



NIH Collaboratory

Health Care Systems Research Collaboratory

D-PRESCRIBE-AD:

**An NIH Collaboratory Distributed Research Network
Pragmatic Trial to Reduce Inappropriate Prescribing
in Dementia**

Jerry Gurwitz, Meyers Health Care Institute and UMass Chan Medical School

Richard Platt, Harvard Pilgrim Health Care Institute and Harvard Medical School

January 7, 2022

A decorative vertical grid pattern on the left side of the slide, consisting of small squares in shades of red, teal, and light blue.

Re-introducing the NIH Collaboratory Distributed Research Network

- FDA Sentinel System, designed to assess medical product safety and effectiveness, has ability to support research topics
- Created to allow investigators supported by NIH and other not-for-profit sponsors to collaborate with Sentinel investigators
- Focus is on multi-center research, especially requiring:
 - Access to full text records
 - Linkage to external sources
 - Contact with clinicians and/or patients
 - Collection of patient generated data
- New research partners welcome!



ABOUT

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DESIGN



CONDUCT



DISSEMINATION

NIH Collaboratory Distributed Research Network (DRN)

Millions of people. Strong collaborations. Privacy first.

Leadership: Richard Platt and Lesley Curtis

Project Manager: [Sarah Malek](#)

[Publications and Supplementary Material](#) | [Presentations](#)

The NIH Collaboratory Distributed Research Network (DRN) enables investigators funded the NIH and other not-for-profit sponsors to collaborate with investigators based in health plans that participate in the FDA's Sentinel System. The DRN is especially useful for supporting multisite research programs.



Drs. Jeffrey Brown and Lesley Curtis explain the NIH Collaboratory DRN

DRN Collaborating Organizations

Coordinating Center:

DEPARTMENT OF POPULATION MEDICINE



Data & Scientific Partners



Hawaii
Mid-Atlantic
Northwest
Washington



NIH Collaboratory DRN's Distributed Database

Database Statistic	Total
Members Currently Accruing New Data	~45 million
Person-years of Data	~450 million
Pharmacy Dispensings	~7 billion
Unique Medical Encounters	~10 billion

Sentinel Common Data Model

Administrative Data						Clinical Data	
Enrollment	Demographic	Dispensing	Encounter	Diagnosis	Procedure	Lab Result	Vital Signs
Patient ID	Patient ID	Patient ID	Patient ID	Patient ID	Patient ID	Patient ID	Patient ID
Enrollment Start & End Dates	Birth date	Dispensing Date	Service Date(s)	Service date(s)	Service Date(s)	Result & Specimen Collection Dates	Measurement Date & Time
Drug Coverage	Sex	National Drug Code (NDC)	Encounter ID	Encounter ID	Encounter ID	Test Type, Immediacy & Location	Height & Weight
Medical Coverage	Zip code	Days Supply	Encounter Type and Provider	Encounter Type and Provider	Encounter Type and Provider	Logical Observation Identifiers Names and Codes (LOINC®)	Diastolic & Systolic BP
Medical Record Availability	Etc.	Amount Dispensed	Facility	Diagnosis Code & Type	Procedure Code & Type	Etc.	Tobacco Use & Type
			Etc.	Principle Discharge Diagnosis	Etc.		Etc.

Registry Data			Inpatient Data		Mother-Infant Linkage Data
Death	Cause of Death	State Vaccine	Inpatient Pharmacy	Inpatient Transfusion	Mother-Infant Linkage
Patient ID	Patient ID	Patient ID	Patient ID	Patient ID	Mother ID
Death Date	Cause of Death	Vaccination Date	Administration Date & Time	Administration Start & End Date & Time	Mother Birth Date
Source	Source	Admission Date	Encounter ID	Encounter ID	Encounter ID & Type
Confidence	Confidence	Vaccine Code & Type	National Drug Code (NDC)	Transfusion Administration ID	Admission & Discharge Date
Etc.	Etc.	Provider	Route	Transfusion Product Code	Child ID
		Etc.	Dose	Blood Type	Child Birth Date
			Etc.	Etc.	Mother-Infant Match Method
					Etc.



Capabilities

- Work with Sentinel's curated distributed dataset
- Obtain full text records
- Link to external registries
- Collect patient reported data
- Contact providers
- Conduct randomized trials



Capabilities

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- Obtain full text records
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- Contact providers
- Conduct randomized trials



To work with the DRN

- The DRN invites partnerships on a wide range of topics
- Learn more – <https://rethinkingclinicaltrials.org/nih-collaboratory-drn>
- Contact us – nih-collaboratory@dm.duke.edu

D-PRESCRIBE-AD

**Developing a Program to Educate and Sensitize Caregivers to
Reduce the Inappropriate Prescription Burden in Elderly with
Alzheimer's Disease (D-PRESCRIBE-AD)**

Jerry H. Gurwitz, MD
Executive Director
Meyers Health Care Institute
Worcester, Massachusetts

January 7, 2022

R56AG061813/R61AG069794/R33AG069794

A collaborative effort



Importance of Deprescribing in Patients with Alzheimer's Disease and ADRD

Significant public health impact of inappropriate prescribing

- ▶ Inappropriate prescribing can act as a “morbidity multiplier.”
- ▶ Inappropriate prescribing substantially increases the likelihood of experiencing prescribing cascades and adverse drug events.

Heightened impact for patients with Alzheimer's disease and Alzheimer's disease-related dementias (AD/ADRD)

- ▶ AD/ADRD patients are more vulnerable to inappropriate prescribing due to multimorbidity, polypharmacy, and the complexities of their care.
- ▶ Patient/caregiver communication with the healthcare provider regarding medications is often suboptimal.

There is a need to activate patients and their caregivers

- ▶ Patients and caregivers have important insights into their care, but often do not speak up about these concerns, leaving healthcare providers unaware.
- ▶ Several direct-to-patient educational efforts have been shown to be effective in improving the quality and safety of pharmacotherapy.

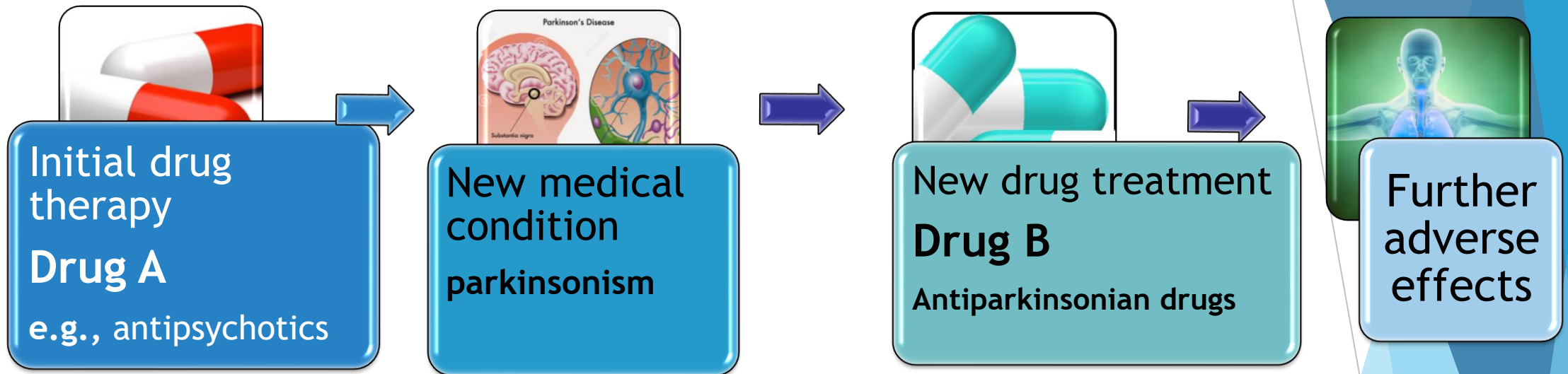
D-PRESCRIBE-AD

D-PRESCRIBE-AD is planned as a rigorous evaluation of a large scale, low-intensity, health plan-based, educational intervention to improve medication safety among AD/ADRD patients who are at risk for preventable medication-related morbidity.

D-PRESCRIBE-AD: What should the target for the deprescribing intervention be?

- ▶ Reduce polypharmacy (i.e., just try to reduce the overall number of meds)?
- ▶ Prevent and interrupt prescribing cascades?
- ▶ Reduce use of selected high-risk categories of medications in patients with AD/ADRD (e.g., antipsychotics, sedative-hypnotics, and strong anticholinergics)?

Prescribing Cascade Concept: Example 1



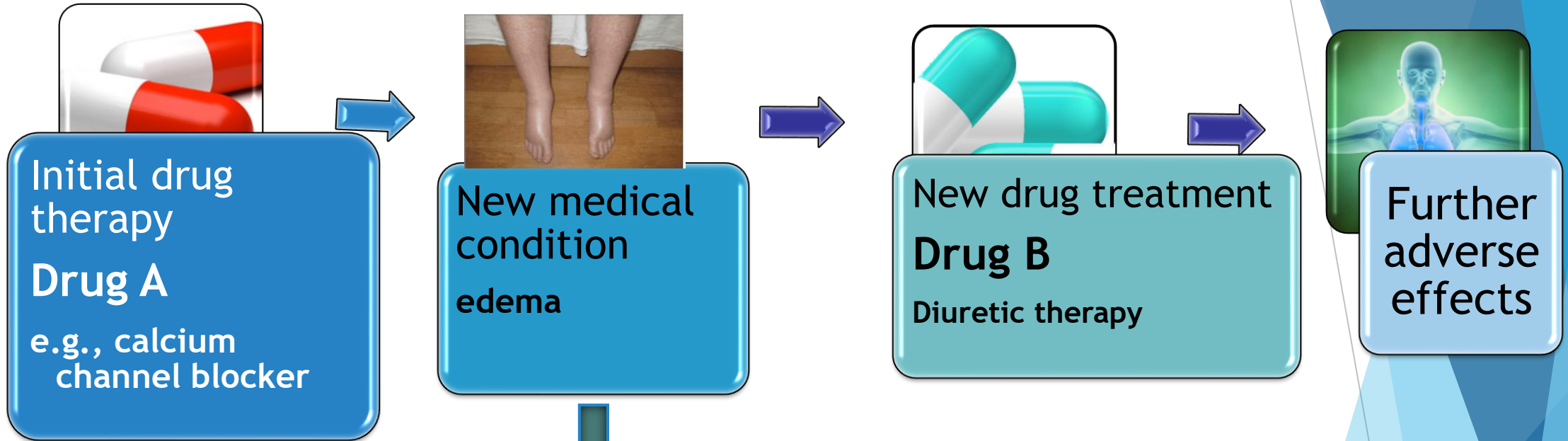
Develops in weeks to months

Not clearly recognized as drug-related

Perhaps confused with age-related changes

Time

Prescribing Cascade Concept: Example 2



Develops in weeks to months

Not clearly recognized as drug-related

Perhaps confused with age-related changes

Time

CASCADES-AD: The Controlling And Stopping Cascades leading to Adverse Drug Effects Study in Alzheimer's Disease

Prescribing cascades in older adults with AD/ADRD are far less common than expected, so maybe this is not the best intervention target for testing with a large scale pragmatic clinical trial:

Antipsychotic-antiparkinsonian medication cascade

- Among 121,538 patients with Alzheimer's disease there were 36 incident antiparkinsonian users among 4,534 incident antipsychotic users (0.8%)*

Calcium Channel Blocker Diuretic Cascade

- Only 2.1% evidenced a prevalent CCB-diuretic prescribing cascade*

Use of Selected High-Risk Medications: Antipsychotics, Sedative/Hypnotics, and Strong Anticholinergics

Characteristics of AD/ADRD Population with current evidence of potentially inappropriate prescribing in Health Plans January 2019-January 2020

Number of health plan members with AD/ADRD	<u>130,682</u>
Number of health plan members with AD/ADRD and evidence of inappropriate prescribing, N (%)	26,259 (20.1%)
Antipsychotics, N (%)	12,581 (9.6%)
Benzodiazepines/sedative-hypnotics, N (%)	6,617 (5.1%)
Strong anticholinergics, N (%)	11,228 (8.6%)

Use of Selected High-Risk Medications: Antipsychotics, Sedative/Hypnotics, and Strong Anticholinergics

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Inspiration for our D-PRESCRIBE-AD Randomized Trial

JAMA | **Original Investigation**

Effect of a Pharmacist-Led Educational Intervention on Inappropriate Medication Prescriptions in Older Adults The D-PRESCRIBE Randomized Clinical Trial

Philippe Martin, PhD; Robyn Tamblyn, PhD; Andrea Benedetti, PhD; Sara Ahmed, PhD; Cara Tannenbaum, MD, MSc

IMPORTANCE High rates of inappropriate prescribing persist among older adults in many outpatient settings, increasing the risk of adverse drug events and drug-related hospitalizations.

OBJECTIVE To compare the effectiveness of a consumer-targeted, pharmacist-led educational intervention vs usual care on discontinuation of inappropriate medication among community-dwelling older adults.

DESIGN, SETTING, AND PARTICIPANTS A cluster randomized trial (D-PRESCRIBE [Developing Pharmacist-Led Research to Educate and Sensitize Community Residents to the Inappropriate Prescriptions Burden in the Elderly]) that recruited community pharmacies in Quebec, Canada, from February 2014 to September 2017, with follow-up until February 2018, and randomly allocated them to intervention or control groups. Patients included were adults aged 65 years and older who were prescribed 1 of 4 Beers Criteria medications (sedative-hypnotics, first-generation antihistamines, glyburide, or nonsteroidal anti-inflammatory drugs), recruited from 69 community pharmacies. Patients were screened and enrolled before randomization.

- ← Editorial [page 1867](#)
- ← Related articles [pages 1933 and 1934](#)
- + [Video and Supplemental content](#)
- + CME Quiz at jamanetwork.com/learning

D-PRESCRIBE Randomized Trial

- ▶ A cluster-randomized trial (pharmacies in Quebec) involving mailings of educational deprescribing brochures to older adult patients and physicians.
- ▶ Among the target medication categories were sedative-hypnotics.
- ▶ Small trial: 219 in intervention group and 218 in control group
- ▶ Compared with usual care, the intervention resulted in greater discontinuation of prescriptions for inappropriate medications after 6 months. In the intervention group, **43%** no longer filled prescriptions for the targeted potentially inappropriate medications vs **12%** in the control group.

Inspiration for our D-PRESCRIBE-AD Randomized Trial



UMass Chan
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Article

CLINICAL
TRIALS

Practical challenges in the conduct of pragmatic trials embedded in health plans: Lessons of IMPACT-AFib, an FDA-Catalyst trial

Clinical Trials
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Abstract

IMPACT-AFib was an 80,000-patient randomized clinical trial implemented by five US insurance companies (health plans) aimed at increasing the use of oral anticoagulants by individuals with atrial fibrillation who were at high risk of stroke and not on treatment. The underlying thesis was that patients could be change agents to initiate prescribing discussions with their providers. We tested the effect of mailing information to both patients and their providers. We used administrative medical claims and pharmacy dispensing data to identify eligible patients, to randomize them to an early or delayed intervention, and to assess clinical outcomes. The core data were analysis-ready datasets each site had created and curated for the FDA's Sentinel System, supplemented by updated "fresh" pharmacy and enrollment data to ensure eligibility at the time of intervention. Following mutually agreed upon procedures, sites linked to additional internal source data to implement the intervention—educational information mailed to patients and their providers in the early intervention arm, and to providers of patients in the delayed intervention arm approximately 12 months later. The primary analysis compares the early intervention arm to the delayed intervention arm, prior to the delayed intervention being conducted (i.e. compares intervention to non-intervention). The endpoints of interest were evidence of initiation of anticoagulation (primary) as well as clinical endpoints, including stroke and hospitalization for bleeding. Major challenges, some unanticipated, identi-

IMPACT-AFib

- ▶ Trial aimed at increasing the use of oral anticoagulants by individuals with atrial fibrillation at high risk of stroke and not on treatment.
- ▶ Implemented across five U.S. health plans.
- ▶ Took advantage of the FDA Sentinel Data Infrastructure.
- ▶ Underlying thesis: patients could be change agents to initiate prescribing discussions with their providers.
- ▶ Trial tested the effect of mailing information to both patients and their providers.
- ▶ 80,000 patients were randomized.
- ▶ Endpoint of primary interest: evidence of initiation of anticoagulation.
- ▶ Focus of IMPACT-AFib was on prescribing rather than deprescribing.

D-PRESCRIBE-AD Aim

To assess the impact of a patient/caregiver educational intervention on **potentially inappropriate prescribing to Alzheimer's Disease or ADRD patients**

- Potentially inappropriate prescribing includes the use of medications that may no longer be necessary or that may increase the risk of harm.
- For the purpose of our study, potentially inappropriate prescribing includes antipsychotics, sedative-hypnotics, and strong anticholinergics.

D-PRESCRIBE-AD Design

Prospective, randomized design:

- ▶ Two national health plans - HealthCore/Anthem and Humana
- ▶ Target drug classes: antipsychotics, sedative-hypnotics, and strong anticholinergics
- ▶ Three arms: patient/caregiver + provider, provider only, or usual care
- ▶ Randomization at the individual patient level
- ▶ **3,750** to be randomized to each of the 3 arms of the trial (11,250 subjects)
- ▶ No prescriber will have more than one patient enrolled in the trial
- ▶ Waiver of informed consent

Study population

Inclusion criteria

- ▶ ≥ 50 years of age as of cohort entry date AND
- ▶ Diagnosis of AD/ADRD based on a modified list of Chronic Conditions Data Warehouse codes and an algorithm published by Moura and colleagues, or treatment with a pharmacologic therapy used for AD within the past 365 days prior to or on study entry date AND
- ▶ Evidence of inappropriate prescribing within past six months prior to cohort entry date AND
- ▶ Continuous medical and pharmacy coverage at least a year prior to cohort entry date.

Exclusion criteria

- ▶ Residing in a nursing home or skilled nursing facility or receiving palliative care.

Outcomes

Primary Outcome

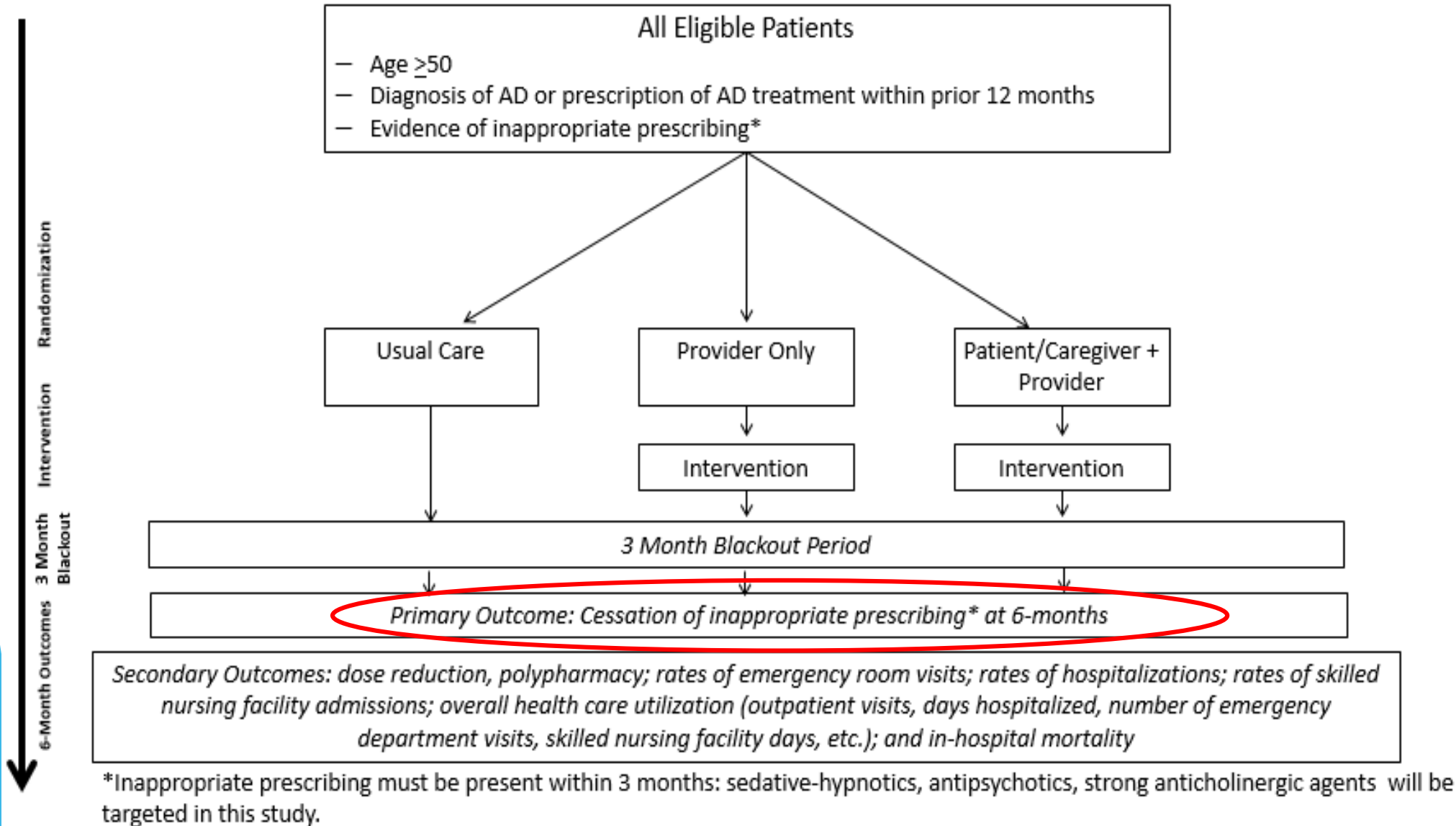
- ▶ The cessation of inappropriate prescribing

Secondary outcomes

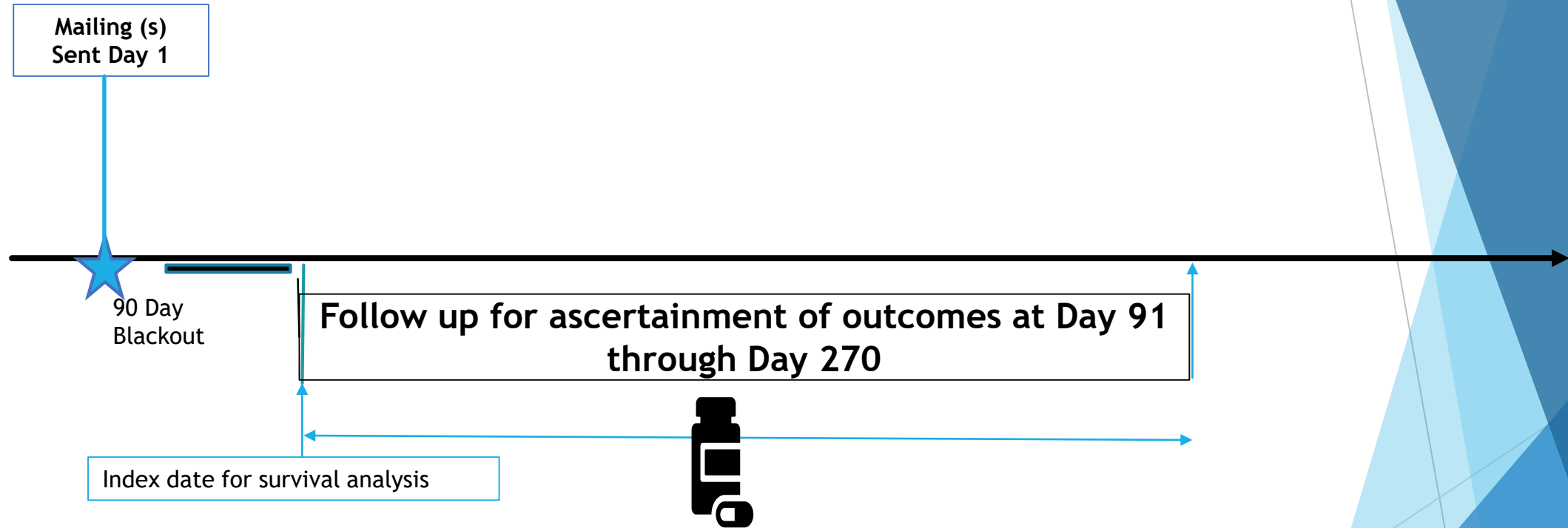
- ▶ Dose reduction of the selected inappropriate medication
- ▶ Prevalence of polypharmacy (>5 prescription medications)
- ▶ Rates of emergency room visits
- ▶ Rates of hospitalizations
- ▶ Rates of non-acute institutional stays (e.g., skilled nursing facilities)
- ▶ Overall health care utilization (number of outpatient visits, days hospitalized, emergency department visits, and non-acute institutional days)
- ▶ In-hospital all-cause mortality



D-PRESCRIBE-AD RCT Design



D-PRESCRIBE-AD RCT



Primary Outcome: Cessation of inappropriate prescribing at the end of 6 months (Day 91 - Day 270)

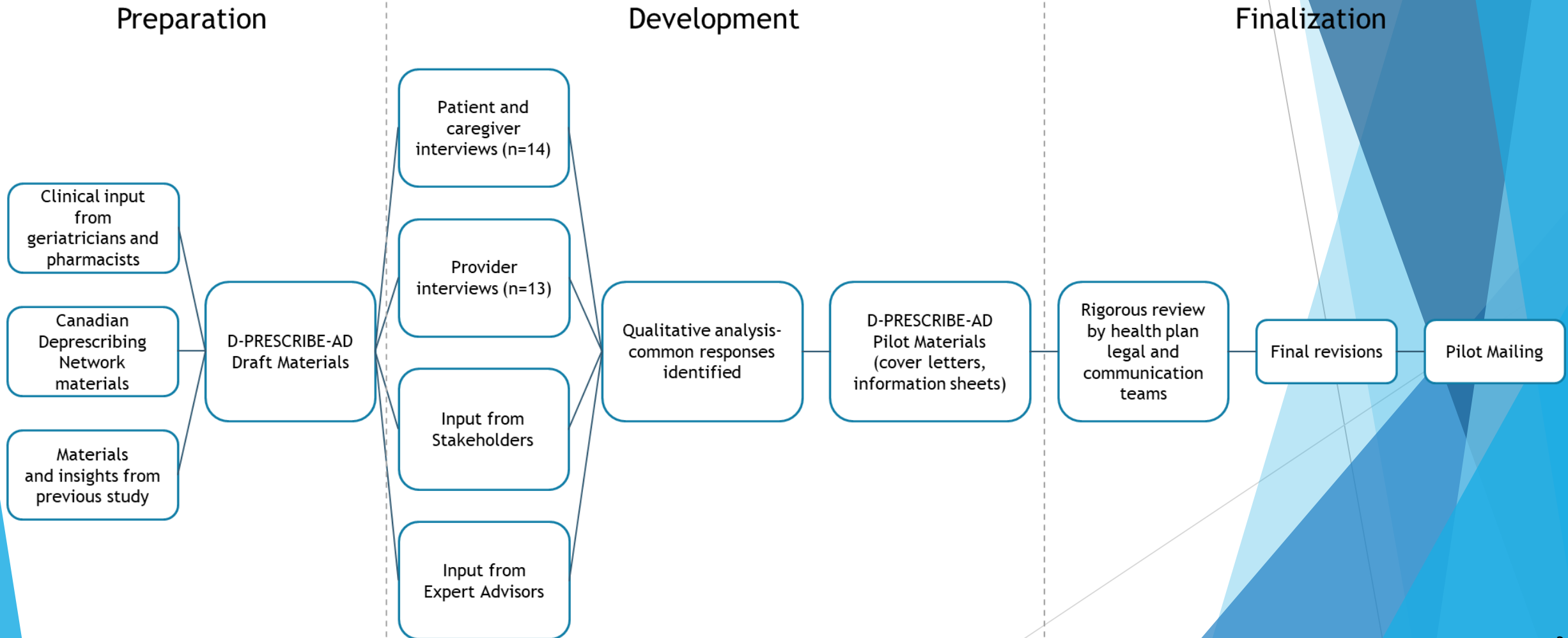
D-PRESCRIBE-AD: Intervention Arms

- ▶ Provider only: only providers will be mailed letters and educational materials
- ▶ Patient/Caregiver + Provider: patients and providers will be mailed letters and educational materials

D-PRESCRIBE-AD: Usual Care

- ▶ No intervention
- ▶ Data collection and outcome assessments will be identical to the intervention arms

Intervention Development



Principles of Patient/Caregiver and Provider material development

- ▶ Materials must be:
 - ▶ concise
 - ▶ understandable
 - ▶ specific to the patient
 - ▶ with clear suggested actions
- ▶ Guided by the [Deprescribing.org](https://www.deprescribing.org) approach used in the creation of educational materials

Patient/Caregiver & Provider Arm

- Patient/caregivers receive:
 - Letter referencing a specific drug
 - Information sheet referencing the drug class
 - Main messages: this drug may be inappropriate for you; talk to your provider
- Providers receive:
 - Letter referencing a specific patient and drug
 - Algorithm to guide decision making about deprescribing
 - Patient information sheet
 - Sample “Tapering Plan” to help patients track dose reductions
 - Main messages: this drug may be inappropriate for this patient; consider deprescribing
- Both sets of materials reference a “KnowMyMeds” **website where additional information and resources will be available**

Provider Only Arm

- Patients do not receive any materials
- Providers receive:
 - Letter referencing a specific patient and drug
 - Algorithm to guide decision making about deprescribing
 - Patient information sheet
 - Sample “Tapering Plan” to help patients track dose reductions
 - Main messages: this drug may be inappropriate for this patient; consider deprescribing

<Member First Name> medication management medications is important for your



Drug name and warning



Recommendation to talk to doctor

It's necessary to talk with your doctor regularly about your medications to ensure they are still right for you. To help you do that, we've included information about **lorazepam (Ativan®)**, which you are currently taking, so you can discuss this medication at your next doctor's visit.

Lorazepam is sometimes prescribed to treat anxiety or sleep problems. Using this medication for a short time may be appropriate. However, taking it for a long time may lead to harmful side effects such as falls and fractures, dizziness, memory problems, or daytime fatigue. These side effects may be more common as you age or if you're taking it with other drugs. **Ask your doctor if lorazepam is still the best treatment for you.**



Warning to not stop prematurely

Important: Do not stop or change this medication without talking to your doctor.

Anthem and HealthCore, Inc. have partnered to bring you this information. If you do not wish to receive any more materials like this, please email dnc@healthcore.com or call **844-203-3796**.

— Your <Anthem> service team

Share this information

Show this letter and the enclosed information sheet to your doctor at your next visit.

If you have someone who helps you with your medications, share these materials with them, too.

For more information

Phone:
833-739-1374 (toll free)

Email:
knowmymeds@umassmed.edu

Website:
knowmymeds.org



Are your medications still right for you?

As life changes, your medication needs may change as well. Medications that were once good for you may not be the best choice for you today.

Specific drugs

The **medications** in this box are sometimes used **for anxiety or sleep**:

- Alprazolam (Xanax®)
- Clonazepam (Klonopin®)
- Diazepam (Valium®)
- Eszopiclone (Lunesta®)
- Lorazepam (Ativan®)
- Temazepam (Restoril®)
- Zolpidem (Ambien®)



These medications can cause **side effects** including:

- falls and fractures
- dizziness
- worsened memory problems
- daytime fatigue
- dependence

Side effects

Recommendations including talk to doctor

As people age, they are more likely to experience side effects. Because of this, experts recommend that people on these medications talk to their healthcare provider about whether they should continue, reduce, or stop these medications.

Do not stop this medication before talking with your doctor. These medications must be reduced slowly. They should not be stopped suddenly. Stopping too quickly may cause problems.

Your doctor may suggest alternative medications or lifestyle changes that may help you.

What should you do?

- If someone helps you with your medications at home, share this information with them.
- **Bring this information sheet to your doctor.**
- Ask your doctor whether reducing or stopping this medication is the right choice for you.



Pocket Card

Questions to ask your doctor

- Do you think I still need this medication?
- Are there other approaches that I could try instead?
- Are there other medications that are safer for me?
- If I don't need this medication, can we make a plan to discontinue it?

Do not stop or change any of your medications without talking to your doctor.

[Health Plan Logo]

Return address

[Date]
[Clinician Name]
[Clinician Address]
[Clinician City, St, Zip]

Suggested Actions:

- ✓ Review enclosed information
- ✓ Discuss with your patient and make any warranted changes in therapy

Dear [Clinician Name],

This letter contains information that may assist you in caring for your patients. According to our records a patient of yours may be taking [medication name].

Sedative-hypnotic medications often have side effects including falls and fractures, dizziness, memory problems, and daytime fatigue. Experts recommend that **these potentially inappropriate medications are best avoided by older adults** in most circumstances.¹

We have mailed a patient information sheet on sedative-hypnotic medications to the following patient (a copy is enclosed).

Name: **[Patient Name]**
Date of Birth: **[Patient Date of Birth]**
Medication: **[Patient Medication]**
Date Initiated: **[Date Medication Initiated]**

Patient specific information

Reference to enclosures

We have enclosed an **algorithm** that may help you decide whether to reduce or discontinue this medication, and a **tapering guide** to help patients understand and track dose reductions. This, along with the patient information sheet, are available at [website].

We realize that our records may not reflect all clinically relevant information or may be incomplete. If you have questions or concerns about this letter, please contact us at [health plan email] or [xxx-xxx-xxxx].

Sincerely,
Chief Medical Officer
Health Plan

Medication Tapering Plan

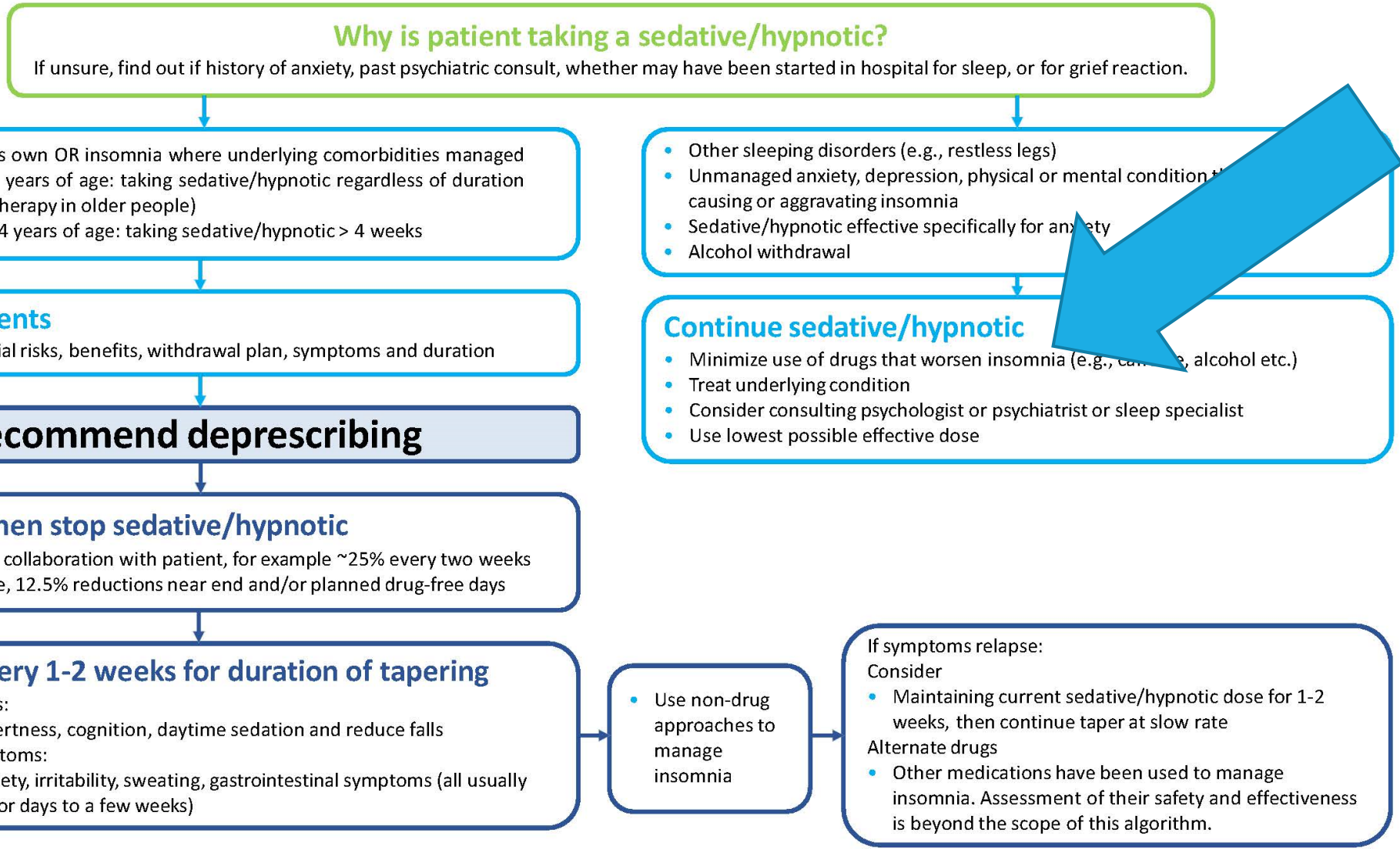
Talk to your doctor, nurse or pharmacist before making any changes to your medication.

Patient Name: _____ Doctor: _____ Medication: _____

Tapering Schedule							
WEEK OF:	SU	MO	TU	WE	TH	FR	SA
1. ___/___							
2. ___/___							
3. ___/___							
4. ___/___							
5. ___/___							
6. ___/___							
7. ___/___							
8. ___/___							
9. ___/___							
10. ___/___							
11. ___/___							
12. ___/___							
13. ___/___							



Sedative/Hypnotic Deprescribing Algorithm



Outcome measurement

Primary outcome

- ▶ **Discontinuation of the potentially inappropriate prescription:** absence of any dispensing of the targeted medication from day 91 to day 270 during the 9 month-period following the mailing.
- ▶ Measured as **hazard ratio:** relative hazard of time to dispensing of the inappropriate medication in the intervention vs control group.

Outcome measurement

Secondary outcomes

- ▶ Dose reduction of the targeted inappropriate medication after 6 months defined as more than a 50% reduction in dose of the targeted medication
- ▶ Prevalence of polypharmacy (defined as >5 active prescriptions for different prescription medications)
- ▶ Rates of emergency room visits; rates of hospitalizations; rates of non-acute institutional stays (e.g., skilled nursing facilities); overall health care utilization (number of outpatient visits, days hospitalized, emergency department visits, and non-acute institutional days).
- ▶ In-hospital all-cause mortality

Data management

Electronic data are accessed, maintained, and protected, as part of a “distributed system.”

- ▶ Data remain in their existing secure environments
- ▶ Health plans maintain physical and operational control over their electronic health data behind their institutional firewalls
- ▶ Health plans transform their data into the Sentinel Common Data Model, execute standardized analytic queries, then share the output of queries with the Operations Center via a secure network portal

This system protects the privacy and confidentiality of individual-level health information and is preferred by participating health plans over a centralized data repository approach.

D-PRESCRIBE-AD: Summary

What we hope to achieve:

- (1) To demonstrate the feasibility of population-based outreach to AD/ADRD patients at high risk for potentially inappropriate prescribing and their family caregivers;
- (2) To demonstrate the feasibility and effectiveness of a low-intensity educational intervention focused on reducing potentially inappropriate prescribing, and involving AD/ADRD patients, their family caregivers, and healthcare providers; and
- (3) To demonstrate the value and efficiency of capitalizing on routinely collected health plan data to identify high-risk populations and to assess primary and secondary outcomes.

D-PRESCRIBE-AD: Challenges, Uncertainties & Lingerin Questions

- (1) Who should receive the provider letter and materials? The primary care provider or the prescriber of the potentially inappropriate medication?
- (2) We don't know if there is a caregiver and if there is a caregiver, we don't know how to identify them. And if there is a caregiver, will that person ever see the mailed materials?
- (3) Does the patient really have AD/ADRD? Does it really matter? (N.B., the educational materials never allude to AD/ADRD)

Thank you!

UMass Chan Medical School/Meyers Health Care Institute

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