

Engaging Community Providers and Patients in Clinical Research

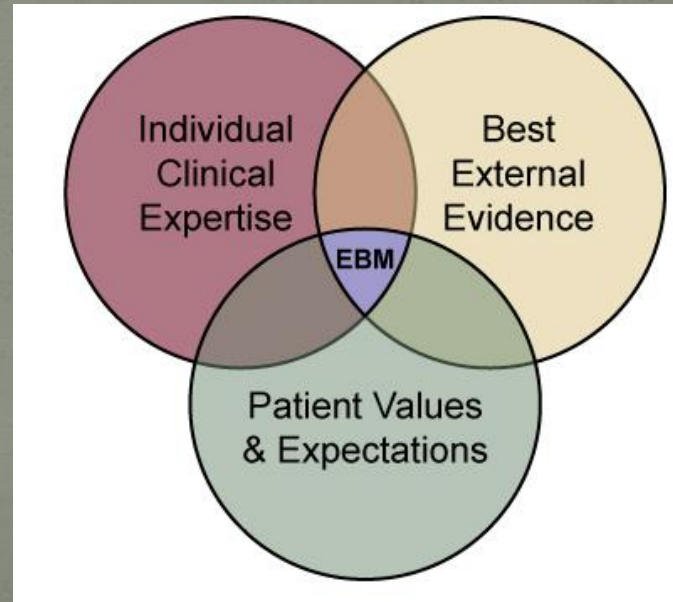
The **BedMed** Experience

Faculty / Presenter Disclosure

- Faculty: **Scott Garrison MD, PhD**
Assoc. Prof, U of A, Family Medicine
Director, Pragmatic Trials Collaborative
- Relationships with commercial interests:
 - Grants/Research Support: ∅
 - Speakers Bureau/Honoraria: ∅
 - Consulting Fees: ∅
 - Other: ∅



Full Time Fee-for-Service Family Physician (1st 20 Years)



The pivot point



Dr.
Garrison...
My cramps
are gone!

Rest Cramps

(Nocturnal Leg Cramps)



Rest Cramps

Coming soon to a leg near you!



Not only the elderly



Treatment?



Diltiazem

More/Less Salt

Drink more water

Verapamil

Stretch

Magnesium

Quinine

Calcium

Potassium

B Complex

Orthotics

Vitamin D

Gabapentin

More / Less Exercise

Magnesium



Magnesium



Research Question

Are magnesium supplements efficacious in providing rest cramp prophylaxis?

RCT



Research Question

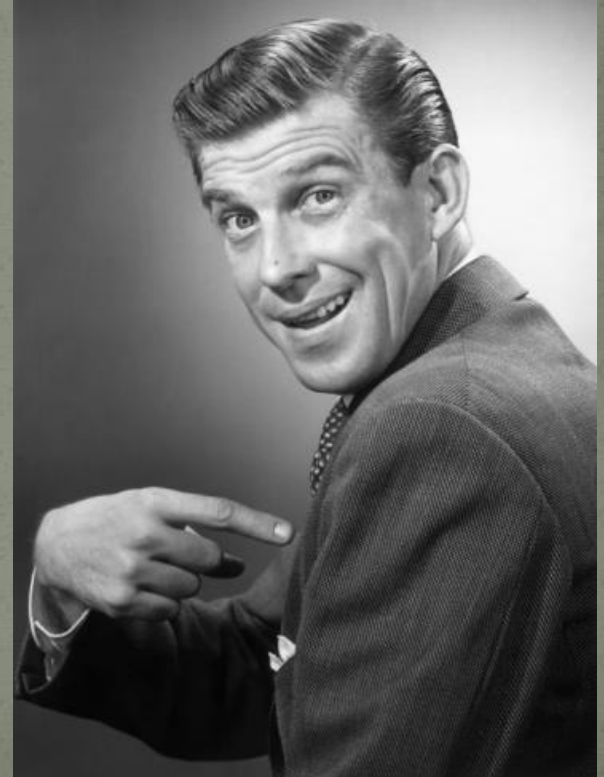
Are magnesium supplements efficacious in providing rest cramp prophylaxis?

RCT



How this relates to YOU...

- Common problem \neq common presentation
- Docs **will not dig** beyond the presenting problem
- “**Compelling**” is subjective
- Expecting Docs to recruit during normal patient care is asking for trouble





A dramatic sky scene featuring a bright sunburst effect with rays of light emanating from the center. The sky is filled with various cloud formations, including large, fluffy white clouds and darker, more textured clouds. The overall color palette is dominated by deep blues and bright whites, creating a high-contrast, ethereal atmosphere.

Data Heaven

A Learning Healthcare System



The big ask...



The big ask...



...the clear answer



Broad Base of Support

- BC Divisions of Family Practice Innovation Fund
- Richmond Family Physicians
- Vancouver Coastal Health Research Institute
- Richmond Hospital Foundation (Donation)



**Pragmatic
Trials Collaborative**

Measuring What Matters



The Pragmatic Trials Collaborative

Measuring What Matters



Physicians engaged ✓



What about Data?



Beware the unexpected...





Alberta

Freedom To Create. Spirit To Achieve.



If you build it...will they come?



INRange





Background
by "pragmatic" randomized trials that
therapeutics on patient-centered
and populations / care settings.
use management takes place in the
care providers and is the optimal
effectiveness research to take place
barrier to engaging clinicians.

Goals
1) Form a primary care-based clinical trial platform, the
Pragmatic Trials Collaborative
www.PragmaticTrials.ca
2) Engage primary care providers in research
physicians/nurses/pharmacists) by
address pivotal clinical questions
disrupting workflow

Beginnings: INRange
WHY: We began by building relationships with primary care providers in British
and Alberta who were interested in both our questions and our approach.
HOW: We conducted a pilot study ("INRange") to set up and refine the infrastructure
means that will become the foundation for how this network engages in research.
RESULTS: INRange had 236 providers participate from 53 Alberta and BC
sites.

Figure 1: Map of Alberta showing the number of providers participating in the INRange pilot study by region.

Region	Number of Providers
North	124
Central	345
South	30
West	7

Introduction
• Blood pressure (BP) normally exhibits a circadian rhythm
lower pressures during sleep.
• Lack of this sleep time "dip", in hypertensive patients,
correlates strongly with adverse cardiovascular events.
• A study looking at the effects of BP medication timing
61% reduction in adverse events for those taking medication
at bedtime versus those in the morning.

Study Design
Prospective Randomized Open Blinded End-Point (PROBE)
Setting: Primary care clinics across Alberta.
Procedures: Phone or online follow-up once consent
specific outcomes measures elicited. Study data is collected
and managed using REDCap electronic data capture
hosted by the Women & Children's Health Research Institute.

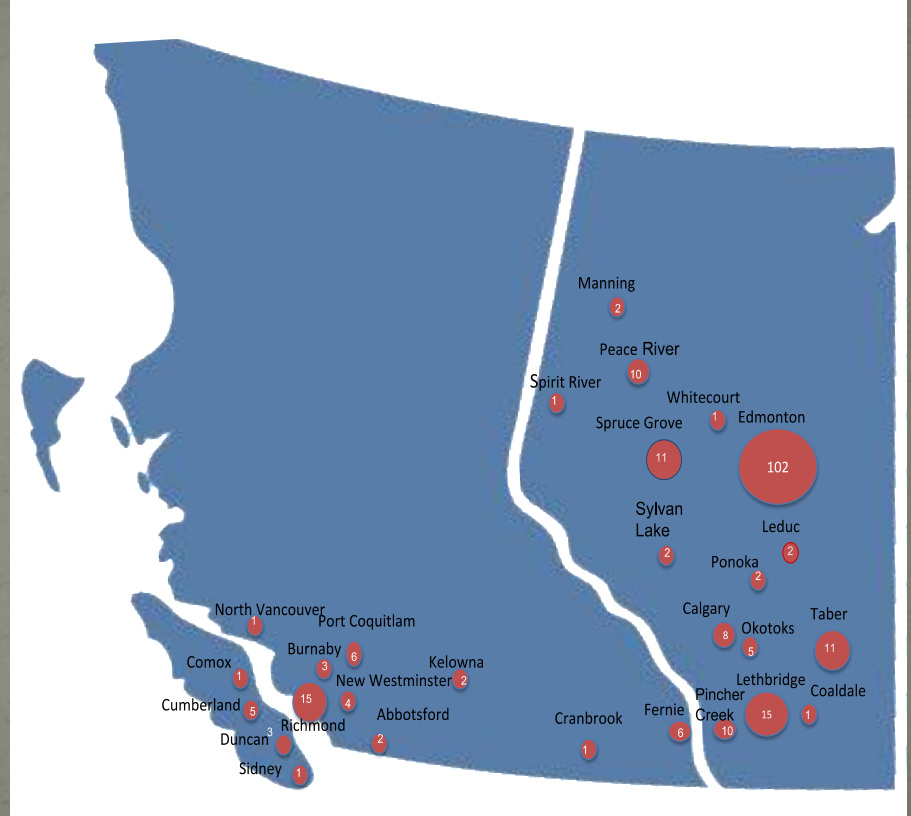
Outcome Measures:
Primary: Death, hospital admission, or emergency department
for acute coronary syndrome/MI, heart failure, or stroke.
Secondary: Each element of the primary outcome or
hospital admission; resource intensity weight & length
of stay; home admission; self-reported quality of life.

Results
referring providers. During the
initial pilot study, another 16
sites joined the study. (Fig. 1)
100 primary care providers across
practitioners and pharmacists). (Fig. 2)
led by Alberta Innovates, Canadian

Goals
determine if switching one or more BP meds to
offers important clinical outcomes
identify populations that might be put at risk by
minimization
determine whether diuretics can be successfully
without excessive visitation

INRange

- 236 Physicians Recruited (51 BC, 185 Alberta)
- 54 Communities (26 BC, 28 Alberta)
- Of those receiving letters 16.7% called to enroll
- Loss to follow-up and non-adherence 3.7%



INRange

- Every Pragmatic Trials Collaborative Physician brought in (on average) an **additional 1.6** physicians to participate.
- i.e. **Our members were recruiting their own officemates** to participate

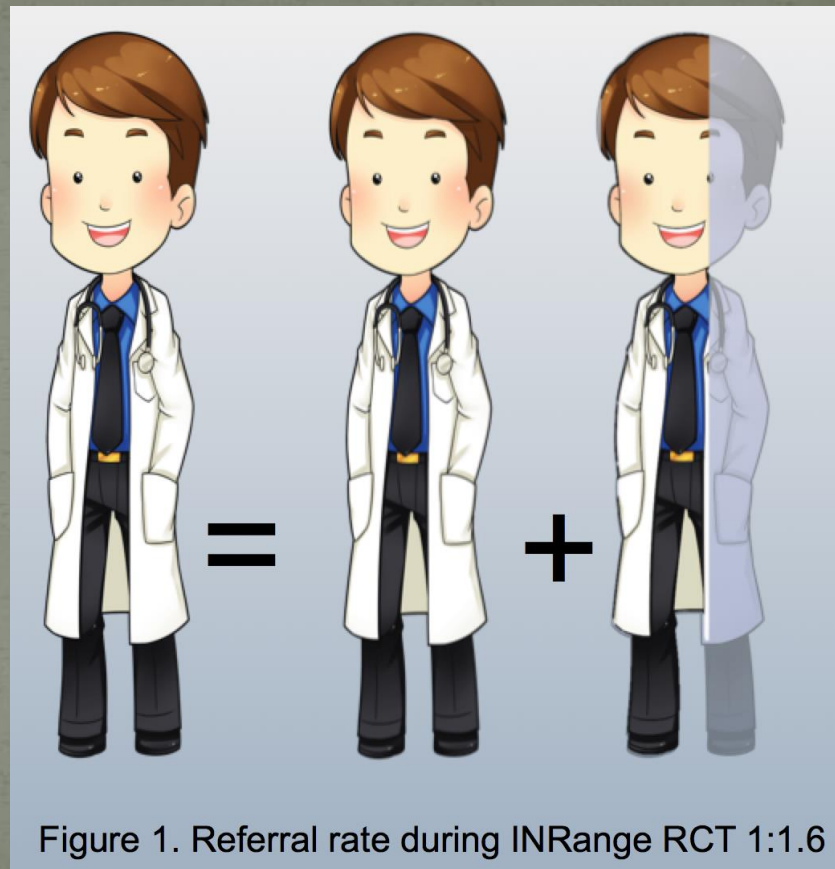
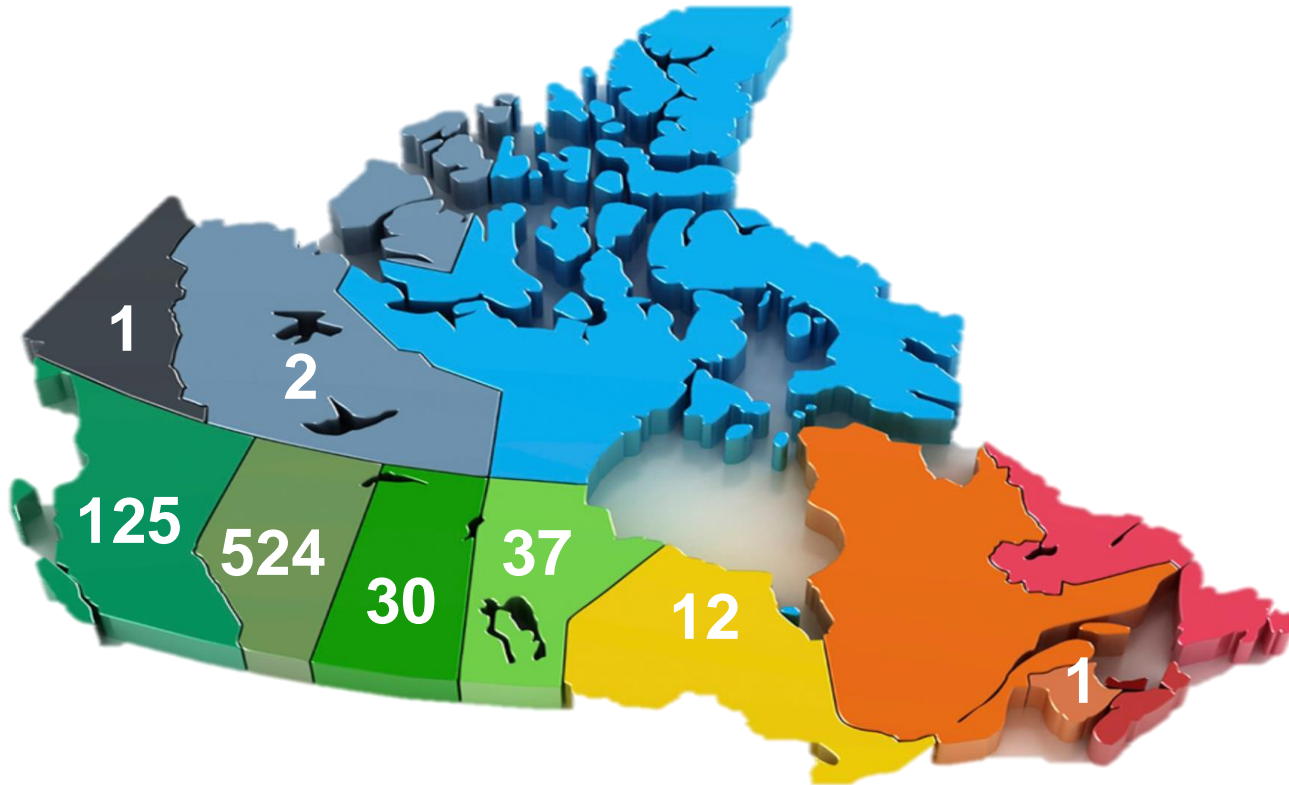


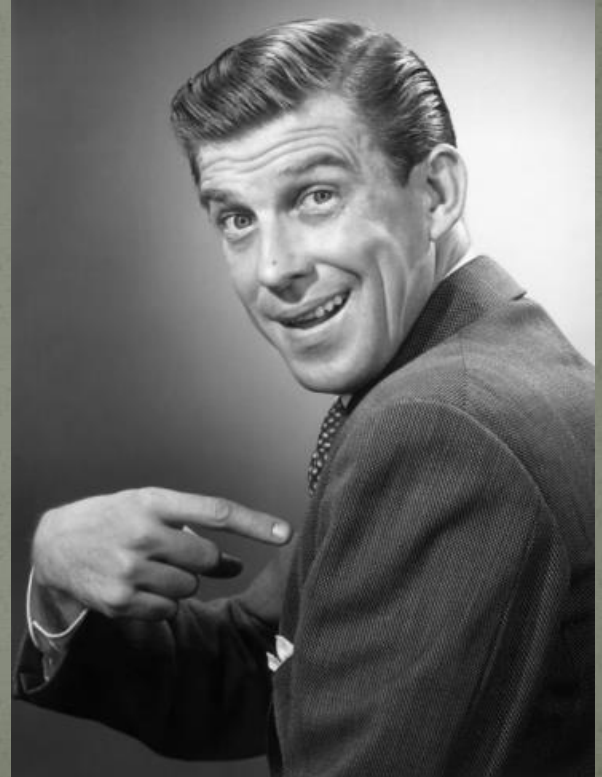
Figure 1. Referral rate during INRange RCT 1:1.6

Our Current Membership



How this relates to YOU...

- **Pilots** aren't compelling
- Docs **will participate** in large numbers if you make it easy and ask the right question
- Very **low loss to follow-up**
- **Running a study is a great way to grow a network!**



ALBERTA 
INNOVATES



CIHR IRSC

Canadian Institutes of
Health Research

Instituts de recherche
en santé du Canada



BedMed

- MAPEC:
 - 2010 Spanish RCT
 - 2,156 Patients x 5.6 years
- 61% reduction in a composite of mortality and cardiovascular morbidity if BP meds taken at bedtime



Making the Case

- Cost Utility Analysis (Markov)
 - 6,943 fewer deaths, 5,550 fewer strokes, 8,448 fewer CHF admissions, 16,418 fewer ACS admissions
 - Discounted lifetime savings of 8.8 billion (current cohort)
 - Life expectancy ↑5.5 years



Making the Case

- New & Unique Research Capacity
 - Many clinicians participating in research for the **first time**
 - Most **remote** from academic centres
- Multiprovincial Network
 - Alberta (SPOR)
 - BC (SPOR)
 - Manitoba (MCHP)



Methods

- Randomized registry trial with admin data outcomes
- 8750 Participants (approx. 3-4 years)
- Event Driven (406 PO)
- Quarterly reporting
- Cochrane IDSMB
- Volunteer Docs
- MOA 25¢/letter
- Online consent



Methods

- Key Outcomes
 - Mortality / Morbidity
 - Independence
 - Costs
- Safety Outcomes
 - Fractures
 - Vision
 - Cognition



Patient Engagement

- 10 member Patient Working Group
- Redrafted all materials
- New Objective
 - Can diuretics be taken at bedtime without causing or worsening nocturia?





Current Status

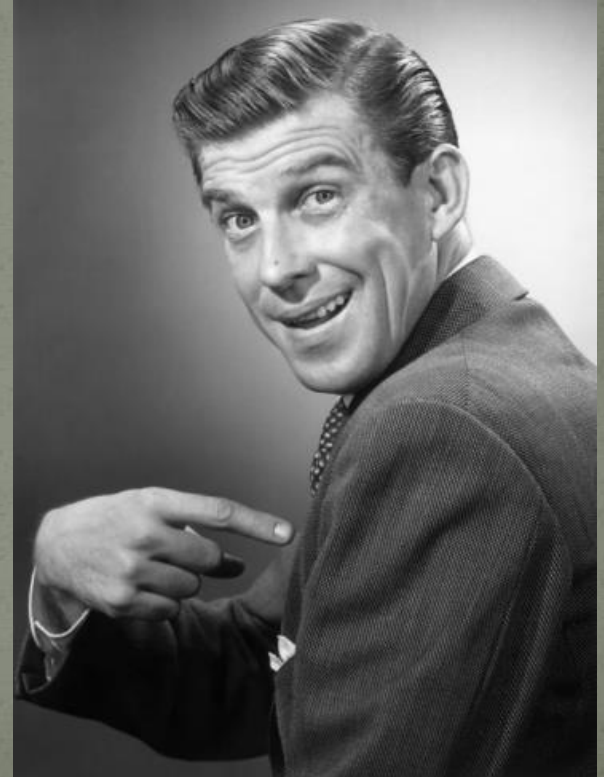
- 219 AB Docs have mailed
- 0.62 office mates
- 1655 randomized pts
 - 66.7 yrs
 - 36.3% rural
 - 19.4% physically frail
 - 23.3% ≥ 6 total Rx
- 79% online consent
- 68% online follow-up for 6 months onward
- Saskatchewan?
- 100 letters mailed per clinic (expected 200)
 - **Telus** pushing EMR query to 50% of Docs
 - **Alberta Health** providing patient lists
 - **CPCSSN** Central Query
- 4% \rightarrow 8% recruitment rate (expected 12%)
 - Remove **consent** / **single page**
 - **Habit** social media campaign

BedMed Social Media Campaign



How this relates to YOU...

- Remove the consent forms from mailouts
- Most pts choose online follow-up
- For physicians, an in person pitch is needed
- Pilot for patient response
- Evolve recruitment info (RCT within the RCT)



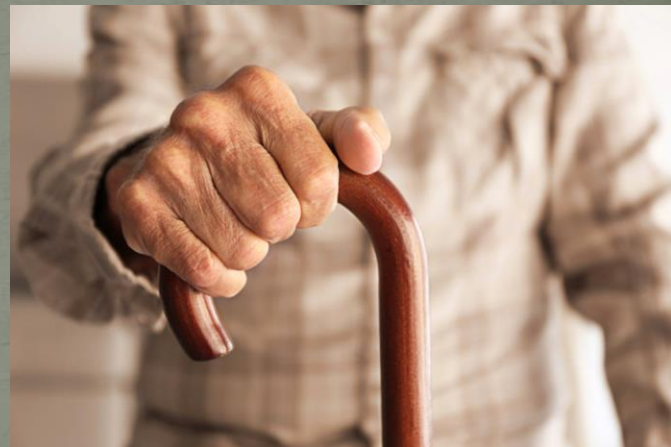
Time Trial

- UK Clinical Research Networks (paid physicians)
 - NIHR Clinical Research Network
 - Scottish Primary Care Research Network
- >8000 physicians → 21,116 pts / 16 months
- Internet based interactions only (younger)
- BID medication users excluded
- 2.7% response to GP letter, 4.1% Biobank
- Social media unhelpful



BedMed-Frail

- Long Term Care Facilities
 - Institute for Continuing Care Education and Research (ICCER)
- ≥ 30 Clusters of 50-100 residents
- 40 participants per cluster (1200 patients total) over roughly 2-3 years to observe 368 primary outcomes
- Hinges on a waiver of consent





RELATIONSHIPS: We began by building relationships with primary care providers in British Columbia and Alberta who were interested in both our questions and our approach.

PILOT STUDY: We conducted a pilot study ("INRange") to set up and refine the infrastructure and processes that will become the foundation for how this network engages in research.

PROVIDERS: INRange will engage and participate from 53 Alberta and BC communities.

Prospective Randomized Open blinded End-Point (PROBE)

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