From randomized controlled trials to population-wide scale up: Using implementation science to get people deprescribing

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Disclosure

• I have no real or perceived conflicts of interest to declare

Overview

- Appropriate medication use
- Implementation science
- From EMPOWER to TAPERING
- From D-PRESCRIBE to SaferMedsNL
- Lessons learned
- Summary



Appropriate medication use

- Controls symptoms
- Minimises harm from chronic diseases
- Prolongs life



Inappropriate medication use

- Is associated with harms:
 - Adverse drug events
 - Falls
 - Hospitalisation
 - Frailty

Passarelli, M.C. et al, *Drugs Aging*, 2005 Diaz-Gutierrez, M. et al, *Maturitas*, 2017 Black, C. et al, *PharmacoEconomics*, 2020 Saaralainen, L.K. et al, *J Geri Onc*, 2014



Implementing evidence is hard

- It takes 17 years for research findings to be translated into practice
 - From controlled setting to real world
- Maybe even longer for de-implementation

 Different approach to behaviour change may be needed



Morris, Z. 2011 Niven, D. 2015

Implementing evidence is hard

- 1998 review of healthcare in the US
 - 30-40% do not receive care according to best evidence
 - 20-25% receive unnecessary or inappropriate care
- 2016, 37% of seniors use potentially inappropriate medications

Schuster M., et al 1998 CIHI 2018

How do we fix this?



Behaviour change in prescribing

• Who needs to do what differently? When? and How?

- Prescriber?
- Pharmacist?
- Patient?
- Policy makers?



Scott, S. et al , BJCP, 2020

Implementation science



Implementation science

Is the scientific study of methods to promote the systematic uptake of consolidated research findings into routine healthcare practice & health policy and, hence, improve the quality and effectiveness of health services and care

Eccles M, et al. 2005

Theoretical approaches in implementation science are like...



Everyone has their own, and no one wants to use someone else's

Consolidated Framework for Implementation Research

Implementation Science BioMed Centra **Open Access** Research article Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science Laura J Damschroder^{*1}, David C Aron², Rosalind E Keith¹, Susan R Kirsh², Jeffery A Alexander³ and Julie C Lowery¹ Address: 1HSR&D Center for Clinical Management Research, VA Ann Arbor Healthcare System (11H), 2215 Fuller Rd, Ann Arbor, MI 48105, USA, ²VA HSR&D Center for Quality Improvement Research (14W), Louis Stokes Cleveland DVAMC, 10701 East Blvd, Cleveland, OH 44106, USA and ³Health Management and Policy, School of Public Health, University of Michigan, 109 S. Observatory (M3507 SPH II), Ann Arbor, Michigan 48109-2029, USA Email: Laura J Damschroder* - laura.damschroder@va.gov; David C Aron - david.aron@va.gov; Rosalind E Keith - rekeith@umich.edu; Susan R Kirsh - susan.kirsh@va.gov; Jeffery A Alexander - jalexand@umich.edu; Julie C Lowery - julie.lowery@va.gov Corresponding author Published: 7 August 2009 Received: 5 June 2008 Accepted: 7 August 2009

Implementation Science 2009, 4:50 doi:10.1186/1748-5908-4-50

Consolidated Framework for Implementation Research (CFIR)

- 5 important domains
 - 1. Intervention
 - 2. Context, Outer setting, e.g. country
 - 3. Context, Inner setting, e.g. health care setting
 - 4. Context, Individuals involved
 - 5. Process of implementation

TAPERING TRIAL, Manitoba

Trial Applying Policy to Eliminate or Reduce Inappropriate Narcotics in the General Population



Methods: This is a pragmatic, prospective, cluster randomized, parallel-arm controlled trial, comparing mailed distribution of a direct-to-patient educational brochure for chronic opioid use (intervention arm) to usual care (control

TAPERING: Background

- Canada was in the grips of an opioid crisis
- Opioid deaths overtook car accident deaths by 50%
- 2nd highest users of opioids world wide
- Direct-to-patient education can reduce chronic sedative use



EMPOWER trial

30 community pharmacies around Montreal 2,716 chronic benzo users 65+, 303 participants, benzo users 3 months+, aged 65 years and older no dementia, not on antipsychotics



Tannenbaum, C, et al. JAMA Int Med, 2014

TAPERING: Aim



 To evaluate the effectiveness of a government-led mail-out of educational information directly to adult, community-dwelling, chronic opioid consumers on the reduction of opioid utilization, compared to usual care.





Le cas de M^{me} Thibodeau

« J'ai 65 ans et je prenais des <u>Ativan</u>[®] depuis plus de 10 ans. Il y a quelques mois, je suis tombée en pleine nuit en allant à la toilette. J'ai été vraiment chanceuse – pas de fractures, que des bleus. J'ai lu que les <u>Ativan</u>[®] pouvaient être la cause de chutes. Je ne savais pas si je pouvais me passer de mes <u>Ativan</u>[®] pour dormir, car j'avais encore de la difficulté à m'endormir ou je me réveillais parfois la nuit.

J'en ai parlé à mon médecin qui m'a dit qu'en vieillissant, on a besoin de moins de sommeil (en moyenne 6 heures par nuit est suffisant). J'ai donc décidé de réduire graduellement les <u>Ativan</u>[®]. Mon pharmacien m'a proposé un programme de sevrage par étapes (voir la page suivante) que j'ai suivi.

J'ai aussi adopté de nouvelles habitudes de sommeil. Je ne lis plus au lit et je ne fais plus d'exercices avant de me coucher. Je me lève tous les jours à la même heure, que j'aie eu une bonne nuit de sommeil ou non.

J'ai réussi à cesser de prendre <u>Ativan</u>[®]. Je me rends compte que je n'ai pas vécu pleinement ces 10 dernières années. Cesser les <u>Ativan</u>[®] a levé un voile sur une vie que je vivais à moitié endormie. J'ai plus d'énergie et mon humeur est plus stable. Je suis plus alerte. Il m'arrive encore d'avoir de la difficulté à m'endormir, mais au moins je me lève le matin sans me sentir somnolente. Je suis fière de ma décision. Si je l'ai fait, vous le pouvez aussi! »

7

Context: Outer Setting in Canada

- Political, social and economical, contexts in which the organisation resides
- For TAPERING,
 - Opioid crisis
 - Media reports
 - Insurance company restrictions
 - Urgency because Canadians are dying



Context: Inner setting in Manitoba

- Structure, networks/communications, political and cultural contexts and implementation climate within the organisation
- For TAPERING,



- Defined hierarchy
- Government wanted to do something
- Actions already undertaken: Manitoba Monitored Drug Review Committee (MMDRC), free naloxone, physician support, pharmacists

Context: Individuals involved

• Knowledge, beliefs, self-efficacy, organisational identity

- Key individuals for TAPERING:
 - Provincial Drugs Program Branch
 - Health Minister
 - College of Physicians and Surgeons







Process of implementation

• Define the active change process: planning, engaging, executing, reflecting & evaluating

- For TAPERING, this involved
 - Top down approach
 - Linear series of approval processes involving different stakeholders

Linear Process

Provincial Drugs Program Branch approval Ministerial approval **MMDRC** approval Health Information Privacy Committee of Manitoba Health, Seniors and Active Living Patient identification Patient randomisation **Printing D**Posting □ Reflecting & evaluating

TAPERING: Methods

- Pragmatic, prospective, cluster randomized, parallel-arm controlled trial
- Step 1. Create educational brochure
 - Identity behaviour change levers from EMPOWER and adapt to opioids
- Step 2. Identify eligible recipients
- Step 3. Create clusters, randomise and mail-out



TAPERING: Results



TAPERING: Results

- n = 4206
- Male = 42.9% (n=887)
- Age = 59.9 years (±14.5, range 19-99)
- Age ≥65 = 31.3% (n=648)
- Urban = 49.5% (n=1024)
- Morphine Milligram Equivalence (MME) = 155.7 ± 179.7MME

TAPERING: Results

Opioid reduction outcome	Intervention n=2136 % (n)	Control n=2070 % (n)	Absolute difference % (95%Cl)
Complete cessation			
All participants	11.0% (235)	11.0% (228)	0.0% (-1.9 to 1.9)



Time (days)

TAPERING: Discussion

- Direct-to-consumer education about benefits and harms of chronic opioid use for non-cancer pain *is possible* at a population level
- Failed to produce significant difference in cessation
- Modest reduction in daily opioid use
 - Particularly for younger adults, men and urban areas
- Significant reduction in mortality

Evaluation framework: CFIR

Consolidated Framework for Implementation Research

- **?** 1. Intervention
- 2. Context, Outer setting, e.g. Manitoba
- 3. Context, Inner setting, e.g. organisational (government)
- 4. Context, Individuals involved
- **5**. Process of implementation

Damschroder, L.J. et al. *Implement Sci.* 2009

TAPERING: Why did the results differ?

- Intervention
 - Adaptability between medication classes?
 - Tapering might take longer?
- Context, outer setting
 - Availability of naloxone
 - Physician education / support
 - Availability of alternatives (urban vs rural)



- What behaviour change determinants were different?
 - Addiction potential higher?
 - Trust in government vs pharmacists?
 - Knowledge of opioid crisis was not new?

TAPERING: Limitations

- Generalisability
- Did patients receive the information
- Did patients understand the information
- Were the correct behaviour change levers used
- Contamination between intervention and control
- Administrative data

TAPERING: Lessons learned

- External contexts are very important
- Behaviour change techniques may be critical
- Behaviour change techniques are likely to be different between medication classes

Turner, JP. et al. *Ther Adv Drug Saf.* 2018



From D-PRESCRIBE to SaferMedsNL

• Implementation of the D-PRESCRIBE trial across Newfoundland and Labrador





Martin, P, et al. JAMA 2018

D-PRESCRIBE trial

70 community pharmacies 503 participants - benzodiazepine, 1st gen. antihistamines, long-acting sulfonylureas or NSAIDs users, for \geq 3 months, age 65 and above, no dementia



Prevalence of inappropriate medications



SaferMedsNL: Aim

 To reduce the prevalence of potentially inappropriate medications (sedatives and PPIs) across Newfoundland and Labrador by 20% within 3 years



How do you go about doing that?

1. Who needs to do what differently and when?

2. Is there **evidence** to support the behaviour change?

3. Is there an implementation science **process model** that can help?



Who needs to do something CARP differently? Choosing Wisely NL **CDSI ICSP** Canadian Patient Safety Institute Institut canadien pour la sécurité des patients PHARMACISTS' ASSOCIATION OF wfoundland-Labrador Quality of *P* Care NL NEWFOUNDLAND AND LABRADOR 50⁺ Federation ensioners & Sen Newfoundland Labrador NEWFOUNDLAND AND LABRADOR MEDICAL ASSOCIATION CADTH Evidence Driven. MEDICATION College of Registered Nurses THERAPY MEMORIAL of Newfoundland & Labrador UNIVERSITY SERVICES CLINIC Canadian Institutes of Instituts de recherche School of Pharmacy Health Research en santé du Canada SCHOOL OF PHARMACY

Process Model: Collective Impact

The Five Conditions of Collective Impact		
Common Agenda	All participants have a shared vision for change including a common understanding of the problem and a joint approach to solving it through agreed upon actions.	
Shared Measurement	Collecting data and measuring results consistently across all participants ensures efforts remain aligned and participants hold each other accountable.	
Mutually Reinforcing Activities	Participant activities must be differentiated while still being coordinated through a mutually reinforcing plan of action.	
Continuous Communi- cation	Consistent and open communication is needed across the many players to build trust, assure mutual objectives, and create common motivation.	
Backbone Support	Creating and managing collective impact requires a separate organization(s) with staff and a specific set of skills to serve as the backbone for the entire initiative and coordinate participat- ing organizations and agencies.	

Flood, J, et al. *Health Educ Behav*, 2015

SaferMedsNL: Methods

Condition	Details
Common Agenda	Reducing the use of benzodiazepines and proton pump inhibitors
Shared Measurement	Prevalence
Mutually reinforcing activities	Policy change to fund expanded scope of practice, Interprofessional communication (POs), Audit and feedback, Education, Public awareness
Continuous communication	Quarterly stakeholder meetings
Backbone organisation	Research team



Some things just aren't meant to be long term.



For most people, heartburn medication is not recommended for more than 3 months. Ask your pharmacist, doctor or nurse if you can safely stop your reflux medication.

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www.SaferMedsNL.ca





Safer MedsNL

Public Awareness Campaign



Counting sheep not working?



SaferMedsNL: Primary outcome

• Change in prevalence of potentially inappropriate medications

- Measured using interrupted time series analysis
 - Since 2017, data on all pharmacy claims is collected
 - Assess the cumulative effects of different interventions
 - Subgroup analysis to consider sex, age, geographic location

SaferMedsNL: Implementation Outcomes

- Implementation of new professional services: Barriers, enablers and practice pearls
- Suitability of collective impact to drive behaviour change across multiple stakeholders
- Effectiveness of academic detailing and audit and feedback
- Reach and adoption of public awareness campaign
- Uptake of pharmacist professional services

Evaluation framework: RE-AIM

- Reach
- Efficacy
- Adoption
- Implementation
- Maintenance





- Random telephone survey, (n=440 adults)
 - Reach (did they hear? how?)
 - Adoption (what did they do?)

Glasgow, R, et al. Am J Public Health, 1999

SaferMedsNL: Limitations

- Observational project, not interventional trial
- Primary outcome
 - The date of "intervention" is difficult to define
 - Multiple contexts that impact medication use
 - Political contexts have a big influence
- Implementation outcomes
 - Small sample size of "keeners" for qualitative research on implementation of deprescribing into practice
 - Public awareness difficult to measure

Summary

- Inappropriate medication use is a common and costly problem for older adults
- Improving appropriate medication use requires behaviour change from prescribers, pharmacists, patients and policy makers
- Implementation science provides guidance on how to move from trials that improve medication use to province wide system changes
- Implementation science starts with data and ends with data and seeks to answer what occurs in-between
- Have you incorporated implementation science into your research?

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Questions?

