Pharmacists in Alberta – A brief history

AB Gov’t: Alberta Health (Ministry of Health of Alberta)
ACP: Alberta College of Pharmacists (Regulatory Body)

1998-2005: Building the Evidence Base:
  • RCTs of pharmacist care (patient engagement, recommendations only)
  • Anticoagulation Management

2000-03: ACP: While papers on pharmacist prescribing

1995-97: AB Gov’t: “Role Statements for health professions”

2000: AB Gov’t: Health Professions Act
  • 29 health professions, one act
  • Removal of exclusive scopes of practice

2004-06: ACP: Wide consultation on prescribing – focus on importance to public and health system

2006/07: AB Gov’t: Regulations and Legislation for pharmacist prescribing

2007-08: ACP: Process for obtaining prescribing

2008: ACP: First pharmacist prescribers

2008-9: Eberhart G, personal communication 2017