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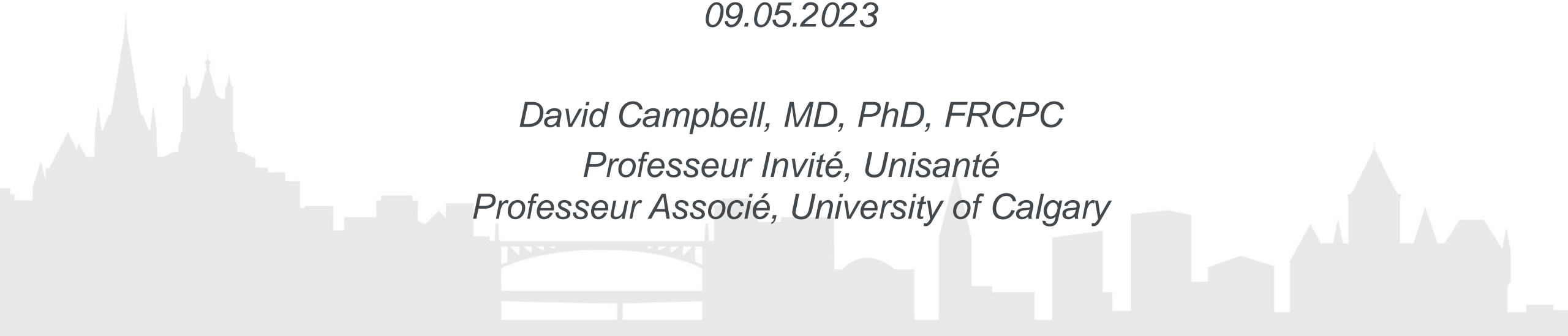
Les essais randomisés contrôlés en politiques de santé pour adresser les déterminants sociaux de la santé

09.05.2023

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Professeur Invité, Unisanté

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Definitions and Terms

Policy

- A guide, course of action, set of rules
- Emphasizes purpose, intention, goals, means
- No universal definition

Public Policy

- A course of action by public authorities to address an identified issue

Health Policy (public health policy & health care policy)

- A course of action related to the health/healthcare of the public

Levels of Policy

- MACRO - high-level, broad, international/national/provincial (financing of health care systems)
- MESO - mid-level, organizational (healthcare insurance policies and coverage decisions)
- MICRO - local-area, individual focus (local programs and offerings chosen over others)

Effective and coherent linkage of levels matters

Health Policy Formulation

What are the drivers/ determinants?

- Health need
- Economics
- Legal
- Social (socio-demographic)
- Ethical & moral
- Others- new **evidence**, environment etc



What kind of evidence influences policy?



What is Evidence?

- ▣ Facts (actual or asserted) intended for use in support of a conclusion
- Perspective matters
 - > Clinicians
 - > Decision-makers
 - > Researchers
 - > Lawyers and judges

Nature of Evidence

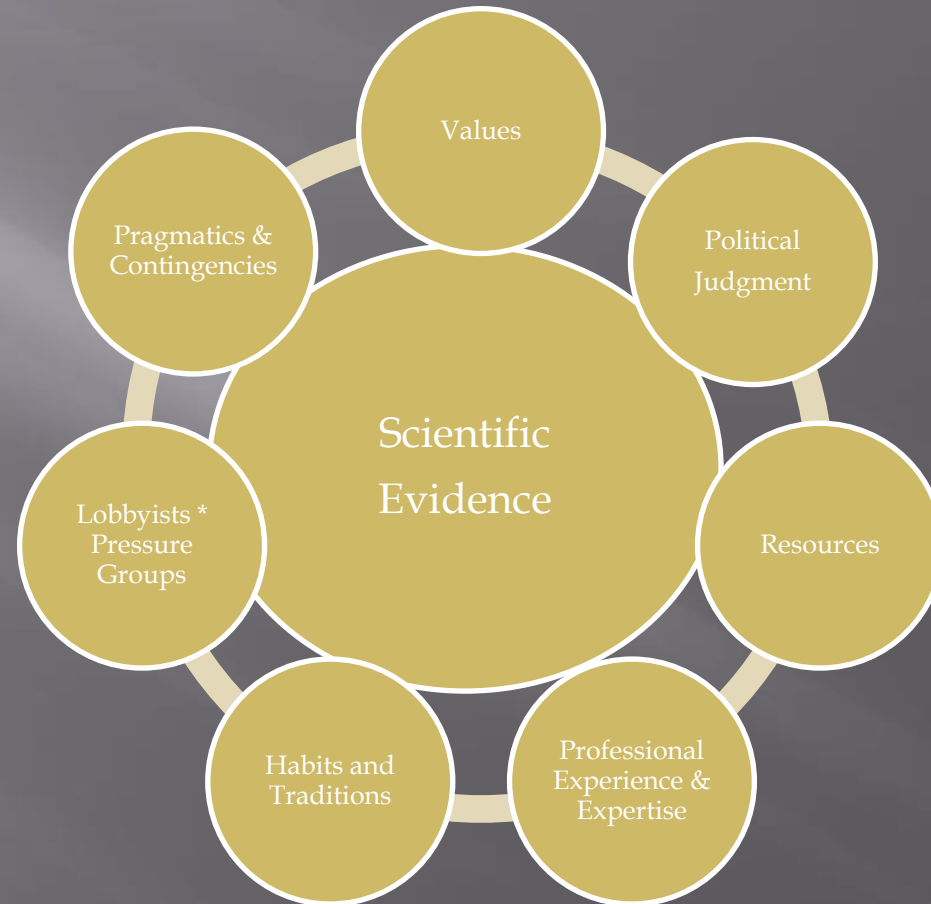
Scientific

- Context-Free – Biomedical Tradition
- Context-Specific – Social Science Tradition

Colloquial

- Stories, Expert Opinion, Political Judgment etc.

Types of Colloquial Evidence Available for Health System Guidance



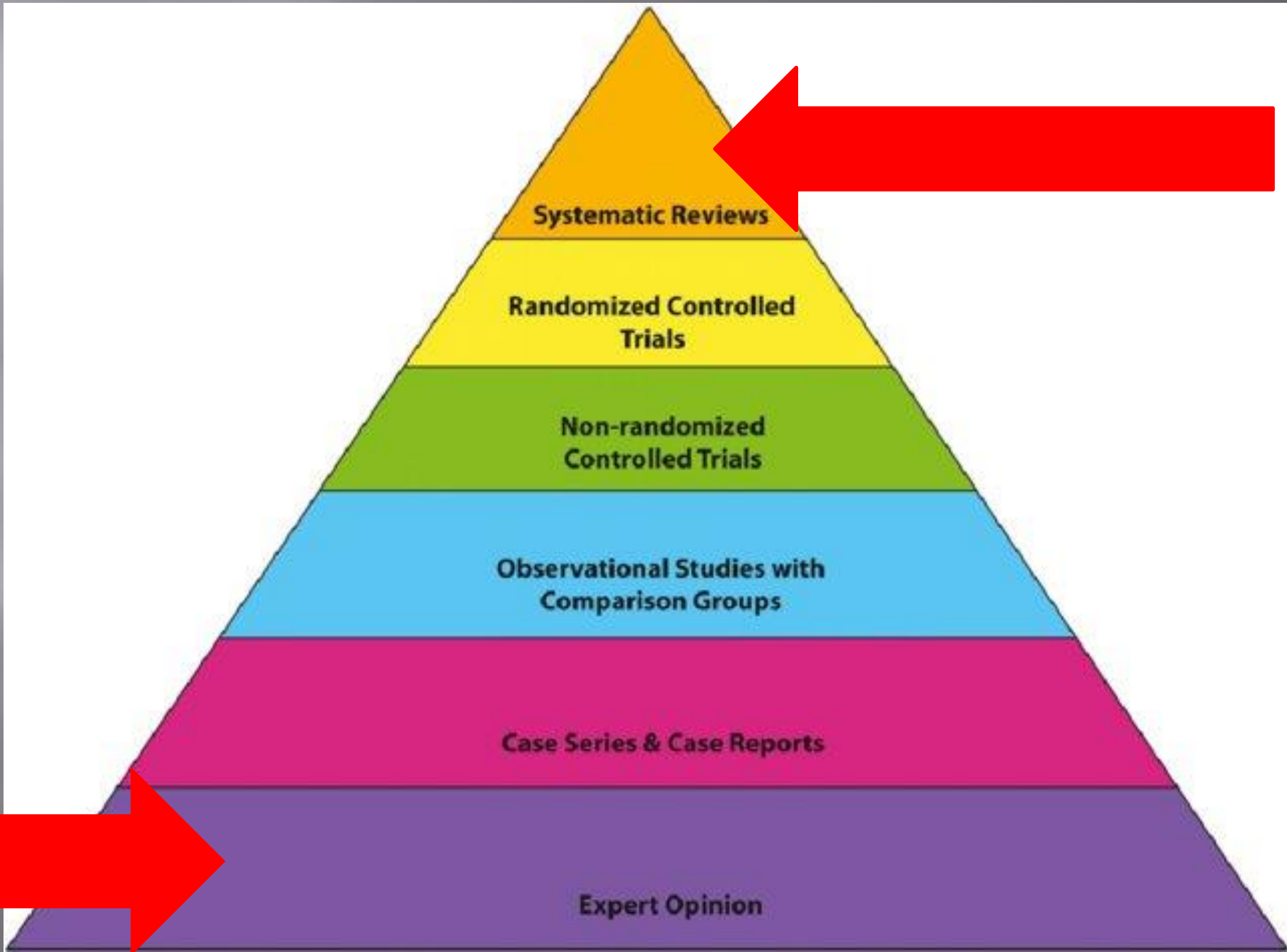
Health Policy Formulation

What are the drivers/ determinants?

- Health Need
- Economics
- Legal
- Social (socio-demographic)
- Ethical & moral
- Others- **evidence**, environment etc

Combining Evidence to Inform Policy

- Often not quantitative or usual systematic review
- Inclusiveness of all evidence necessary
- Context and perspective matters
- Interpretation is necessary
- Risk of bias from interpretation/perspective
- Evidence-informed 'judgment' often requires a deliberative process



Knowledge Transfer for Health Policy

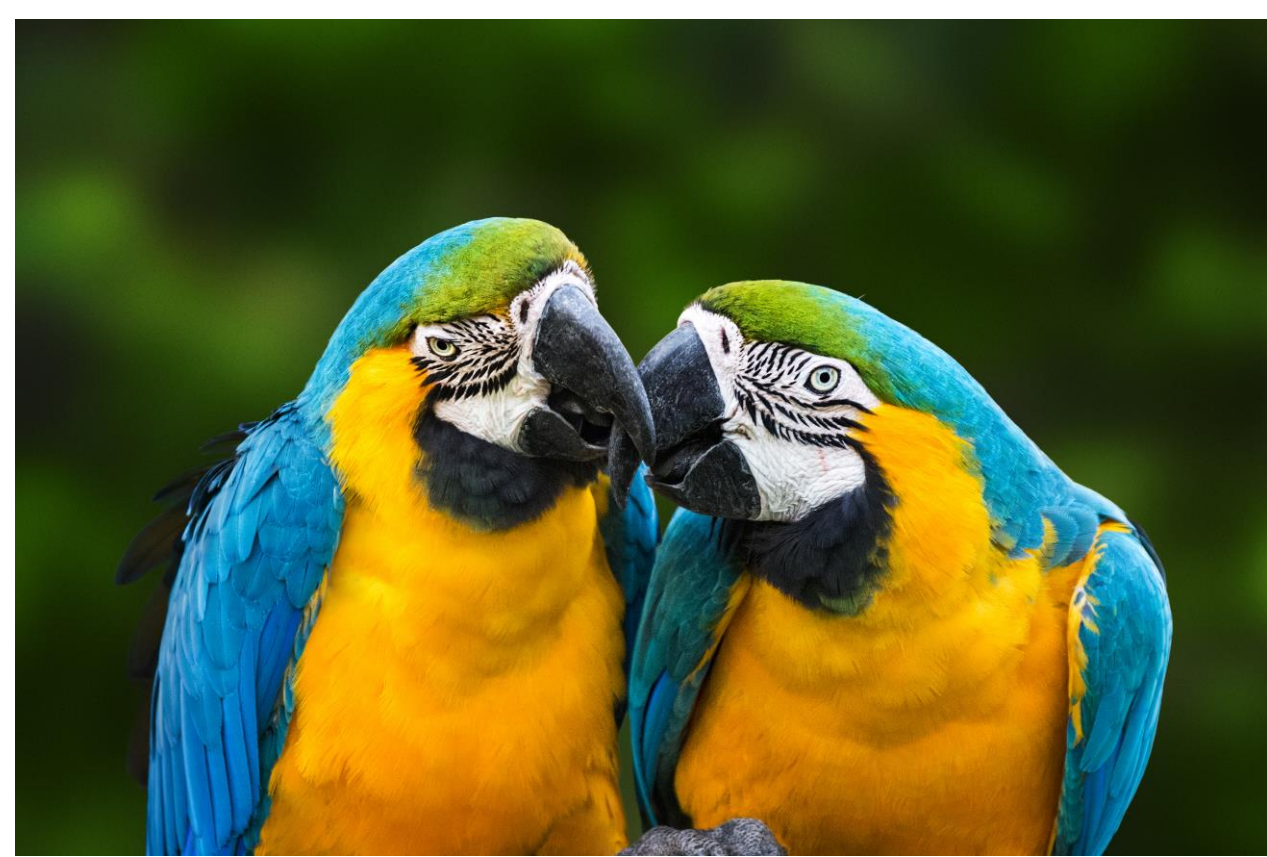
- ▣ Producer push
- ▣ User pull
- ▣ Linkage and exchange
- ▣ The embedded researcher

What is a policy trial?

Tests which social, economic, and health care interventions improve *health*.

And *why*.





How is it different from a clinical trial?

REVIEW ARTICLE

THE CHANGING FACE OF CLINICAL TRIALS

Jeffrey M. Drazen, M.D., David P. Harrington, Ph.D., John J.V. McMurray, M.D., James H. Ware, Ph.D.,
and Janet Woodcock, M.D., *Editors*

Health Policy Trials

Joseph P. Newhouse, Ph.D., and Sharon-Lise T. Normand, Ph.D.

Health Policy Trials vs. Clinical Trials

As is apparent from the foregoing discussion, trials in the policy sphere pose many of the same issues for design and analysis as clinical trials. There are also important differences. The use of cluster designs is probably more common in policy trials. Unlike clinical trials, policy trials may arise opportunistically, as in the case of the Oregon experiment. Because there is no legal requirement to conduct a policy trial and generally no commercial gain to be had from it, obtaining funding for policy trials is more challenging. Health policy trials are complex and can be difficult to execute. Thus, they resemble trials of treatment or diagnostic strategies more than trials of drugs or devices. Nonetheless, randomization can be and has been successfully conducted in the sphere of policy.



<p><u>Can</u> treatment work? → EFFICACY</p> <ul style="list-style-type: none"> - Hypothesis testing - Ideal circumstances 	<p><i>WHAT?</i></p>	<p><u>Does</u> treatment work? → EFFECTIVENESS</p> <ul style="list-style-type: none"> - Comparing treatment strategies - Usual care
<p>Assess <u>cause – effect</u> of drug</p>	<p><i>WHY?</i></p>	<p>Inform <u>decision makers</u></p>
<p><u>Minimize</u> variation:</p> <ul style="list-style-type: none"> - Rigid protocol 	<p><i>HOW?</i></p>	<p><u>Maximise</u> generalisability:</p> <ul style="list-style-type: none"> - Protocol reflecting usual care
<p><u>Selective</u> inclusion</p>	<p><i>WHO?</i></p>	<p><u>Broad</u> inclusion</p>
<ul style="list-style-type: none"> - Data collection > usual care - Outcomes <u>research</u> relevant 	<p><i>METHOD?</i></p>	<ul style="list-style-type: none"> - Data collection = usual care - Outcomes <u>clinically</u> relevant

Why do policy trials need special support?

Complex

Not legally required

Hard to get funding

Stakeholder engagement

Eyes on the prize

A Randomized Trial Assessing The Impact Of Eliminating Copayment For High Value Preventive Medications and a Novel Tailored Self-Management Education and Support Program For Low-income Seniors With Cardiovascular-related Chronic Diseases

David Campbell, Chad Mitchell, Brenda Hemmelgarn, Marcello Tonelli, Peter Faris, Jianguo Zhang, Ross T. Tsuyuki, Jane Fletcher, Scott Klarenbach, Derek V. Exner, Braden Manns


University of Calgary, Calgary, Canada



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Self-management Support Using Advertising Principles for Older Low Income Adults at High Cardiovascular Risk: a Randomized Controlled Trial


David J.T. Campbell, Marcello Tonelli, Brenda R. Hemmelgarn, Peter Faris, Jianguo Zhang, Flora Au, Ross T. Tsuyuki, Chad Mitchell, Raj Pannu, Tavis Campbell, Noah Ivers, Jane Fletcher, Derek V. Exner and Braden J. Manns 
and for the Interdisciplinary Chronic Disease Collaboration

Originally published 5 Mar 2023 | <https://doi.org/10.1161/CIRCULATIONAHA.123.064189> | Circulation. 2023;0

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Eliminating Medication Copayments for Low-income Older Adults at High Cardiovascular Risk: A Randomized Controlled Trial

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Originally published 5 Mar 2023 | <https://doi.org/10.1161/CIRCULATIONAHA.123.064188> | Circulation. 2023;0

Background

- One in eight people with heart disease has poor medication adherence - in part related to copayment costs
- Most individuals with medication insurance are subject to some form of cost-sharing - typically 20-30%
- While some patients lack the financial resources to allow adherence, others lack the requisite knowledge and/or motivation to engage in prevention

Hypothesis: addressing these two barriers to medication adherence could result in a small but meaningful improvement in adherence to effective medications and improved clinical outcomes

Methods - Objectives

- The ACCESS study* tested the impact of two interventions in low-income older adults at high cardiovascular risk on cardiovascular outcomes, mortality and hospitalizations for cardiovascular-related ambulatory care-sensitive conditions over a 3-year follow-up period

Two interventions tested within a factorial trial:

- **a value-based formulary that eliminated copayment for 15 classes of medications commonly used to lower cardiovascular risk, compared with usual copayment, and**
- **a comprehensive, novel brand engagement and self-management support program aimed at promoting health behavior change**

*ACCESS study - **Assessing outcomes of enhanced Chronic disease Care through patient Education and a value-based formulary Study**

Methods – Eligibility Criteria

- community-based participants living in Alberta, Canada.
- Inclusion criteria:
 - age \geq 65 years
 - coverage by provincially-sponsored seniors' medication insurance
 - high cardiovascular risk based on one or more of (coronary artery disease, stroke, chronic kidney disease, or heart failure) OR two or more of (current smoking, diabetes, hypertension, or high cholesterol)
 - household income <\$50,000 CAD/y.
- Exclusion criteria:
 - additional insurance coverage that reduced cost sharing
 - receiving medications administered by a nurse or facility
 - or the inability to participate in self-management modules due to cognitive impairment or a language barrier

Methods - Intervention 1

- Intervention – no copayments for 15 classes of preventive medications commonly used to reduce cardiovascular risk – implemented through their usual pharmacy / existing government-sponsored medication insurance plan.

Antiarrhythmics	Nitrates & nitrites	Statins	Non-statin Cholesterol lowering drugs	Beta blockers
ACE-inhibitors	Angiotensin receptor blockers	Calcium Channel blockers	Diuretics	Other blood pressure medication
Anticoagulants	Anti-diabetes medication	Ant-platelet agents	Insulin	Smoking cessation aids

- Control arm (usual copayment) usual universal public pharmaceutical insurance plan for seniors - 30% copayment to a maximum of \$25 CAD per prescription.

Methods - Intervention 2



- Control arm (usual care) health education from their usual care provider plus addition of a quarterly general health magazine.

Weekly Mailers

As you get older you realize that no one has all the answers. But there are some common items and advice that are passed along the generations, and still seem relevant no matter what the century.

When President Franklin Roosevelt took the stand wearing a morning coat over striped trousers for his inauguration as the 32nd president of the United States, there's no way he could have known the influence the first few lines of his speech would have almost 100 years later.

Those lines were:

"So, first of all, let me assert my firm belief that the only thing we have to fear is... fear itself- nameless, unreasoning, unjustified terror which paralyzes needed efforts to convert retreat into advance." - March 4, 1933.

These were iconic words whose meaning can apply to fears of both internal and external threats. But this wasn't a verse Roosevelt pulled from thin air.

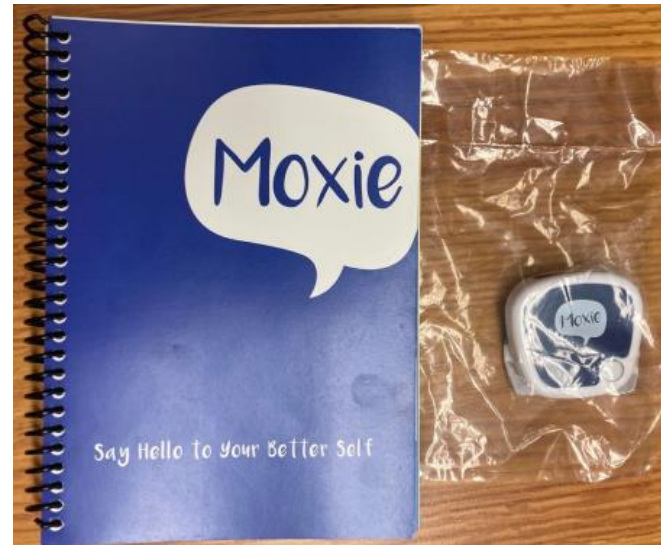
Three hundred years earlier, an English philosopher put down this sentiment on paper for the first time, or something quite close to. He is commonly considered a father of modern science, and this was on his mind when he sat down and wrote:

"Nothing is terrible except fear itself." - 1623.

This was found in Bacon's De Augmentis Scientiarum or Partitions of the Sciences, a volume in a series written in pursuit of looking to science over religion in understanding the world. It's six book format is designed to mimic the six days of the creation story in the Old Testament.

It might be helpful to keep these quotes in mind when living with a chronic condition. Many times, symptoms noticed or side effects feared are the most dangerous when they stop us from living our life well, taking medication, and simply enjoying ourselves.

Periodic Gifts



Web-portal & 2x weekly emails

NOTICES 2 AWARDS 1

Hi, Liz Admin

TOTAL 440

Moxie sends points your way whenever you do something to make your day a little bit healthier, like eating well, exercising, taking medication and logging on to check in. And, just like in real life, your choices add up.

MY AWARDS TODAY - NOVEMBER 4, 2015

	Making the Most of Your Medicine - 04 November, 2015 Thanks for taking your medicine. You're on the right track!	+100
	Make the Most of Moxie - 04 November, 2015 Thank you for letting Moxie know that you took your medicine. Keep it up!	+100
	Know Your Food - 04 November, 2015 Oo is la! Great food choice, keep things rolling!	+100
	And We're Off! - 04 November, 2015 You're off to a great start! Flip another card to keep the momentum rolling!	+100

LOOK AT THAT GREAT TRACK RECORD

OVERVIEW OF ALL AWARDS

Facilitated Relay

Dear Pharmacist,

Your patient, [full name], has enrolled in the **ACCESS trial: Assessing outcomes of enhanced Chronic disease Care through patient Education and a value-based formulary Study**, a randomized clinical trial based out of the University of Calgary. This is an investigator-initiated trial with no funding or association with the pharmaceutical industry.

Your patient has been randomly selected to use **MOXIE: a patient health + wellness support platform**. **MOXIE** will encourage them to live a healthier lifestyle and follow your good advice in their everyday lives.

As you know, [full name] is at high risk of heart disease, strokes and other problems because of their medical history and risk factors. Over the coming months and years, your patient will receive scheduled messaging to help them understand the importance and role of preventive medications, specifically **statins** and **ACE inhibitors/ARBs** – which your patient told us they were already taking. In accordance with all major clinical practice guidelines, these medications are cornerstones of therapy for patients with and at risk of cardiovascular disease. The goal of **MOXIE** is to help [first name] stay on track, adhere to therapy, and make healthier decisions that make sense for them.

We recognize the importance of the relationship that you have with your patients – and that a technological platform such as **MOXIE** certainly cannot replace the influence that you have on patients' lives and decisions. We hope that **MOXIE** can work with you towards improved health for [full name]. Our messaging may occasionally ask [first name] to seek your advice and input on various aspects of their cardiovascular health.

Finally, we know that pharmacists are an important member of a patient's health care team. We are aware that medication reconciliation by pharmacists has been demonstrated to reduce adverse events and improve outcomes¹. We encourage you to book a comprehensive medication review with [insert name], which as you know, is now a billable service in Alberta. Depending on their needs, it may also be very helpful to schedule regular reminders when [first name] is due for medication refills.

For more information about **MOXIE** and the **ACCESS** trial, please contact our project coordinator at 1-844-310-0585 (Toll Free).

Thanks!

Braden Manns, MD, FRCPC, University of Calgary
& the **MOXIE** Team

Methods - Outcomes

- **Primary outcome** - composite rate of all-cause mortality, MI, stroke, coronary revascularization, and hospitalizations for cardiovascular-related ambulatory care-sensitive conditions (i.e., heart failure, coronary artery disease, diabetes, hypertension, and chronic kidney disease)
- **Secondary outcomes**
 - individual components of the primary endpoint *
 - medication adherence (Proportion of days covered (PDC80))
 - overall quality of life (EQ-5D index score) (survey baseline and end of study)
 - overall healthcare costs

* Measured using validated algorithms applied to provincial administrative health data

Methods - Randomization and analysis

Randomization:

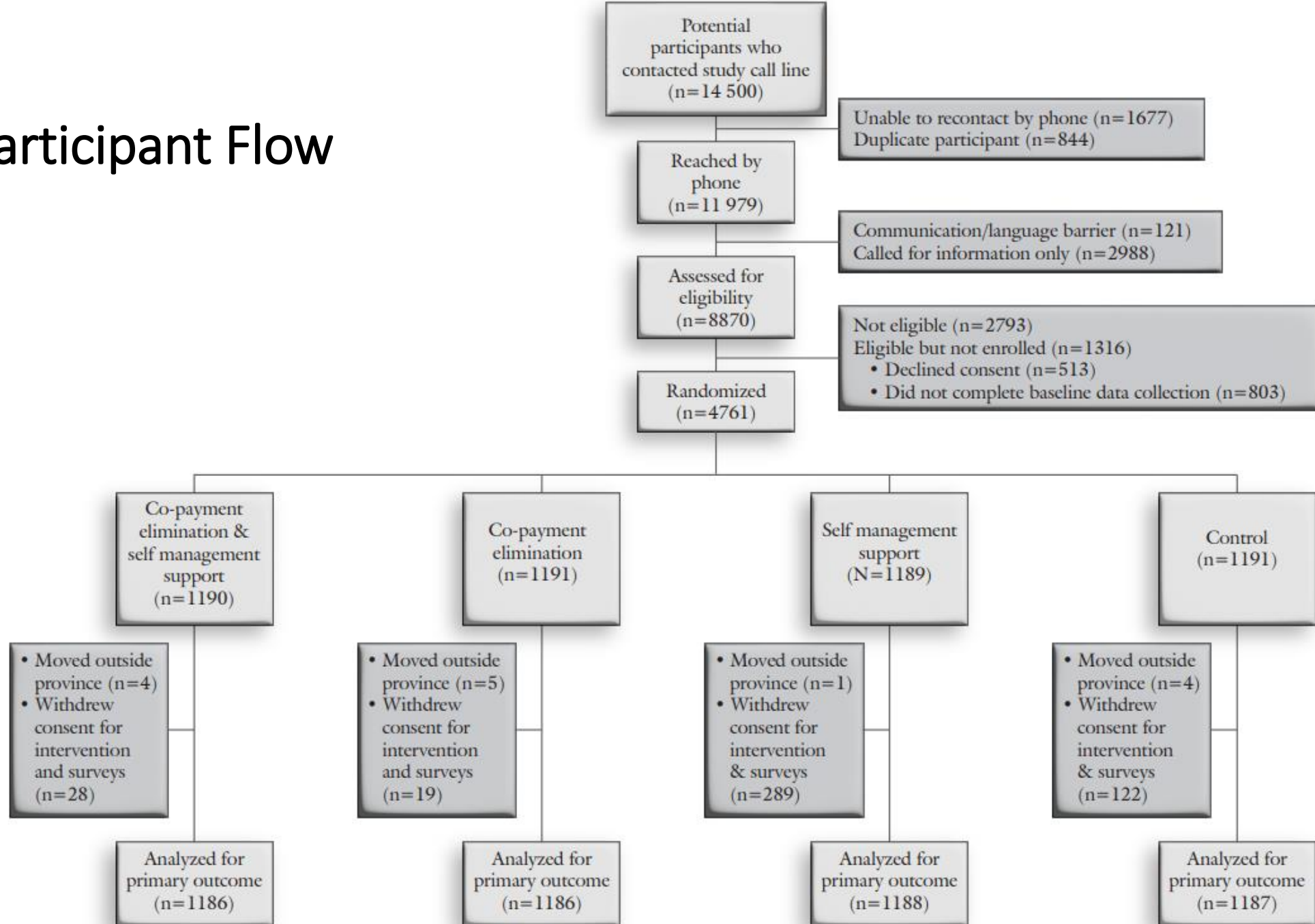
- 1:1:1:1 randomization (using variable block sizes)
- stratified by age (< / \geq 70 years); annual income (< / \geq \$30,000); and sex

Statistical Analysis:

- negative binomial model for the primary outcome
- Participants with statin supplies to cover ≥ 80 % of observed treatment days were considered adherent (PDC 80)
- Mixed models to compare EQ-5D index scores
- All analyses - intention to treat principle

Results

Participant Flow



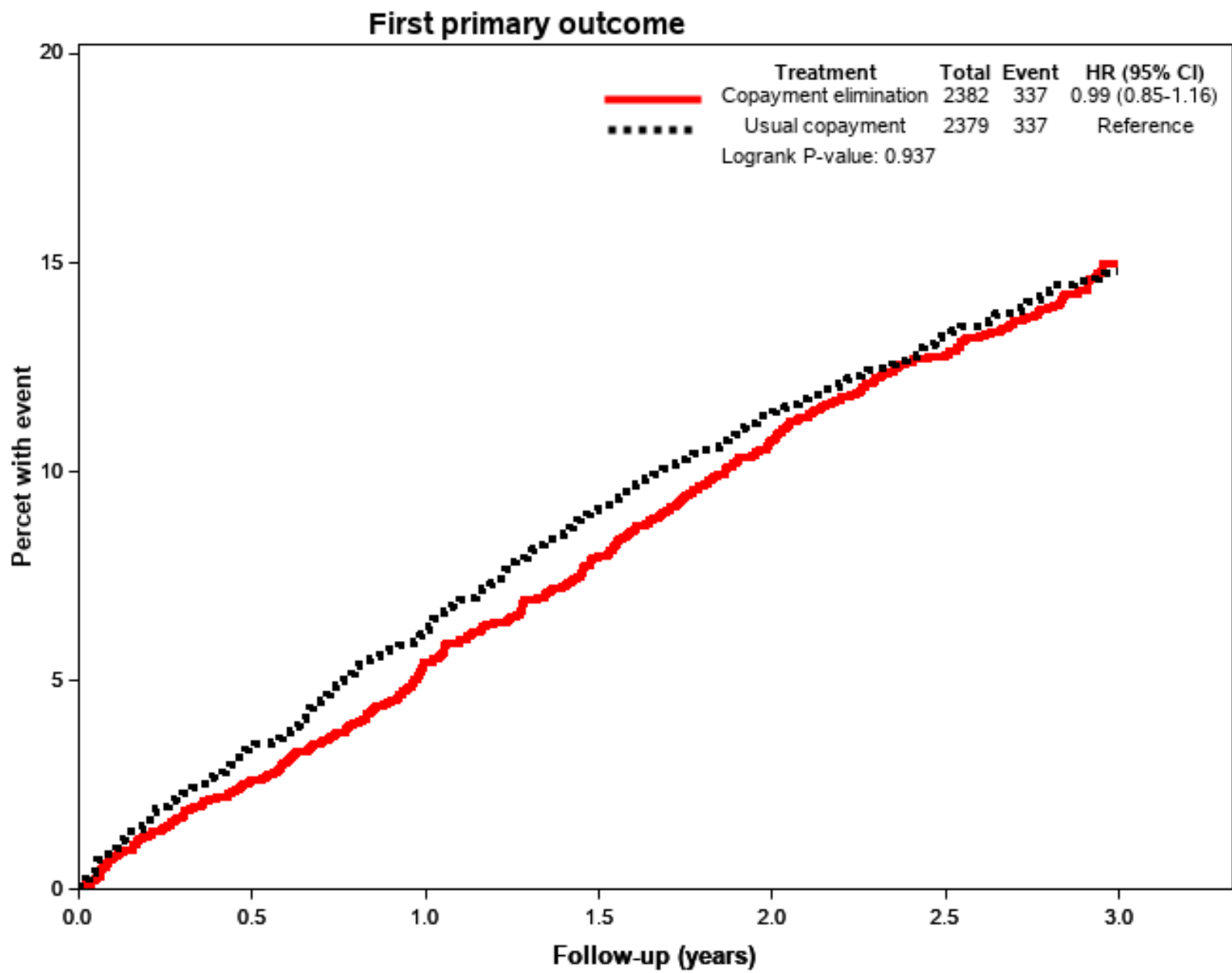
Baseline patient characteristics

Characteristic		Copayment elimination (n=2382)	Usual copayment (n=2379)
Age group, (n%)	65-70	632 (26.5)	633 (26.6)
	70-75	656 (28.8)	673 (28.3)
	75-80	563 (23.6)	519 (21.8)
	>80	201 (21.0)	554 (23.3)
Sex	Female	1113 (46.7)	1113 (46.8)
	Male	1269 (53.3)	1266 (53.2)
Income	Less than \$15,000	264 (11.1)	250 (10.5)
	\$15,000 - \$29,999	1109 (46.5)	1120 (47.1)
	\$30,000 - \$50,000	1009 (42.4)	1009 (42.4)
Coronary Artery Disease	No	1231 (51.7)	1135 (47.7)
	Yes	1151 (48.3)	1244 (52.3)
Heart Failure	No	1699 (71.3)	1761 (74.0)
	Yes	683 (28.7)	618 (26.0)
Diabetes	Yes	1055 (44.3)	1061 (44.6)
	No	1327 (55.7)	1317 (55.4)

I1: Primary outcome (over median follow-up of 3 years)

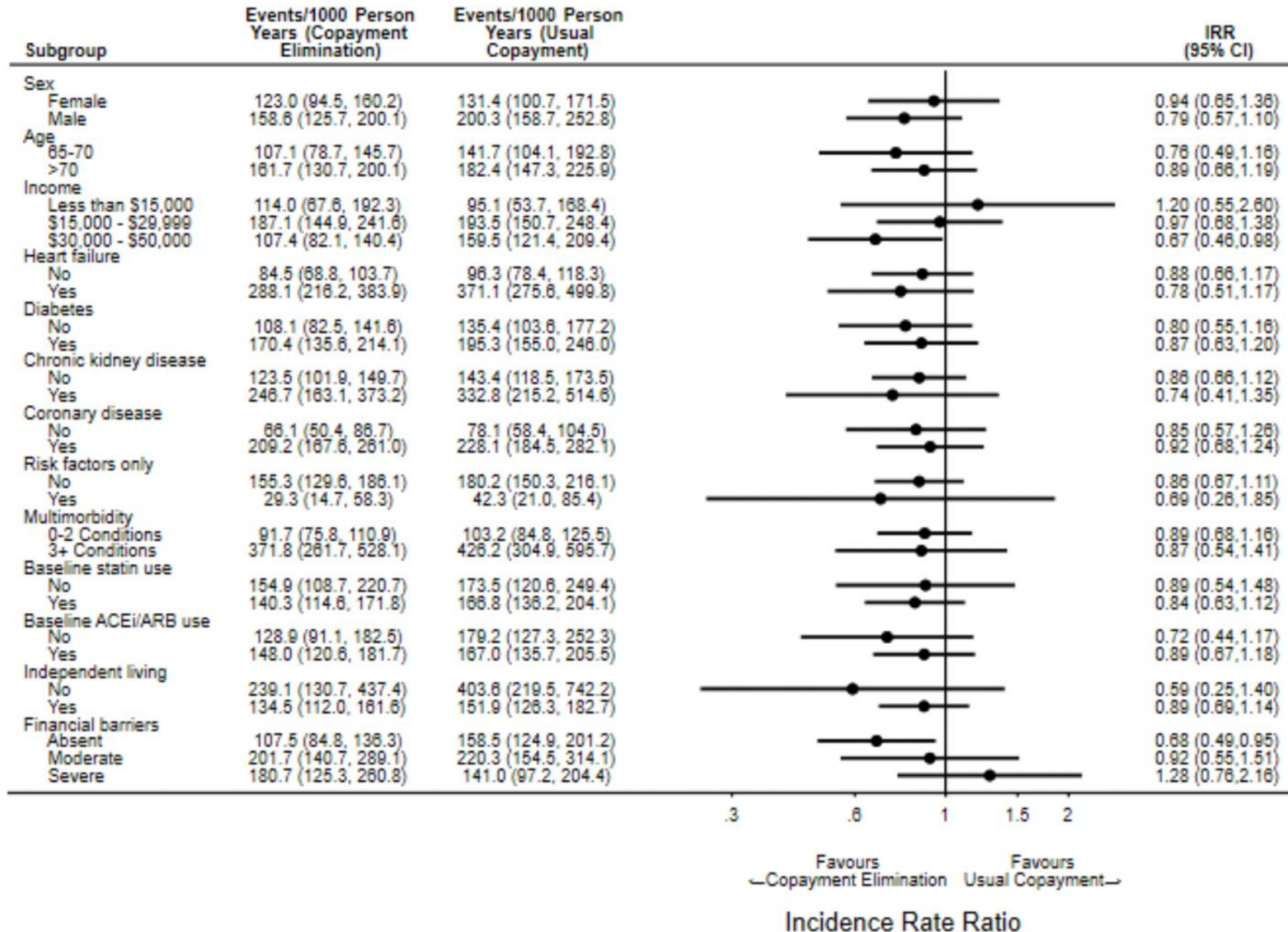
Outcome	Copayment elimination (n=2382)		Usual copayment (n=2379)		Incidence rate ratio (95% CI)	P-value
	Events (n)	Adjusted event rate per 1000 person years	Events (n)	Adjusted event rate per 1000 person years		
Primary composite outcome	521	135 (114,161)	533	161 (135,192)	0.84 (0.66,1.07)	0.16
Major adverse cardiovascular events (non-fatal MI, non-fatal stroke, CV death)	169	40.4 (31.1,52.6)	157	41.9 (31.6,55.6)	0.97 (0.67,1.39)	0.85
All-cause death	282	40.6 (36.0,45.8)	298	43.0 (38.3,48.3)	0.94 (0.80,1.11)	0.50
Number of cardiovascular-related hospitalizations	287	67.8 (54.0,85.0)	311	87.3 (69.5,109.6)	0.78 (0.57,1.06)	0.12

Time-to-first event analyses, Kaplan-Meier Curves



Number at Risk (No. Cumulative Events)							
Copayment elimination	2382 (0)	2296 (61)	2203 (127)	2105 (185)	2004 (249)	1912 (293)	1414 (337)
Usual copayment	2379 (0)	2270 (81)	2186 (145)	2084 (212)	1996 (264)	1916 (306)	1430 (337)

Prespecified subgroup analyses – Intervention 1



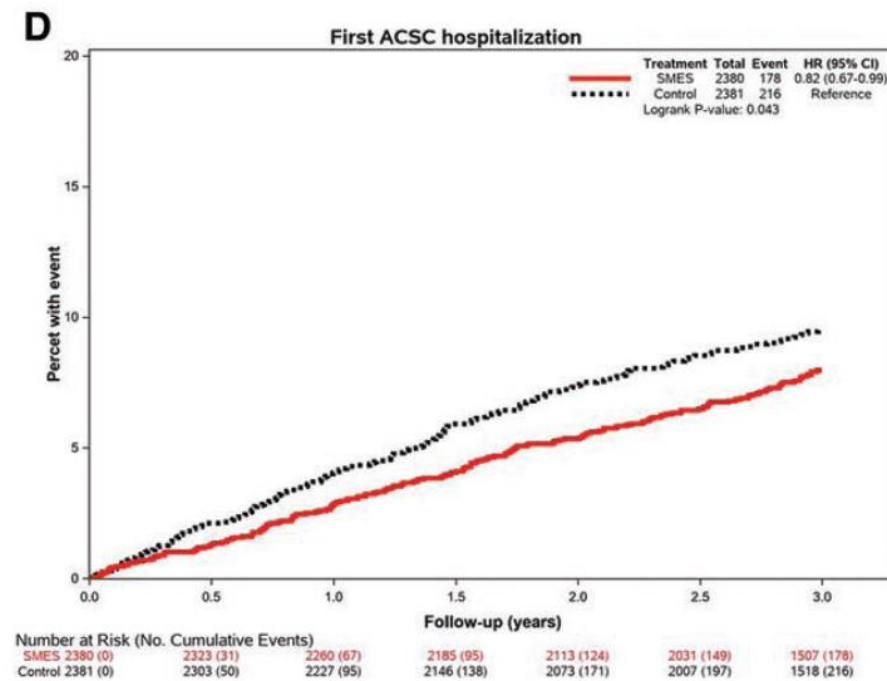
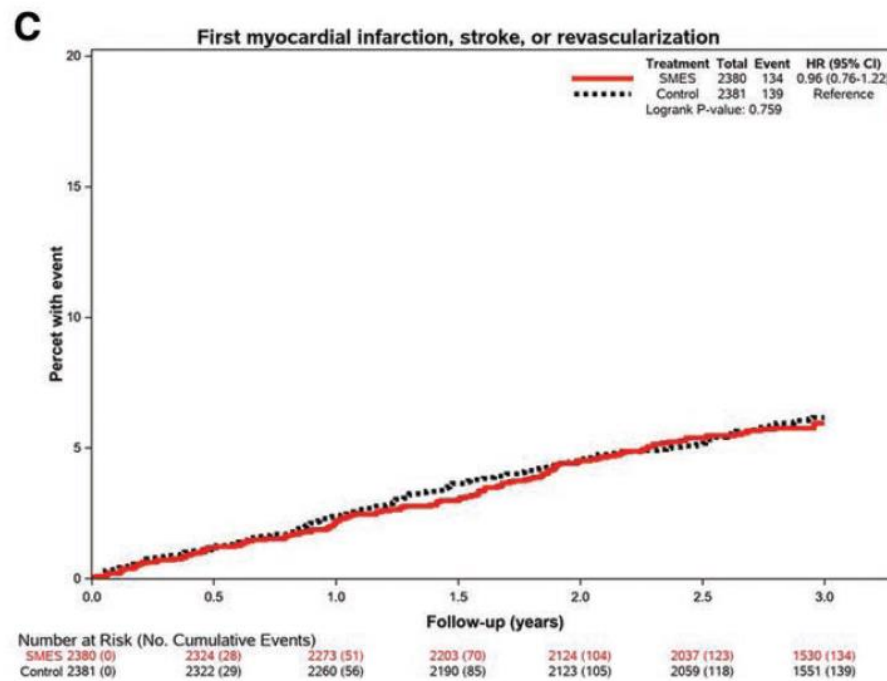
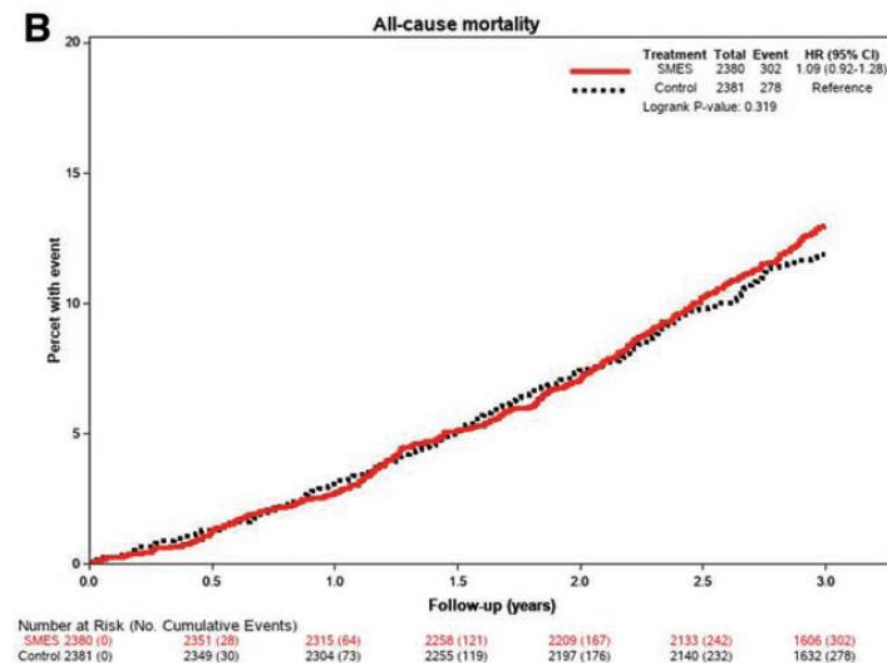
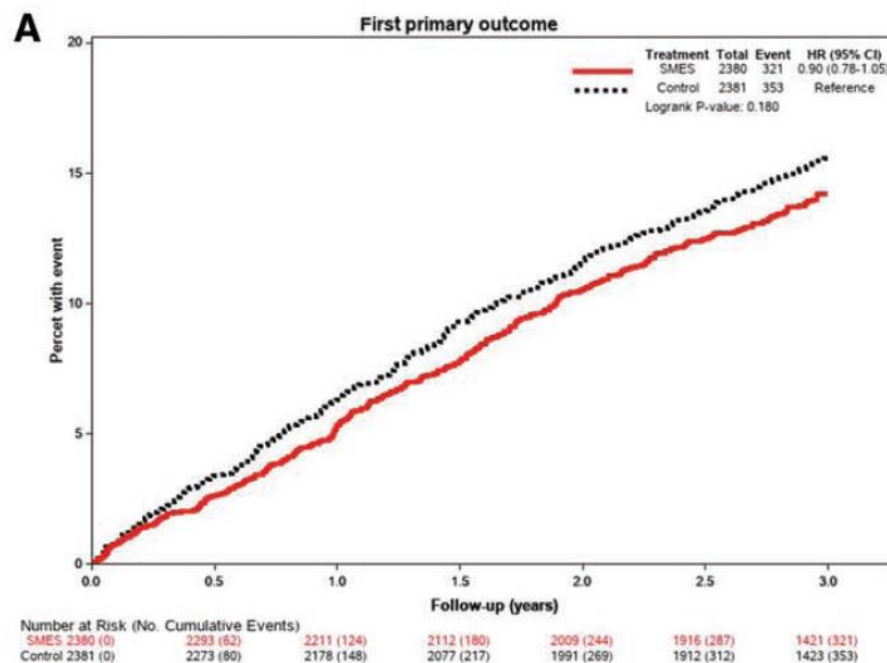
I1: Proportion of participants who were adherent (PDC80) to statins, and unadjusted mean difference, Overall

	Copayment elimination n=2382 Proportion	Usual Copayment n=2379 Proportion	Mean Difference (Copayment elimination vs usual copayment) Proportion (95%CI)	P value
Overall				
PDC80 for statin - out of total study population	0.72	0.68	0.032 (0.006 to 0.06)	0.02
PDC80 for ACEi/ARB - out of total study population	0.66	0.63	0.034 (0.007 to 0.061)	0.01

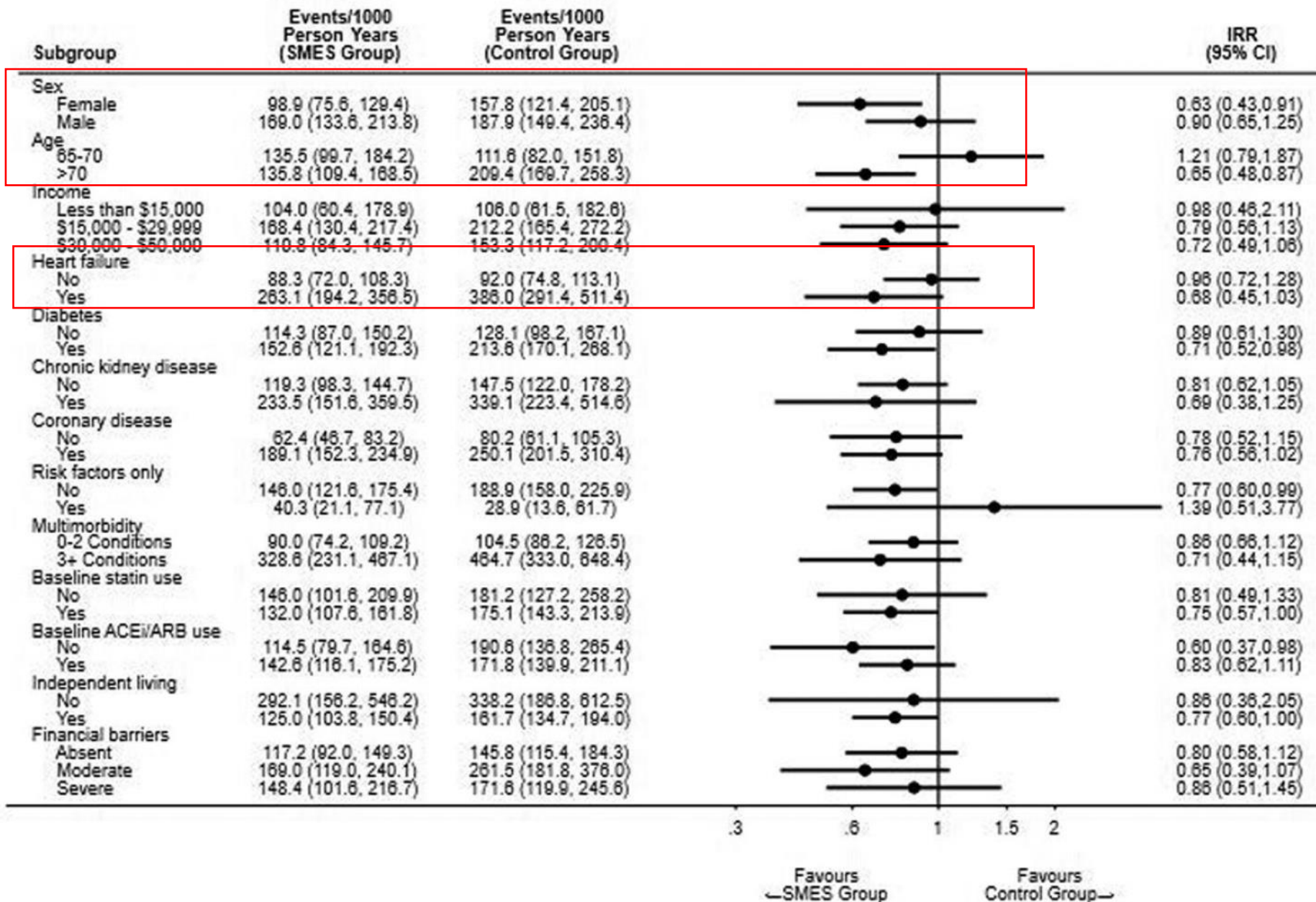
I2: Primary outcome (over median follow-up of 3 years)

Outcome	SMES intervention (n=2380)		Usual copayment (n=2381)		Incidence rate ratio (95% CI)	P- value
	Events (n)	Adjusted event rate per 1000 person years	Events (n)	Adjusted event rate per 1000 person years		
Primary composite outcome	482	130 (109, 156)	572	170 (140, 199)	0.78 (0.61, 1.00)	0.047
Major adverse cardiovascular events (non-fatal MI, non-fatal stroke, CV death)	162	40 (31, 53)	164	42 (32, 55)	0.98 (0.68, 1.40)	0.89
All-cause death	302	45 (41, 51)	278	40 (36, 45)	1.08 (0.92, 1.27)	0.34
Number of cardiovascular- related hospitalizations	253	62 (50, 79)	345	95 (76, 119)	0.66 (0.48, 0.90)	0.01

Time-to-first event analyses, Kaplan-Meier Curves



Prespecified subgroup analyses – Intervention 2



I2: Proportion of participants who were adherent (PDC80) to statins, and unadjusted mean difference, Overall

	SMES Proportion (95% CI)	Control Proportion (95% CI)	Mean Difference Proportion (95%CI)	P value
Overall				
PDC80 for statin - out of total study population	0.71 (0.69, 0.73)	0.69 (0.67 - 0.71)	0.017 (-0.009 – 0.043)	0.198
PDC80 for ACEi/ARB - out of total study population	0.64 (0.63 – 0.66)	0.65 (0.63 – 0.67)	-0.004 (-0.031 – 0.023)	0.754

Limitations

- powered to detect a minimally important relative risk reduction of 12% and assumed an annual composite primary outcome event rate of 14 per 100 participant years (observed rate was 8.4 per 100 participant years)
- adherence was relatively high at baseline
- The monthly copayment avoided (\$35 per month) may not have been high enough to affect patient behavior, or reduce medication use and impact cardiovascular complications.
- We do not exactly know WHY the SMES intervention worked

Conclusion

- In low-income adults at high cardiovascular risk, eliminating copayments of approximately \$35 a month did not improve clinical outcomes or reduce healthcare costs, despite a modest improvement in adherence to medications
- However, the provision of self-management education, based on advertising principles has the potential to reduce adverse cardiovascular events

**The trials and tribulations of FoodRx:
A pragmatic RCT of a healthy food prescription
incentive program for adults
with diabetes and food insecurity**



High cost of healthy foods a barrier to diabetes management

- Healthy dietary pattern essential for diabetes self-management
- Inadequate income + high costs of basic necessities a barrier to diabetes management
 - Particularly for those who are food insecure
- Individuals with food insecurity have higher risk of hyperglycemia
 - Leads to diabetes complications: neuropathy, kidney disease, blindness
 - Increased acute care usage and costs

What is household food insecurity?

Mild Food Insecurity

Worrying about the ability to obtain food

Moderate Food Insecurity

Compromising quality and variety of food

Severe Food Insecurity

Reducing food quantity, skipping meals

Not eating for an entire day

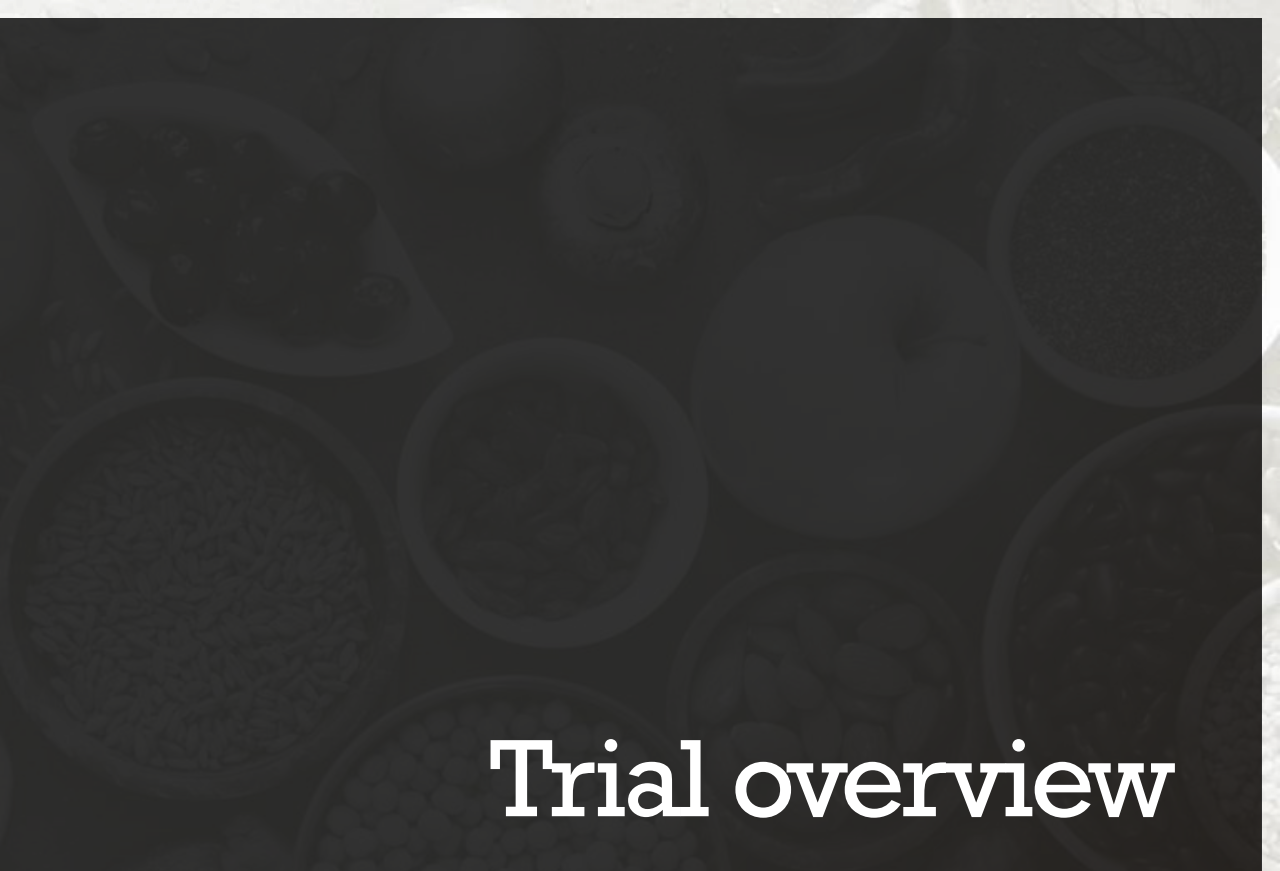


Clinicians lack effective responses to food insecurity

“A lot of my food comes from the food bank. They only give you certain types of foods that don’t really help you with diabetes, more or less go against your diabetes – a lot of sugar, cookies”

Subsidized healthy food prescription programs

- Clinicians prescribe a healthy dietary pattern + financial support to purchase it
- Experimental
 - Examine pre- and post-program outcomes – usually surrogates
 - No control group
 - Cannot attribute outcomes to the intervention
- Observational
 - Compare outcomes in adults who accessed a program with eligible adults who did not access it
 - Non-equivalent control group
 - Groups may differ in important ways that affect the outcome



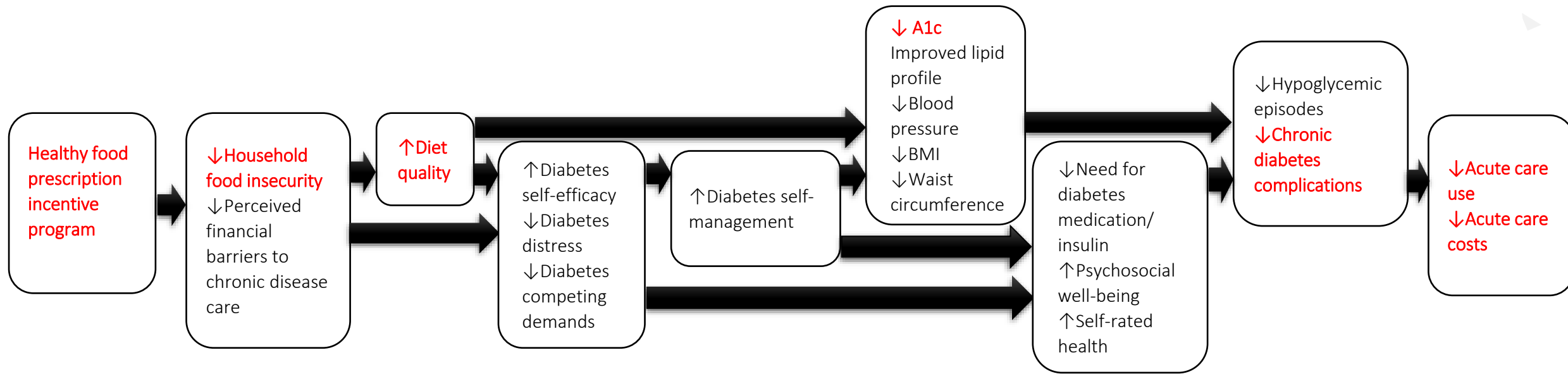
Trial overview



Objectives

To examine the effectiveness of a healthy food prescription incentive program, compared with a healthy food prescription alone, in improving the following outcomes among 594 adults with food insecurity and persistent hyperglycemia:

- Primary Outcome:
 - **Blood glucose levels: Hemoglobin A1C**
- Secondary outcomes:
 - **Dietary intake:** Diet quality; intake of ultra-processed foods, skin carotenoids
 - **Intermediate clinical outcomes:** Blood lipids; blood pressure; BMI; waist circumference; need for diabetes medication/insulin
 - **Patient-reported outcomes:** **Household food insecurity**; psychosocial well-being; self-rated health; diabetes self-efficacy; diabetes self-management; diabetes distress; diabetes competing demands; perceived financial barriers to chronic disease care; hypoglycemic episodes;



Participants

INCLUSION CRITERIA

- 18-85 years
- Hemoglobin A1C 6.5-12%
- Food insecure, low perceived income inadequacy
- Can communicate in English or have someone to assist them

Intervention

594 adults experiencing food insecurity and persistent hyperglycemia randomized to:



Healthy food prescription incentive group (n=297)

- One-time healthy food prescription + \$1.50/day/household member for 12 mos



Healthy food prescription comparison group (n=297)

- One-time healthy food prescription

Healthy eating prescription

A Healthy Eating Prescription to Help Your Diabetes

Your healthy eating prescription

Healthy eating and exercise can help you manage your blood sugar.

I prescribe a healthy eating pattern of minimally processed foods that have little to no added fat, sugar or salt.

This handout shows some ways to follow the healthy eating prescription. Check off the one(s) you want to try, or add your own.

- Choose healthy foods
- Make a healthy plate
- Eat 3 meals a day to spread carbohydrate foods over the day
- Limit highly processed foods that are higher in fat, sugar or salt
- Try small changes to make your meals and snacks healthier
- Make water your drink of choice

Clinic Info:

Patient Info:

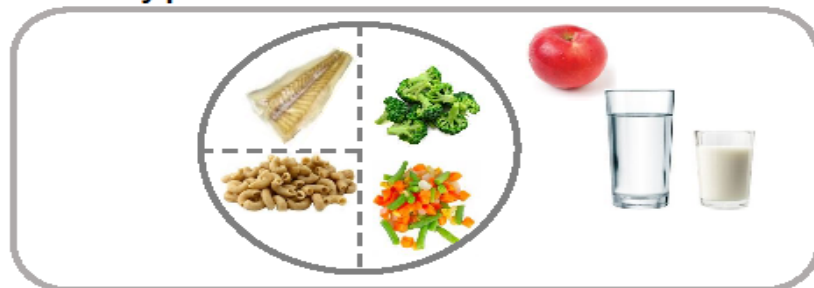
Healthcare provider
Signature

Date

Choose healthy foods



Make a healthy plate



Eat 3 meals a day to spread carbohydrate foods over the day

Morning



Or



Mid-day



Or



Evening



Or



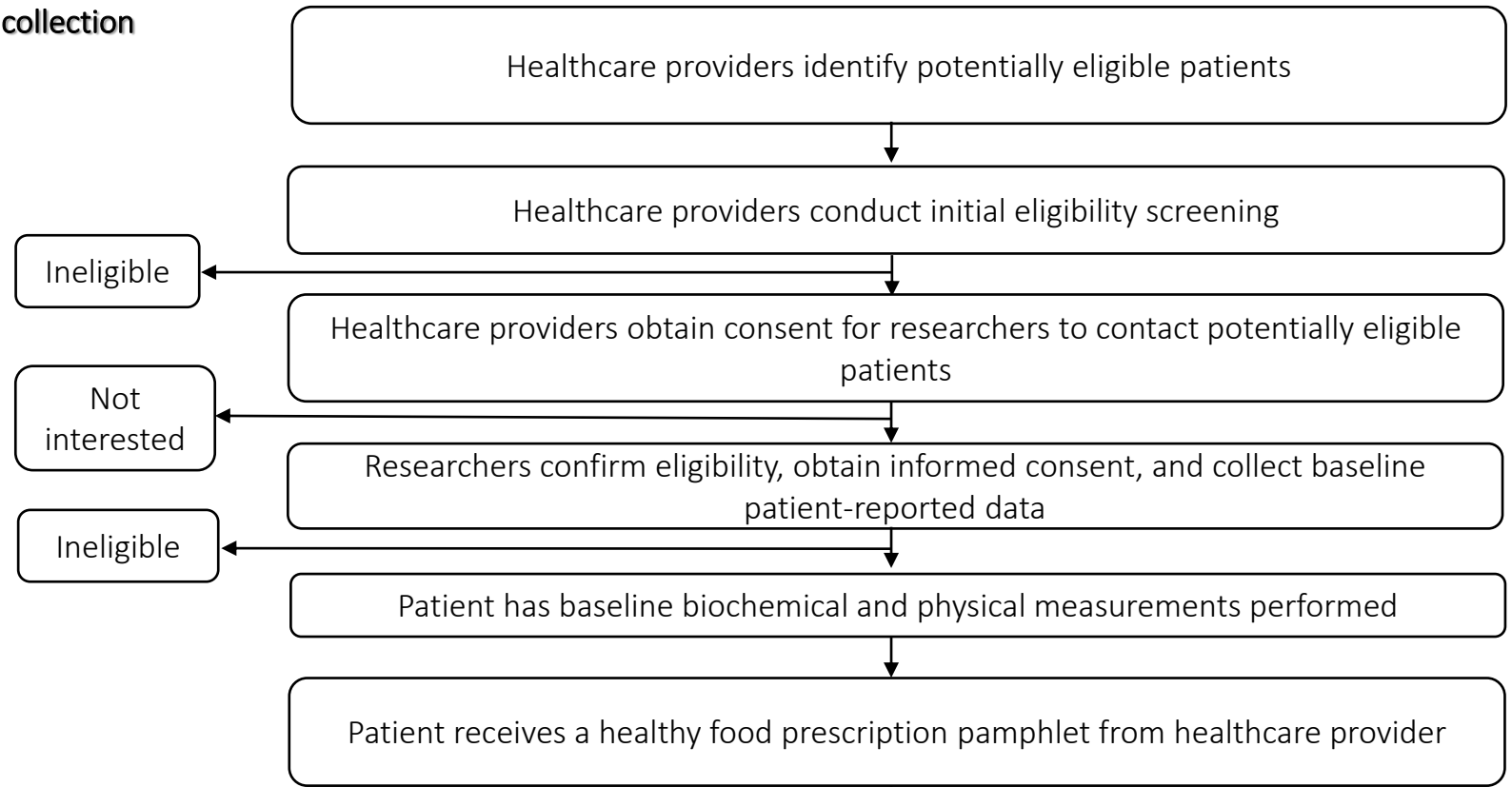
Limit highly processed foods that are higher in fat, sugar or salt



Healthy food incentive list (\$1.50/day/household member)

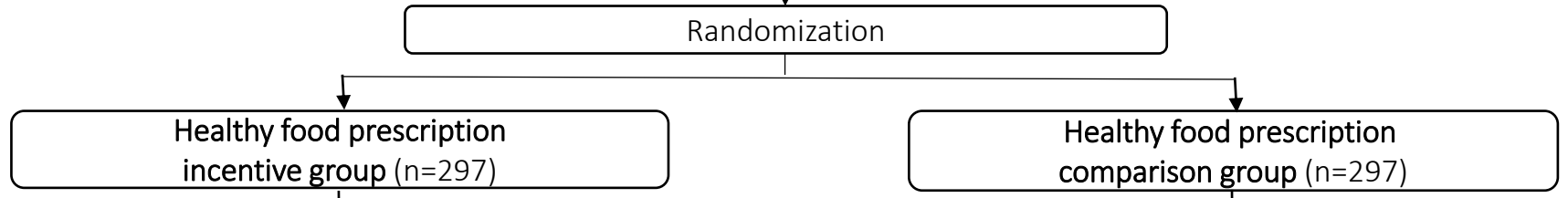
FOOD GROUPS	ELIGIBLE ITEMS
Vegetables and fruits	Fresh vegetables and fruit
	Frozen vegetables and fruit
	Canned vegetables
Meat, poultry and fish	Fresh meat, poultry and fish
	Canned fish
Meat alternatives	Dried or canned lentils, chickpeas or beans
	Whole eggs
	Whole almonds
Dairy products	White cow's milk
	Unsweetened fortified soy beverage
	Plain yogurt
	Hard cheddar cheese
Whole grain foods	Whole grain pasta
	Brown rice
	Large flake rolled oats
	100% whole wheat bread
	Bran Flakes cereal

Baseline data collection



*Aim: Mimic
real-world
implementation*

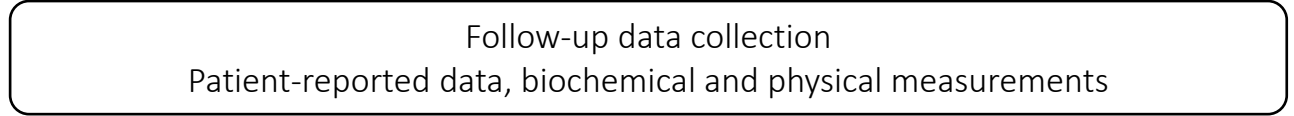
Randomization



Intervention



Follow-up data collection



Recruitment

- **Plan:** Primary care clinics identify potential participants, do initial screening, refer to researchers
- **Challenges:**
 - Staff time and workload
 - Difficult to know who to approach
 - Identifying food insecurity
 - Outdated hemoglobin A1C values and/or change since last measurement
- **Result: Low yield (n~100)**
- **Solution:** Add 2 recruitment pathways
 - **Pathway 2:** Clinicians in any setting (pharmacists, specialists, dietitians) identify potential participants, do brief initial screening (age, diabetes, A1C), refer to researchers
 - **Pathway 3:** Advertise the study widely (e.g. email, website, Food Banks, community events), potential participants contact researchers, complete initial online screening

Confirming eligibility

- **Plan:** Confirm eligibility during baseline data collection
 - Not reasonable to send for lab tests and complete 18-item Food Insecurity Questionnaire during screening
- **Challenges:**
 - Food insecurity
 - Clinicians 'knew' patients were food insecure but some responded negatively to all 18 questions
 - Well validated measure, used extensively
 - Participants embarrassed to admit they were food insecure?
 - Lab tests for A1C: below cut-off
- **Result:**
 - Slow recruitment: Many participants ineligible
 - High costs: paid for lab tests and \$100 to participants for completing baseline data collection

Confirming eligibility

- Solutions:
 - Lower A1C eligibility
 - 8.0% → 7.0% → 6.5%
 - Trade-off between statistical power and malleability of lower A1Cs
 - Better A1C data: access electronic medical records
 - Expand indicators of household food insecurity
 - Perceived inadequate income to afford monthly expenses




Data collection

- **Plan:** Primary care clinics perform physical measures
 - Participants answer online questionnaires from home
- **Challenges:**
 - Most clinics unable/unwilling to perform physical measures due to COVID-19
 - Some participants required assistance with questionnaires
- **Result:** Risk of no data or poor quality data
- **Solutions:**
 - Central data collection sites in Edmonton and Calgary at known clinical trial centres
 - Train study staff to perform physical measurements
 - Assist participants with questionnaires over the phone

Budget

- **Original funding = \$1.6M**
 - \$1.4M PRIHS-5, Alberta Innovates and Alberta Health Services
 - \$220,000 Alberta Blue Cross
- Challenges encountered significantly increased study costs
- Wanted to increase duration (6 to 12 mos) and sample size (n=404 to n=594)
- **Current funding = \$2.6M**
 - \$1.4M PRIHS-5, Alberta Innovates and Alberta Health Services
 - \$370,000 Alberta Blue Cross
 - \$840,000 CIHR

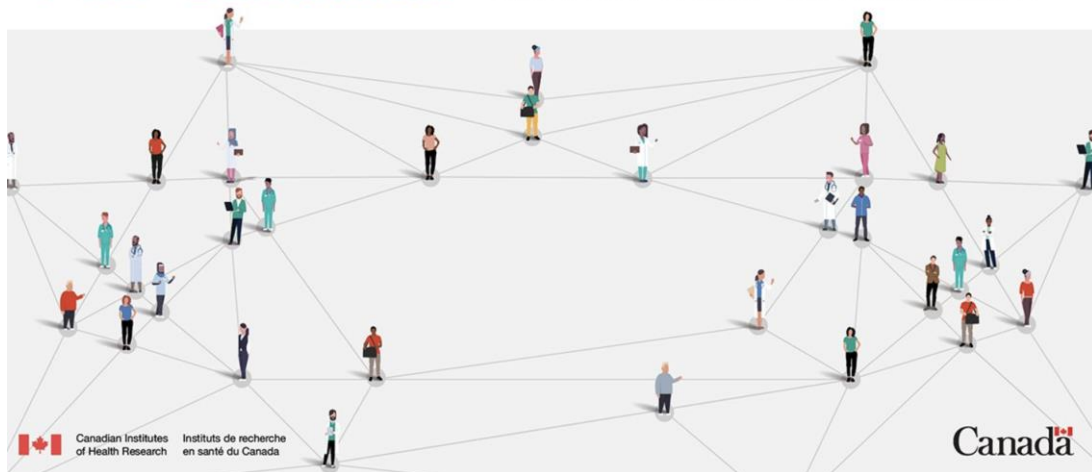
Healthy food prescription incentive programme for adults with type 2 diabetes who are experiencing food insecurity: protocol for a randomised controlled trial, modelling and implementation studies

 Dana Lee Olstad¹, Reed Beall¹, Eldon Spackman¹, Sharlette Dunn¹, Lorraine L Lipscombe², Kienan Williams³, Richard Oster⁴, Sara Scott¹, Gabrielle L Zimmermann^{1, 5}, Kerry A McBrien^{1, 6}, Kieran J D Steer¹, Catherine B Chan^{4, 7, 8}, Sheila Tyminski⁹,  Seth Berkowitz¹⁰, Alun L Edwards¹¹, Terry Saunders-Smith¹, Saania Tariq¹, Naomi Popeski⁸, Laura White¹², Tyler Williamson¹, Mary L'Abbé¹³, Kim D Raine¹⁴, Sara Nejatinamini¹, Aruba Naser¹, Carlota Basualdo-Hammond⁹, Colleen Norris^{15, 16}, Petra O'Connell⁸, Judy Seidel^{1, 17}, Richard Lewanczuk¹⁸, Jason Cabaj¹,  David J T Campbell^{1, 11, 19}

The Centre for
Health Policy



New funding opportunity Pan-Canadian Clinical Trials Consortium



Health Policy Trials Unit Co-Directors



Dr. Amity Quinn



Dr. David Campbell



Health Policy Trials Unit
Science in Service of Health

What support can the HPTU offer?



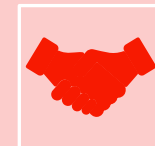
**Identify Areas of
Need For Policy
Change**



**Operational
Support and
Advice**



**Analytics to
Support
Implementation**



**Partner
Engagement**

Levels of Policy

Politics



Politics

MACRO

- high-level, broad, international/national/provincial (financing of health care systems)

MESO

- mid-level, organizational (healthcare insurance policies and coverage decisions)

MICRO

- local-area, individual focus (local programs and offerings chosen over others)

Effective and coherent linkage of levels matters

What else are we working on?

- Provision of diabetes specialist care through a mobile diabetes wellness clinic
- Utility of a mobile health intervention to help patients with chronic diseases manage medication use during 'sick days'
- Pharmaceutical reimbursement plan reform in BC (deductible reduction for low income individuals)
- BC Farmers Market Nutrition Coupon Program
- Medically tailored meals for heart failure patients
- Expansion of MOXIE SMES program in heart failure
- Reimbursement for diabetes self-monitoring supplies
- Nudges for enhancing vaccine uptake
- Health coaching and prescription for physical activity
- Culinary medicine for socioeconomically disadvantaged populations
- Impact of frank patient feedback of healthcare providers using the "Care Opinion" platform
- Assessment of video capsules, in coached and non-coached modes, in the Canton de Vaud

Thank you
Merci

Dr. Amity Quinn & Terry Saunders-Smith, HPTU

Dr. Braden Manns – ACCESS trial co-PI

James Zhang – statistician

Dr. Dana Olstad – FoodRx trial co-PI

Slide credit: Dr. Tom Noseworthy