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Maine Medical Association

Department of Health and Human Services
Maine People Living Safe, Healthy and Productive Lives

Co-Prescribing Benzodiazepines and Opioids:

the Black Box of Increased Overdose Risk

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Speaker:

Elisabeth Fowlie Mock, MD, MPH, FAAFP

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Disclosures

- MICIS does not accept any money from pharmaceutical companies
- Speakers and planners have no significant or relevant financial relationships to disclose
- This presentation includes “off label use” of medications
- Prizes provided by private donation

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Objectives

- Review the trends in benzodiazepine prescribing
- Evaluate risks of co-prescribing benzodiazepines and opioids
- Consider taper plans
- Recall importance of risk reduction

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Materials

- Academic detailing handout
- Patient materials:
  - Dealing with Stress & Anxiety
  - Treating Insomnia & Anxiety in Older People

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Patient Handout

To access webinars, blogs, and other tools to help you manage stress and anxiety visit:
www.adaa.org

MHA Mental Health America

ADAA

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Patient Handout

Choosing Wisely®

An initiative of the ABIM Foundation

ABIM FOUNDATION

AGS Geriatrics Healthcare Professionals

Leading Change. Improving Care for Older Adults.

Insomnia and anxiety in older people

Sleeping pills are usually not the best solution

Almost one-third of older people in the United States take sleeping pills. These medicines are also sometimes called "sedative-hypnotics" or "tranquilizers." They affect the brain and spinal cord.

people who take one of these medicines sleep only a little longer and better than those who don't take a medicine.

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Jeopardy rules

- 3 people per team, discuss answers quietly!
- No smart devices or books, do not look at the handout-HONOR system
- Earn money/points for correct “question” (use best judgement)
- NO POINTS OFF FOR INCORRECT GUESSES

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Benzo properties

- Anxiolytic (anxiety, panic attacks)
- Hypnotic (insomnia, anesthesia)
- Anticonvulsive (seizure, EtOH w/d)
- Muscle relaxant

BENZOS for $100

- The most frequently prescribed benzodiazepine

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Commonly prescribed benzodiazepines

- alprazolam (Xanax)*
- clonazepam (Klonopin)
- diazepam (Valium)
- lorazepam (Ativan)
- temazepam (Restoril)

*One of the top three diverted prescription drugs-DEA, 2013

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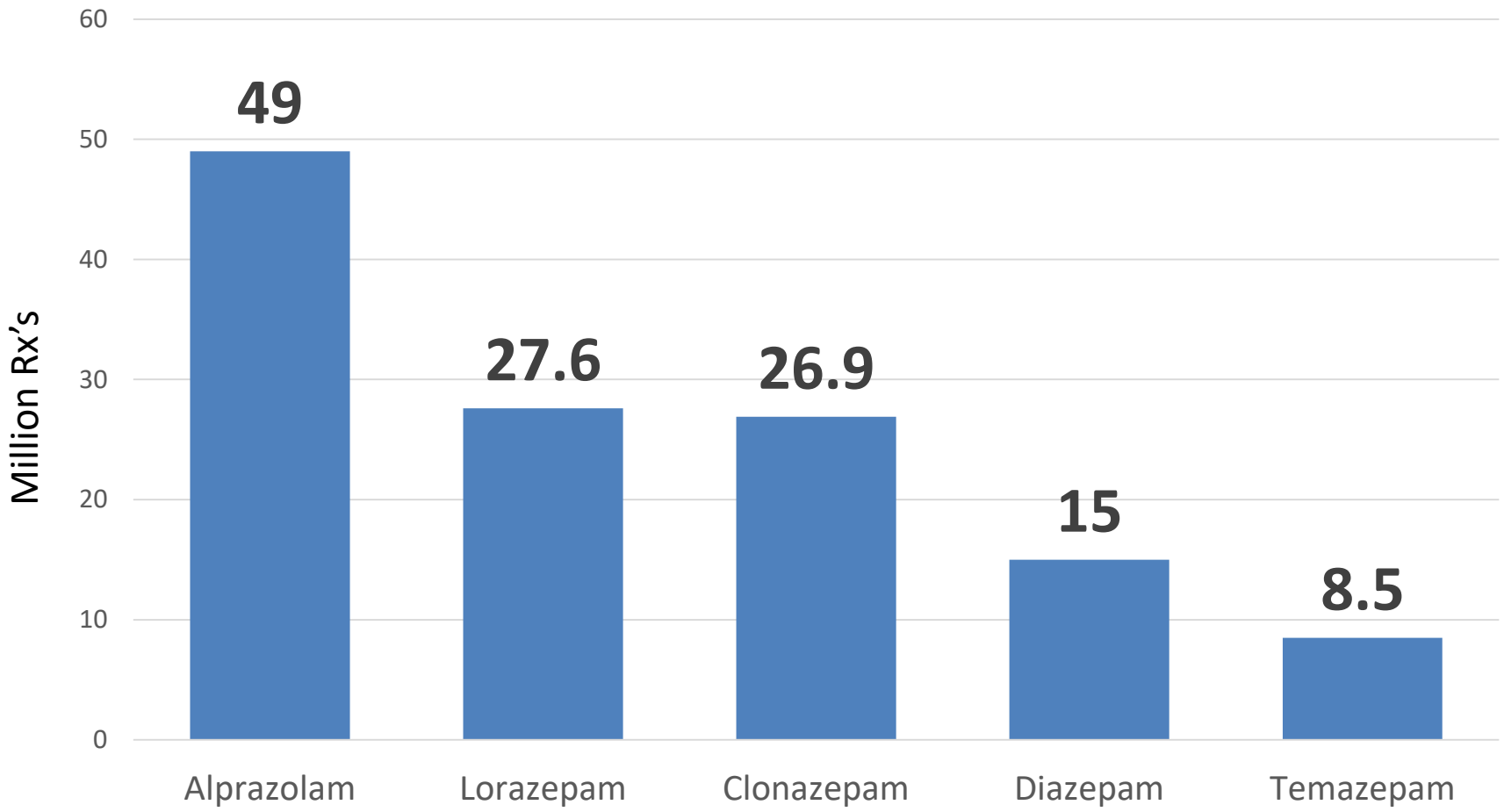
USA 2011-Top 5 Benzos



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DEA 2013

BENZOS for $200

- A generic name for a “z-drug” or sedative-hypnotic (any 1 of the 3)

Consider benzodiazepines to include “z-drugs” (sedative-hypnotic sleep aids)

“z-drugs”

- zolpidem (Ambien)
- zaleplon (Sonata)
- eszopiclone (Lunesta)

zolpidem impairment: levels >50

- Blood levels >50 ng/mL impair driving sufficiently to increase risk of MVC
- 8 hrs after 10 mg zolpidem
  - 15% women
  - 3% men
- 8 hrs after 10 mg zolpidem ER
  - 33% women
  - 25% men

2013 FDA Safety Communication

BENZODIAZEPINE PRESCRIBING TRENDS

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It is likely that benzo prescribing is safe for many patients, particularly when rx is limited in dose and duration

*emphasis added

Sallman, 1991 + Kroll, 2016

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"On the other hand,

‘we have all these physicians who have been prescribing opioids and benzos together for years to tens of millions of patients ... [and] maybe don't perceive this to be as big a risk."

Dasgupta, 2016

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BENZOS for $300

- The presumed primary reason for the increase in opioid prescribing from 1990s-2010s

“Pharmaceutical marketing is often said to be a key cause of the opioid crisis. That doesn't explain the deadly rise of benzos.”

Szalavitz, 2018

BENZOS for $400

- Demographic group prescribed benzodiazepines at twice the rate of their counterparts

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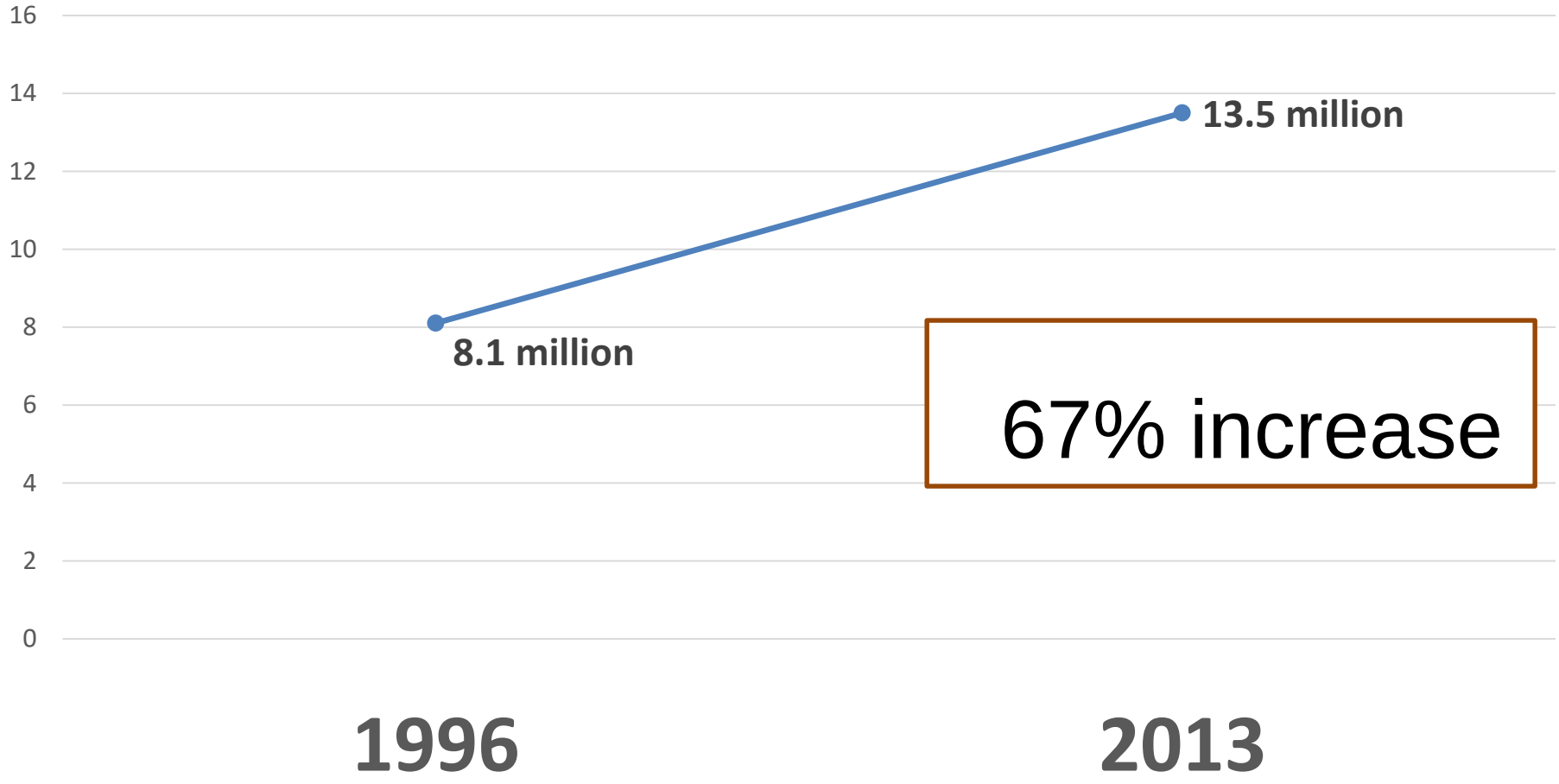
Benzo Use

- Nearly 2x F>M
- Increased used w/ age
  - 15% (18-35)
  - 31% (65-80)

long-term benzo use: >120d

Olfsan, 2015

Adults Who Filled Benzo Rx



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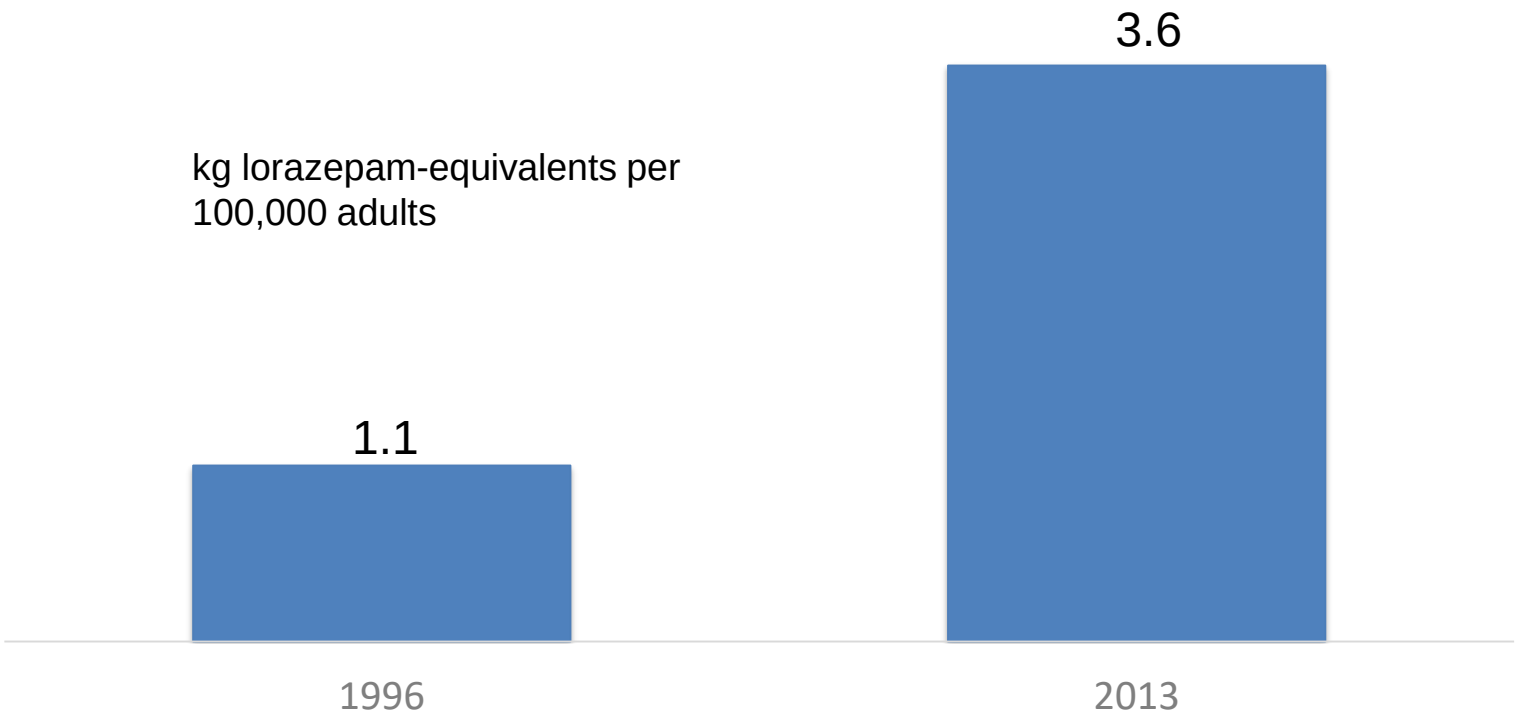
Bachhuber 2016

Amount of Benzo per Rx



Bachhuber 2016

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BENZOS for $500

- Class of psychiatric drug most prescribed in 2016 (happily, not a benzodiazepine)

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Most Rx'd Psych Drugs -2016

1. sertraline
2. alprazolam
3. escitalopram
4. citalopram

….

9. lorazepam

Grohol, 2017

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Key risks of benzos

- Risk of OD when prescribed with opioids
- Major falls (risk increases with age)
- Cognitive dysfunction ("pseudodementia")
- Decreased efficacy with long term use

Other risks:

- COPD: increased resp suppression, exacerbation & pneumonia
- OSA: increased severity
- Possible increased CA risk
  (association with tobacco may confound)

Kroll, 2016; Prescriber's Letter 2014

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Prevalence of sedative-hypnotic* use disorder

0.5% total population

6% patients with other SUD

*includes benzo, barbiturates, “z-drugs,” other sedative meds

Park, 2018

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ALTERNATIVES TO BENZODIAZEPINES

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BENZOS for $600

- Specific type of psychotherapy recommended as first line treatment (BEFORE DRUGS) for multiple anxiety-related diagnoses

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Psychotherapy & Behavioral Treatment

- Acute relief with 8-10 weeks of focused therapy
- Ongoing treatment to maintain and support change
- Most effective therapies focus on cognitive and behavioral change

SFHN, 2018

Academic Detailing Handout

Safer Treatments for Anxiety and Insomnia

Maine Independent Clinical Information Service • 2019

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Take Home Messages:

- Benzos are neither safe nor effective for long-term use
- Risk of death increases 4-10x when benzos & opioids co-prescribed
- 'Z-Drugs,' gabapentin/pregabalin & carisoprodol are also risky to co-prescribe with opioids
- Enlist Behavioral Health support & start benzo tapers
- Prescribe naloxone to all pts currently co-prescribed benzos & opioids

Non sedative-hypnotic treatment of ANXIETY

- assure proper diagnosis; anxiety may be a symptom of multiple psychiatric conditions
- rule out underlying medical problems
- consider medication side-effects as a cause of anxiety-related symptoms

Evidence-based medication treatments for Anxiety & PTSD

Class/Medication	Anxiety	PTSD
SSRI	X	X
SNRI	X	X
TCA	X	X

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Evidence-based medication treatments for Anxiety & PTSD

Class/Medication	Anxiety	PTSD
SSRI	X	X
SNRI	X	X
TCA	X	X
mirtazapine	X	X
buspirone	X	
hydroxyzine	X	
pregabalin/gabapentin*	X	
propranolol	X	
prazosin/clonidine/guanfacine		X
nefazodone		X

*some abuse potential, but less than benzos; can potentiate respiratory depression when combined with opioids

Reference: SFNH, Table 8.

FIRST, A STUDY OF BENZOS (NOT CO-PRESCRIBING)

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Boston Community Study

- Just under 66,000 patients
- 15% rx'd benzo
  - 44% from PCP
  - 56% from specialist
- Counted rx, not fills
  - possible overestimation

Kroll, 2016

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Pts rx'd benzos had

- MORE PCP visits
- MORE Specialist visits
- MORE ED Visits
- MORE Hospitalizations
- LONGER LOS

$p < 0.001$ for all

Kroll, 2016

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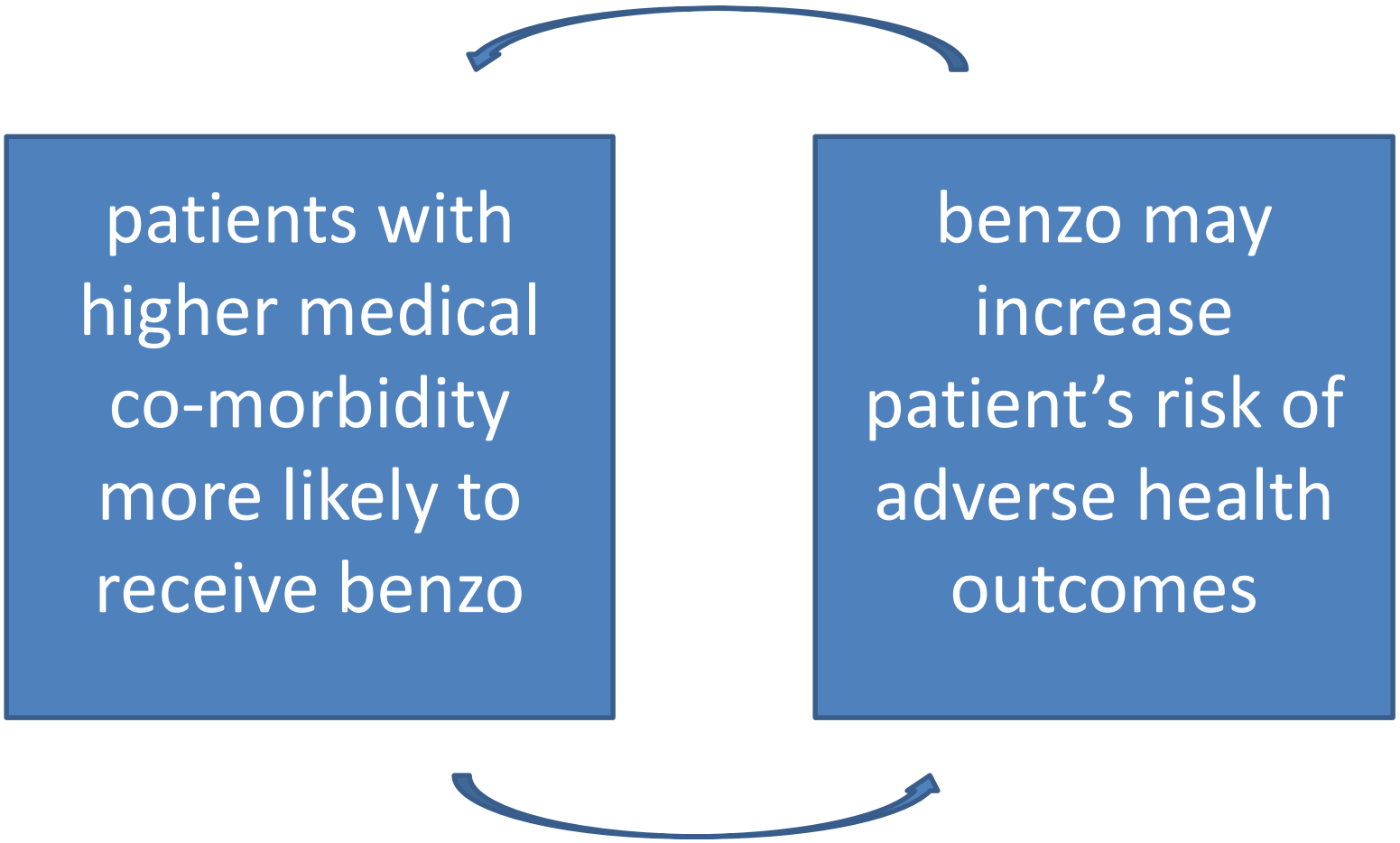

Both may be correct

Kroll, 2016

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Compared to non-recipients, benzo recipients more likely to have

	OR
Depression	2.7
Substance Use	2.2
Tobacco Use	1.7
Osteoporosis	1.6
COPD	1.6
ETOH Use	1.5
OSA	1.5
Asthma	1.5

Kroll 2016

Kroll Conclusion

- Patients with known risk factors for benzo related-adverse events were rx'd benzos more frequently

Kroll, 2016

BENZOS for $700

- Combining these two drug classes increases the risk of death by 4-10 fold

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SECOND, A LOOK AT CO-PRESCRIBING

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Rates of co-prescribing opioids plus benzos

From 2001 to 2013

DOUBLED

Patients co-prescribed opioids & benzos:

- Greater risk of ED visit
- Greater risk of hospitalization for drug-related emergency

Benzodiazepines in Overdose

- In 2011, **31**% of US opioid overdoses involved benzos
- Roughly **18**% of Maine opioid overdose deaths involved benzos in 2017 (ME Atty Gen)

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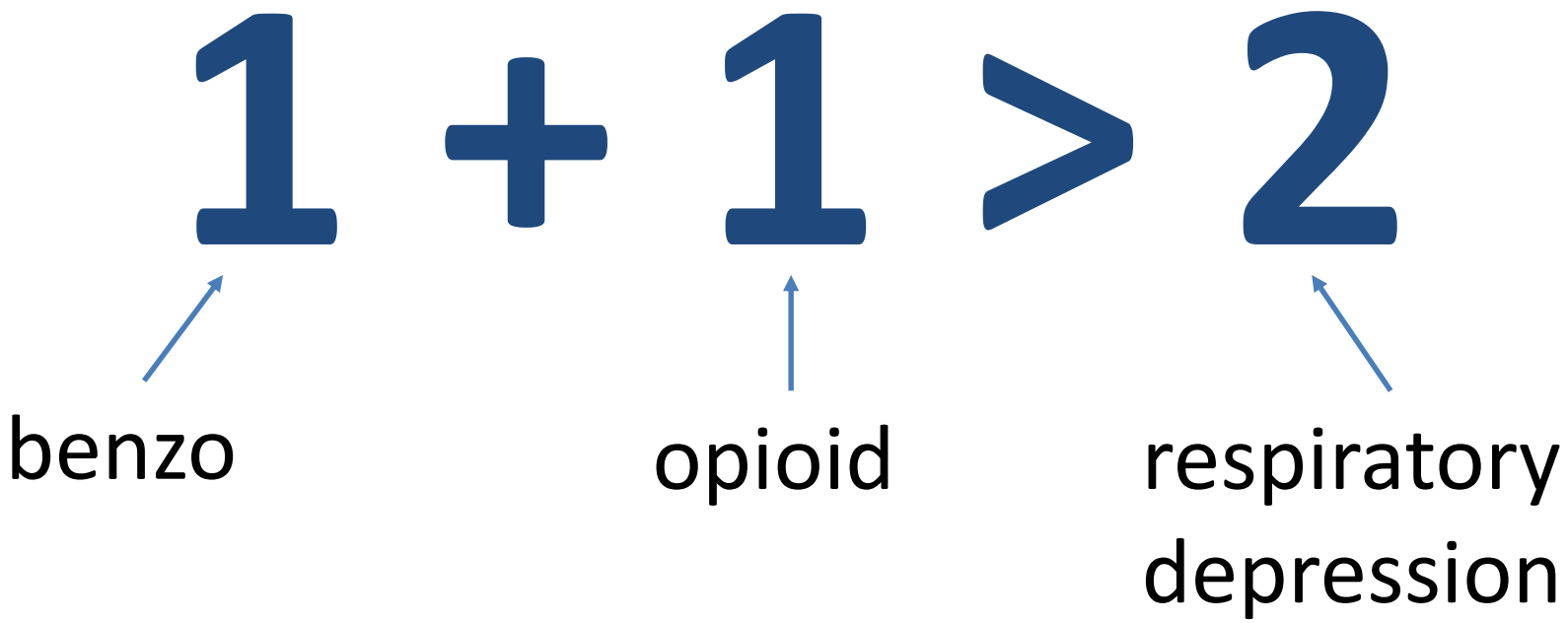

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opioid + benzo=

4-10x

more likely to die from overdose

(vs. opioid rx alone)

NIDA

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NC Cohort Study

- Nearly 2.2 million patients on opioids
  - 80% were co-prescribed benzos
  - Mortality rates increased gradually across the range of MME's
  - Rates of OD death among those co-dispensed 10x higher (7.0 person per year vs. 0.7)

Dasgupta, 2016

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BLACK BOX WARNING

opioids and benzodiazepines when combined can result in serious side effects including slowed/difficult breathing and death

FDA, August 2016

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BENZOS for $800

- This third medication that should always be prescribed for patients taking opioids and benzodiazepines.

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Overarching Concepts of co-rx'ing

- Stop starting!
- Taper, titrate, do not escalate
- Monitor closely, reassess frequently
- Limit dose & duration
- Warn pts & caregivers
- Co-rx naloxone

If already on benzo & opioid absolutely necessary:

Be sure to add the third rx: NALOXONE

*Occurred in <1% of visits when a patient already on benzo was rx'd a new opioid

CDC; Ladapo, 2018

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BE PREPARED.
GET NALOXONE.
SAVE A LIFE.

US Surgeon General, 8/1/18

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BENZOS for $900

- How often prescribers should have a face to face visit with any patient receiving a controlled substance prescription (guideline/best practice, not a law)

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Universal Precautions

- Document informed consent and treatment agreement (see BACSWG document summarized on handout)
- Discuss a clear plan
- Be explicit about length of rx
- Don't initiate co-prescribing of opioids & benzos/sedatives

Controlled Substance Prescribing Best Practices

- Document informed consent and treatment agreement
- Discuss a clear plan
- Be explicit about length of rx
- Don't initiate co-prescribing of opioids & benzos/sedatives
- See patient regularly (at least every 90 days)
- Do PMP checks + urine drug screens + pill counts
- Monitor efficacy + side effects
- Document, document, document

SAMPLE:

Informed Consent for Benzodiazepines for Anxiety Disorders

prepared by the Bangor Area Controlled Substance Work Group (BACSWG), Adopted November, 2015

Uses: I understand that benzodiazepines (drugs like lorazepam or Ativan, diazepam or Valium, clonazepam or Klonopin, alprazolam or Xanax) are sometimes used to lower high levels of anxiety. Some people report improved levels of anxiety when they take these drugs, but I understand that these drugs may not help people with anxiety when taken for more than 12 weeks. There are no studies that have answered this question.

Benefits Expected: Improved function and lower levels of anxiety

Alternatives: I understand that benzodiazepines are not the first choice of treatment for anxiety disorders. There

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Prescriber Oversight

- Benzos should be treated administratively like opioids or any other controlled substance
  - See patient regularly (at least every 90 days)
  - Do PMP checks + urine drug screens + pill counts
  - Monitor efficacy + side effects
  - Document, document, document
- If prescribed for more than 2 weeks, TAPERING is medically necessary

BENZOS for $1000

- Possible symptom of abrupt benzodiazepine withdrawal

Abrupt benzo withdrawal

- Rebound anxiety
- Hallucinations
- Seizure
- Delirium tremens
- Rare death

Which one to taper first?

- Risks of benzo w/d > risks of opioid w/d
- ? Safer + more practical to taper opioid first
- Opioid tapers can generally be done more quickly (rapid taper: dec by 25% q4-7d)

CDC, 2016

Scripts to discuss BENZO taper

- “I care about your safety…”
- “I am worried…”
- Acknowledge fears: “So you feel…”
- Reassure many pts do better without benzos, even if they feel briefly worse at first
- Reassure non-abandonment: “I’ll stick by you…”

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When tapering benzos or opioids,

- Offer
  - Evidence-based psychotherapy
  - Specific anti-depressants
  - Non-benzo anxiety meds
- And then, co-manage with behavioral health
- Involve family/friends

CDC, 2016

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Tapering benzos

- Just introducing topic induces panic in patient
- Faster initial, slower later
- Anticonvulsant rx when tapering high doses
- Once committed, OK to pause, but never reverse taper
- Ask patients for input into schedule (give some control)

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General tapering advice

- Commonly used tapering schedule (safe and moderately successful, relatively fast)
  - Decrease dose by 25% q1-2 w

CDC, 2016

Equivalent doses*

alprazolam	0.5
clonazepam	0.5
diazepam	10
lorazepam	1

**not precise*

Slower tapering schedules

- Multiple proposed “slow withdrawal schedules” for different products
- Generally converts to longer-acting product
- Last 2-12 months
- https://benzo.org.uk/manual/bzsched.htm

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FINAL JEOPARDY

- Category: prescription drug combinations in overdose
- Place your wager!!

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FINAL JEOPARDY

- Prescription drug found in 33% of overdose persons in Kentucky in 2016 (not a benzodiazepine, not an opioid)

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NON-BENZO SEDATIVE/HYPNOTICS INCLUDING MISUSE

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Caution: gabapentin

- 33% of persons in KY who died from overdose in 2016 were found to have gabapentin in their system (among other drugs)
- Schedule 5 (controlled) in KY since 2017, monitored in other states
- Patient risk factors should be considered

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gabapentin

- Widely used ‘off-label’: fibromyalgia, neuropathy, chronic pain, migraines, restless leg syndrome (*good evidence, NNT for chronic pain 7-8)
- Recommended as safer alternative to opioids and benzos
- May independently cause somnolence & CNS depression
- Concomitant treatment with morphine may cause increase in gabapentin concentrations

gabapentin stats

- Approved in 1993, widely used
- $945M in settlements for off-label marketing from 1994-2014
- 50% increase in sales from 2011-2016

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gabapentin misuse

- Euphoria
- Improved sociability
- Marijuana-like high
- Sense of calm, relaxation, helps with sleep
- “zombie-like” feeling
- Heightens effects of heroin, marijuana, cocaine, other substances

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The “Holy Trinity”

- Short-acting opioids, benzos & carisoprodol
- carisoprodol (Soma)
  - Metabolites have anti-anxiety properties similar to benzos
  - But from a toxicity standpoint, metabolites more closely resemble sedative properties of phenobarbital

JEOPARDY CHAMPS

- Tally your group total

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In Summary...

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In Summary...

- Benzos are neither safe nor effective for long-term use
- Risk of death increases 4-10x when benzos & opioids co-prescribed
- 'Z-Drugs,' gabapentin/pregabalin & carisoprodol are also risky to co-prescribe with opioids
- Enlist Behavioral Health support & start benzo tapers
- Prescribe naloxone to all pts currently co-prescribed benzos and opioids

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references: MICISMaine.org

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Balanced Data About Medications

https://qclearninglab.org/course-cat/caring-for-me/

BENZODIAZEPINE USE AND OPIOID USE: A DEADLY COMBINATION

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Video Resources

- https://www.youtube.com/watch?v=ZJZE6_z3-Tw (3 min focus on benzo w/d)
- https://www.youtube.com/watch?v=xzHIRGPeuqo (12 min documentary on Xanax pop culture)

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ADDITIONAL SLIDES (OVERFLOW)

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Pregabalin

- Widely used ‘off-label’ for chronic pain (*good evidence, NNT for chronic pain 7-8)
- Relaxation & euphoria w/ misuse
- Enhances effects of other misused substances
- When misused, usually taken with other substances such as heroin & benzos

Caution: pregabalin

- Recommended as safer alternative to opioids and benzos but when combined with opioids, benzos or alcohol may increase risk of unintentional OD
- Schedule 5 (controlled) by FDA—shows up on PMP

eszopliclone impairment

- Impairs
  - Driving skills
  - Memory
  - Coordination
- May last more than 11 hours without subjective awareness

2013 FDA Safety Communication

DISCUSS: WHAT ARE YOUR PRESCRIBING PRACTICES REGARDING BENZODIAZEPINES AND HAVE THEY CHANGED IN THE LAST 5 YEARS?

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A reversal of numbers

- In 1999, 13% of US opioid overdoses involved benzos
- In 2011, 31% of US opioid overdoses involved benzos
- Roughly **18**% of Maine opioid overdose deaths involved benzos in 2017 (ME Atty Gen)

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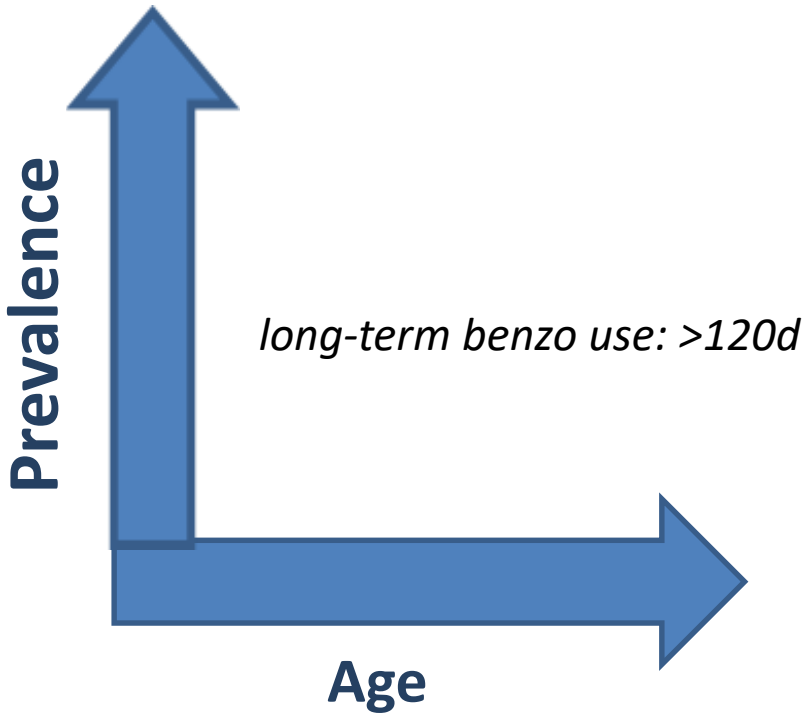
Benzo Use

- Nearly 2x F>M
- Increased used w/ age
  - 15% (18-35)
  - 31% (65-80)



Olfsan, 2015

Higher rates of initial opioid Rx were given to patients concurrently taking BZDP compared with general population.

ARR 1.83, p<0.001

Ladapo, 2018

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In elderly, benzos associated with

- Delirium (especially in hospital)
- Falls*
- Hip fx
- Disability
- Dementia
- Motor vehicle crashes

*increased risk of falls found with older studies of SSRI as well

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Kroll, 2016

USE EVEN GREATER CAUTION CHOOSING TO RX BENZO:

- COPD
- AGE >65
- OSTEOPOROSIS
- HX SUBSTANCE USE DISORDER (inc. EtOH)

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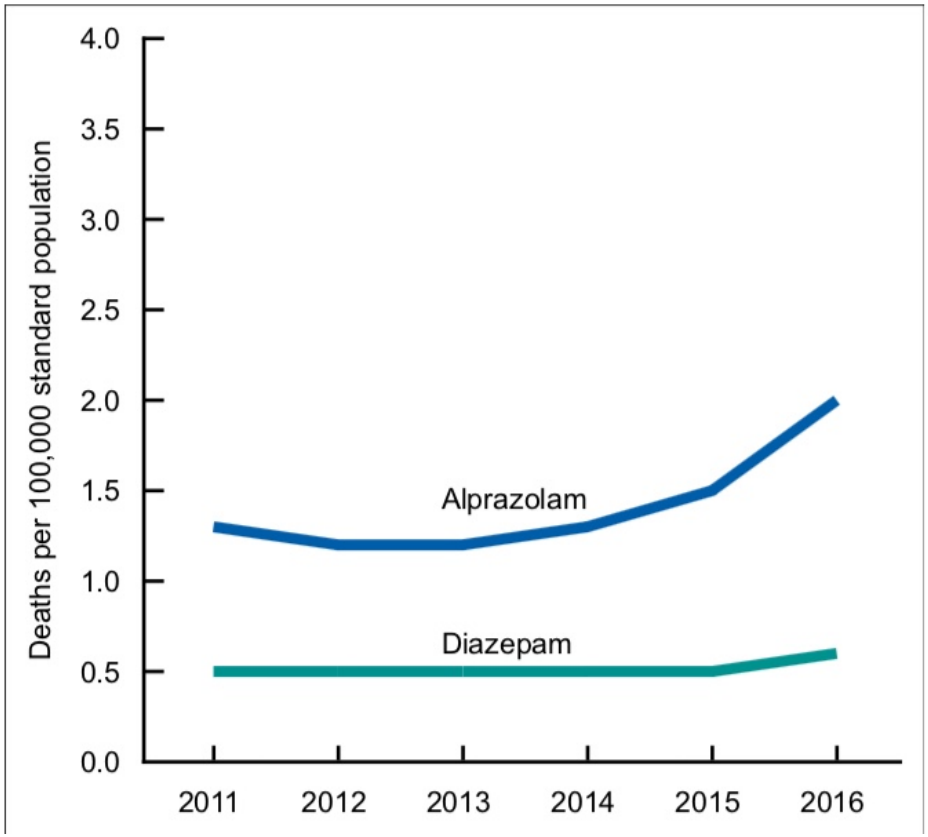
Kroll, 2016

Alprazolam in overdose



Hegegaard, 2018

Suicide by overdose

- Alprazolam is the 4th most common drug associated with intentional fatal overdose
- Oxycodone, diphenhydramine, hydrocodone are #1-3

Hegegaard, 2018

American Geriatrics Society Beers Criteria®

- Goal to improve care of older adults by reducing exposure to Potentially Inappropriate Medications (PIMs)
- PIMs have unfavorable balance of benefits + harms compared with alternative treatment options
- 2018 draft available online “DO NOT CITE OR QUOTE”

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Risk of death among veterans co-rx'd increased in dose-response fashion

Park, 2015

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CDC 2016 Guidelines

- Avoid Rx opioids and benzos concurrently whenever possible
- Category A Recommendation
  - Applies to all persons
  - Most pts should receive this course of action

In extenuating circumstances, it might be appropriate to co-prescribe

(avoid whenever possible)

CDC 2016 Guidelines

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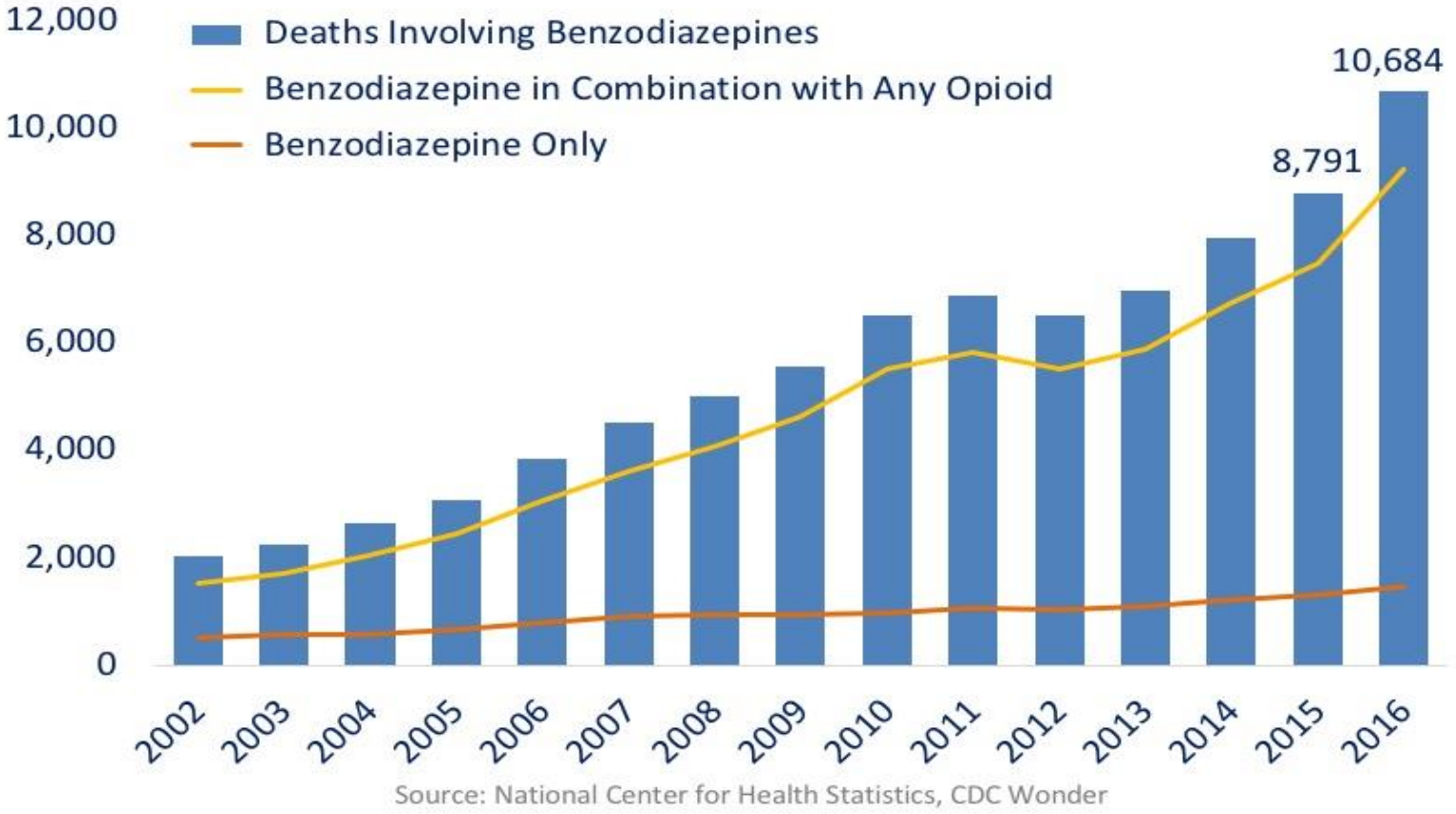
National Institute on Drug Abuse

Opioid Involvement in Benzodiazepine Overdose



Source: National Center for Health Statistics, CDC Wonder

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THE MAGNITUDE OF THE ASSN BETWEEN BENZOS + MORTALITY IN GENERAL APPEARS TO BE DOSE-DEPENDENT

Weich, 1996; Kripke, 2012; Park 2015

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Half-life

SHORTER

- Higher risk of dependence
- More significant withdrawal

LONGER

- Not as high risk of dependence
- Not as significant withdrawal

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Offer naloxone to all patients with concurrent opiod +benzo Rx

CDC, 2016

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Information for Prescribers from the Surgeon General

- **You have an important role to play in addressing this public health crisis**
- Learn how to identify patients at high risk for overdose
- Follow the 2016 CDC Guideline for Prescribing Opioids for Chronic Pain
- Utilize the prescription drug monitoring program (PMP)-required by law in Maine

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US Surgeon General, 8/1/18

Information for Prescribers from the Surgeon General

- Ask your local pharmacists/pharmacies if they are approved to prescribe naloxone
- Prescribe naloxone to individuals who are at elevated risk for opioid overdose and to their friends and family
- Naloxone may be covered by insurance or available at low or no cost to your patients

US Surgeon General, 8/1/18

Beyond opioids & benzos:

- In addition, given that other central nervous system depressants (e.g., muscle relaxants, [non-benzo] hypnotics) can potentiate central nervous system depression associated with opioids, clinicians should consider whether benefits outweigh risks of concurrent use of these drugs.

Paquin, 2014

Concomitant

COGNITIVE BEHAVIORAL THERAPY

increases benzo tapering success

CDC, 2016

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Psychotherapy & Behavioral Treatment

- Uncovers underlying causes of fears
- Teaches clients
  - to relax
  - to decrease anxiety responses
  - to look at situations in new ways
  - to develop better coping skills
  - to develop problem-solving skills

Psychotherapeutic technique examples

- Cognitive behavioral therapy (CBT)
- Behavioral techniques
- Acceptance and commitment therapy (ACT)
- Prolonged exposure therapy (PE)
- Cognitive processing therapy (CPT)

Other Behavioral Interventions

- Relaxation techniques
- Breathing exercises
- Stress reduction
- Lifestyle changes-including diet & exercise
- Self-help manuals
- Worksheets with instruction
- Mobile applications; many for use WITH a professional provider

adaa.org/resources-professionals/mental-health-apps

"It would be a tragedy if measures to target overprescribing and overuse of opioids diverted people from one class of life-threatening drugs to another. We believe that the growing infrastructure to address the opioid epidemic should be harnessed to respond to dangerous trends in benzodiazepine overuse, misuse, and addiction as well."

Lembke, NEJM, 2018

Academic Detailing Handout

Non sedative-hypnotic treatment of INSOMNIA

- Treat co-morbidities (depression, pain, movement disorders, sleep study to assess for sleep apnea)
- Eliminate activating medications/substances
- Employ psychological (e.g. CBT specifically for insomnia) and/or behavioral treatments (e.g. sleep diary) to restructure maladaptive cognitions and promote healthy sleep habits/sleep hygiene
- Consider concurrent SHORT-TERM pharmacological treatment

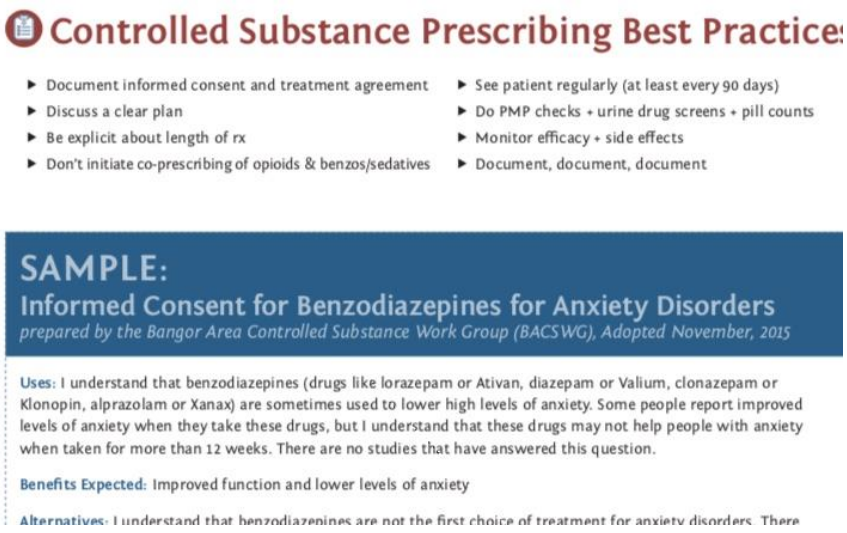
Evidence-based medication treatments for Insomnia

Treating anxiety:

Medications/Supplements in Addition to SSRI/SNRI/TCA

(see also table bottom of page 1)

Medication/Supplement	Daily Dose Range	Comments
		Best in conjunction w/SSRI/SNRI. Onset of effect 2 weeks, thus



Controlled Substance Prescribing Best Practices

- Document informed consent and treatment agreement
- Discuss a clear plan
- Be explicit about length of rx
- Don't initiate co-prescribing of opioids & benzos/sedatives
- See patient regularly (at least every 90 days)
- Do PMP checks + urine drug screens + pill counts
- Monitor efficacy + side effects
- Document, document, document

SAMPLE:

Informed Consent for Benzodiazepines for Anxiety Disorders

prepared by the Bangor Area Controlled Substance Work Group (BACSWG), Adopted November, 2015

Uses: I understand that benzodiazepines (drugs like lorazepam or Ativan, diazepam or Valium, clonazepam or Klonopin, alprazolam or Xanax) are sometimes used to lower high levels of anxiety. Some people report improved levels of anxiety when they take these drugs, but I understand that these drugs may not help people with anxiety when taken for more than 12 weeks. There are no studies that have answered this question.

Benefits Expected: Improved function and lower levels of anxiety

Alternatives: I understand that benzodiazepines are not the first choice of treatment for anxiety disorders. There

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gabapentin

- Indicated for post-herpetic neuralgia & adjuvant for seizures
- Widely used ‘off-label’: fibromyalgia, neuropathy, chronic pain, migraines, restless leg syndrome (*good evidence, NNT for chronic pain 7-8)
- Recommended as safer alternative to opioids and benzos

Summarized from gabapentin drug insert

- May independently cause somnolence & CNS depression
- Concomitant treatment with morphine may cause increase in gabapentin concentrations
  - Carefully observe for signs of CNS depression & reduce dose of gabapentin or morphine as appropriate

Labeled in email by a pharmaceutical company executive as “the snake oil of the twentieth century”

Pregabalin

- Indicated for post-herpetic neuralgia & adjuvant for seizures (same as gabapentin)
  - As well as: diabetic neuropathy, fibromyalgia, neuropathy assoc w/spinal cord injury
- Widely used 'off-label' for chronic pain (*good evidence, NNT for chronic pain 7-8)
- The "new valium" or "Budweiser" due to 'drunken'-like effect

opioids & benzos when intentionally combined:

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