Polypharmacy in the Elderly: I Take So Many Pills That I Rattle When I Walk

Ariel Cole, MD, CAQ Geriatrics, CMD, FAAFP
Robert Vandervoort, PhamD

FMX

ACTIVITY DISCLAIMER

The material presented here is being made available by the American Academy of Family Physicians for educational purposes only. This material is not intended to represent the only, nor necessarily best, methods or procedures appropriate for the medical situations discussed. Rather, it is intended to present an approach, view, statement, or opinion of the faculty, which may be helpful to others who face similar situations.

The AAFP disclaims any and all liability for injury or other damages resulting to any individual using this material and for all claims that might arise out of the use of the techniques demonstrated therein by such individuals, whether these claims shall be asserted by a physician or any other person. Every effort has been made to ensure the accuracy of the data presented here. Physicians may care to check specific details such as drug doses and contraindications, etc., in standard sources prior to clinical application. This material might contain recommendations/guidelines developed by other organizations. Please note that although these guidelines might be included, this does not necessarily imply the endorsement by the AAFP.

FMX

DISCLOSURE

It is the policy of the AAFP that all individuals in a position to control content disclose any relationships with commercial interests upon nomination/invitation of participation. Disclosure documents are reviewed for potential conflict of interest (COI), and if identified, conflicts are resolved prior to confirmation of participation. Only those participants who had no conflict of interest or who agreed to an identified resolution process prior to their participation were involved in this CME activity.

All individuals in a position to control content for this activity have indicated they have no relevant financial relationships to disclose.

The content of my material/presentation in this CME activity will not include discussion of unapproved or investigational uses of products or devices.

FMX

Ariel Cole, MD, CAQ Geriatrics, CMD, FAAFP

Director, Geriatric Fellowship, Florida Hospital, Orlando; Assistant Director, Family Medicine Residency, Florida Hospital, Orlando; Clerkship Director, Geriatrics, Florida State University College of Medicine, Orlando; Assistant Professor, College of Medicine, University of Central Florida

Dr. Cole practices family medicine in Winter Park, Florida. In addition to seeing patients in an outpatient setting, she also provides care at three nursing homes, as well as inpatient care and home visits. Dr. Cole has been teaching for 12 years and is interested in topics including dementia, delirium, polypharmacy, and caregiver burden.

FMX

Robert Vandervoort, PhamD

Director, Anticoagulation Clinic and the Chronic Disease Management Clinic; Assistant Professor of Pharmacy, University of Florida, Gainesville; Assistant Professor of Nursing, University of Central Florida, Florida Hospital College of Health Sciences, Orlando.

Dr. Vandervoort is a graduate of the University of Florida in Gainesville where he earned his Doctor of Pharmacy degree. He completed a residency in primary care pharmacy practice at the Family Health Center at Florida Hospital, where he has served the past twenty years as the faculty pharmacist for Florida Hospital's Family Practice Residency. Dr. Vandervoort also serves as director of the Anticoagulation Clinic and the Chronic Disease Management Clinic. His practice interests include literature review and analysis, diabetes, infectious disease, and anticoagulation.

FMX

Learning Objectives/Goals

1. Use evidence-based criteria (e.g. BEERS, STOPP, START) to evaluate for potentially adverse drug events among elderly patients receiving multiple medications.
2. Develop a systematic approach, including applicable REMS, to managing elderly patients with multiple chronic conditions that focus on the quality-of-life outcomes most valued by the patient.
3. Develop collaborative care plans to address the needs of patients who have poor health literacy or reduced cognitive function, or those patients who have language barriers, in order to foster appropriate self-administration of medications.
4. Counsel elderly patients and caregivers about tools, resources, and strategies to aid in the self-administration of medications.

FMX

Audience Engagement System

Presentation Topics

- Rational deprescribing
- Multiple chronic conditions
- Medication self-administration in challenging populations
- REMS

Rational Deprescribing

- Use evidence-based criteria (e.g. BEERS, STOPP, START) to evaluate for potentially adverse drug events among elderly patients receiving multiple medications.

Deprescribing

- In certain patient populations does not worsen outcomes
- Decreases risk of adverse drug reactions
- Reduces cost
- Makes patients happy!

Deprescribing Steps

1. Recognize an indication for discontinuing
2. Identify and prioritize the medications targeted for discontinuation
3. Discontinue, communicate with patient and other providers
4. Monitor for effects

Bain et al. JAGS 56:1946-1952

Indication ➡ Drug

- Is the original indication still present?
- Is the drug still appropriate given aging, decline in renal function, comorbidities?

New Beers List Publication

- J Am Geriatr Soc 2015.DOI:10.1111/jgs.13702
  - Collaboration with AGS
  - Second time the Beers list is the product of an evidence-based review process (first was the previous 2012 Publication)
  - Each recommendation is given a "Quality of Evidence" Rating and a "Strength of Recommendation" Rating
  - Three tiers of meds
    - PIM for all elderly (age 65 and older)
    - PIM for elderly with certain conditions
    - Caution in elderly
  - Two New Sections:
    - Drug Interactions
    - Dose adjustments for kidney function

Beers List Highlights

Potentially Inappropriate Medications for all Older Adults

First Generation Antihistamines

- Includes OTC sleep aids and allergy meds containing diphenhydramine, chlorpheniramine, doxylamine, hydroxyzine, and others.
- Promethazine (Phenergan) is also included on this list
  - Bioavailability is not significantly different between rectal and oral administration

Quality of Evidence	Strength of Recommendation
Moderate	Strong

Rationale

Highly anticholinergic, risk of confusion, constipation, clearance reduced with advanced age

Exception

Diphenhydramine when used for acute treatment of severe allergic reaction

Nitrofurantoin (Macrodantin)

- In 2012, the Beers publication recommended avoiding nitrofurantoin if CrCl<60 and for long-term suppression of UTI
- This made UTI treatment problematic for patients taking warfarin
- Based on two recent publications the authors revised this for 2015 to CrCl<30.

Quality of Evidence	Strength of Recommendation
Low	Strong

Rationale

Pulmonary toxicity (6 mo), hepatotoxicity, peripheral neuropathy (may develop within 2 weeks);safer alternatives available

Exception

May use if CrCl ≥30 for short term UTI treatment. Still avoid for suppression.

Non-Benzodiazepine BZD receptor Agonist Hypnotics

- Includes eszopiclone, zolpidem, zaleplon
- Previously in 2012 these were not recommended for longer than 90 days' use
- Now they are recommended to be avoided at any duration due to the balance of harm vs benefit even with short use

Quality of Evidence	Strength of Recommendation
Moderate	Strong

Rationale

High rate of physical dependence, AE similar to BZD (delirium ,falls, fractures), minimal improvement in sleep latency and duration

Exception

The previous exception for short-term use has been removed

Antipsychotics

- Applies to first and second generation agents
- Most concerns are specific to pts with pre-existing dementia (boxed warning against use in dementia-related psychosis)
- Often used off-label for delirium, specifically if pts manifest behavioral disturbances

Quality of Evidence	Strength of Recommendation
Moderate	Strong

Rationale

Increased risk for stroke, increased rate of cognitive decline and mortality in pts with dementia

Exception

May be used for schizophrenia, bipolar, or as chemo anti-emetic. May only use for behavioral problems of dementia or delirium if nonpharm interventions fail **and** the pt is threatening harm.

Nonselective NSAIDs

- Indomethacin (CNS) and ketorolac (GI bleeding and AKI) are singled out for avoidance without qualification
- Other nonselective NSAIDs are to be avoided for chronic use unless alternatives are ineffective and pt can take a protective agent
- ASA counts as an NSAID if dose is >325mg/day

Quality of Evidence	Strength of Recommendation
Moderate	Strong
Rationale	
Increased risk for PUD/GI bleed, especially in those age>75, taking oral steroids, anticoagulants or antiplatelets	
Exception	
May be used short-term (not defined in the document)	

FMX

Proton Pump Inhibitors

- New on the list as of 2015
- Reflects the recent appreciation that long-term PPIs are not benign
- "Demonstrated need" for chronic PPI could be failure of H-2 blockers, pathological hypersecretory condition, Barrett's
- H-2 blockers are not cautioned against by the authors in pts without delirium or dementia

Quality of Evidence	Strength of Recommendation
High	Strong
Rationale	
C difficile infection, bone loss, fractures	
Exception	
May be used for up to 8 weeks in anyone; may be used chronically if at high risk for NSAID ulcer or other 'demonstrated need'	

FMX

Sliding Scale Insulin

- Was new to Beers list in 2012- verbiage added in 2015 to clarify the caution
- Applies to Regular or rapid-acting analogues
- Does not apply to the use of scheduled pre-meal insulin or the practice of adding correctional insulin to scheduled prandial doses based on pre-meal glucose readings

Quality of Evidence	Strength of Recommendation
Moderate	Strong
Rationale	
Higher risk of hypoglycemia; lack of improvement in hyperglycemia	
Exception	
Does not apply to "correctional" insulin	

FMX

Beers List Highlights

Potentially Inappropriate Medications for Older Adults with Specific Medical Conditions

FMX

Beers List Highlights- By Disease State

Heart Failure	NSAIDS (including Cox-2)
Delirium	Corticosteroids (excludes inhaled and topical forms)
	H-2 blockers
Dementia	H-2 blockers
	Anticholinergics (includes urinary antimuscarinics, TCAs, antispasmodics, muscle relaxants, antihistamines)

FMX

Beers List Highlights- By Disease State

History of Falls or Fractures- "avoid unless safer alternatives not available"	BZDs and non-BZDs
	Anticonvulsants ("except for seizure")
	Antipsychotics
	TCAs and SSRIs
Parkinsons	All antipsychotics except for aripiprazole, quetiapine and clozapine
	Antiemetics (metoclopramide, prochlorperazine, promethazine)

FMX

Beers List Highlights

Potentially Inappropriate Medications to be used with Caution in Older Adults

FMX

Beers List Highlights- "Caution" List

ASA for Primary Prevention

- Caution in ≥80yo due to lack of data establishing risk/benefit

Dabigatran

- Increased bleeding risk in age ≥75
- Caution if CrCl<30

Prasugrel

- Increased bleeding in older adults; may be offset by benefit in very high risk pts
- Use with caution in age >75

FMX

Beers List Highlights

Potentially Clinically Important Drug-Drug Interactions that Should be Avoided in Older Adults

FMX

Minimize the number of Anticholinergic Drugs

- A table within the Guideline lists around fifty specific meds
- Quality of evidence is rated as moderate, recommendation level is rated as strong
- Rationale is increased risk of cognitive decline

- Antihistamines
- Muscle Relaxants
- Antidepressants (paroxetine is the only SSRI)
- Antipsychotics (Olanzapine is the only Atypical)
- Antimuscarinics (for urinary incontinence)
- Antispasmodics
- Antiemetics

FMX

Minimize the number of CNS-Active Drugs

- Quality of evidence is rated as Moderate (High for BZD/non-BZDs), recommendation level is rated as strong
- Rationale is increased risk of falls, and in the case of BZDs and Non-BZDs, fractures as well

- Antipsyhcotics
- TCAs and SSRIs
- Opioids
- Benzodiazepines and non-BZD Hypnotics

FMX

Beers List Highlights

Medications that Should be Avoided or Have Their Dosage Reduced with Varying Levels of Kidney Function in Older Adults

FMX

Newer Oral Anticoagulants (Recs based on clinical trial exclusion, not product labeling)

Agent	CrCl Cutoff	Recommendation
Apixaban (Eliquis)	<25	Avoid
Dabigatran (Pradaxa)	<30	Avoid
Edoxaban (Savaysa)	30-50 <30 or >95	Reduce Dose Avoid
Rivaroxaban (Xarelto)	30-50 <30	Reduce Dose Avoid

Spironolactone: Avoid at any dose if CrCl < 30

- In the 2012 publication, doses of Spironolactone greater than those used for HF (25mg daily) were not recommended
- In the 2015 publication this prohibition is removed and replaced with this recommendation
- Rationale is the potential for increased potassium
- In RALES, SCr>2.5 was an exclusion criteria.

H-2 Blockers

Drug	CrCl cutoff	Beers Rec	PI Rec
Cimetidine (Tagamet)	<50	Reduce Dose	300mg q12h
Famotidine (Pepcid)	<50	Reduce Dose	Reduce Dose by half or prolong interval to 36-48h
Nizatidine (Axid)	<50	Reduce Dose	CrCl 20-50: 150mng QD to QOD CrCl<20:150mg q2-3 days
Ranitidine (Zantac)	<50	Reduce Dose	150mg q24h

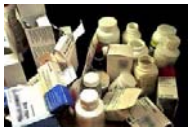
QOE: Moderate SOR: Strong Rationale: Mental Status Changes

Bedside reference

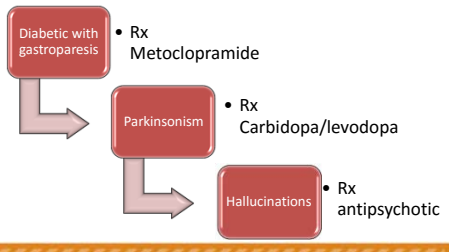
- AGS iGeriatrics
- Geriatrics at Your Fingertips

- Beers Criteria: J Am Geriatr Soc 2015;63:2227-2246
- STOPP/START: Int J Clin Pharmacol Ther 2007;46:72-83

- Avoid inappropriate meds
- Use appropriate drugs for appropriate indications
- Monitor for side effects, drug levels
- Keep creatinine clearance in mind
- Avoid drug-drug interactions
- Incorporate patient values



The prescribing cascade



AES Question 1

79 y/o patient, first visit to your practice, recent fall with minor injuries at home. Has Alzheimer's dementia, HTN, and BPH.

Which drug would you prioritize to "deprescribe" first?

A. Temazepam 15 mg qhs for sleep
B. Quetiapine 50 mg BID for agitation
C. Diphenhydramine 25 mg QAM for allergic rhinitis
D. Tamsulosin 0.4 mg QD for BPH

FMX

Patient Preferences

- Many patients prefer to make changes in diet, lifestyle rather than take a prescription drug to manage a symptom
- Older patients often choose to accept risks rather than "take another pill"

FMX

Multiple chronic conditions

- Develop a systematic approach, including applicable REMS, to managing elderly patients with multiple chronic conditions that focus on the quality-of-life outcomes most valued by the patient.

FMX

- Betty Smith is 80 years old
  - COPD
  - DM type 2
  - Osteoporosis
  - HTN
  - Osteoarthritis

- Clinical practice guidelines recommend 12 medications
- Which meds are appropriate?

FMX

Betty Smith: Med List

Rx	OTC
Glyburide 5mg daily	Naproxen 500mg BID prn joint pains
Lisinopril 20mg daily	Melatonin 3mg qhs
Alendronate 70mg Q weekly	Tylenol PM qhs
Fluticasone/Salmetrol 250/50 BID	Glucosamine
Metformin 1000mg BID	Vitamin B complex
Meloxicam 15mg daily	Calcium with Vitamin D

FMX

AES Question 2: Which of Betty Smith's meds are on the BEERS list?

A. Glyburide
B. Lisinopril
C. Alendronate
D. Metformin
E. Fluticasone

FMX

Heterogeneity

- Illness severity
- Functional status
- Prognosis
- Personal priorities
- Risk of adverse events

Patient preferences

- Patients not comfortable with treatment plan are much more likely to be nonadherent
- One therapy may worsen another condition
- Medications often confer long-term benefits at the risk of short-term harm

Interpret the Evidence

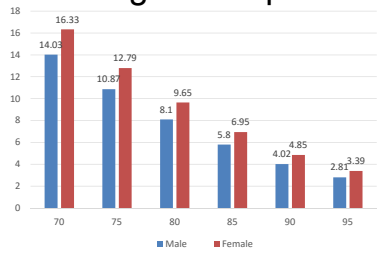
- Assess applicability and quality
- Most trials do not include > 75 y/o or patients with multiple conditions
- Extrapolating evidence to older adults could be harmful
- Consider time horizon to benefit in NNT

Prognosis

- Consider remaining life expectancy, quality of life, and functional status
- Is patient likely to live long enough to benefit?
- Particularly important in screening decisions

- Eprognosis.org

Remaining Life Expectancy



Clinical Feasibility

- Consider treatment complexity and feasibility
- ↑ Complexity
  - ↑ risk of nonadherence
  - ↑ adverse reactions
  - ↓ quality of life
  - ↑ economic burden
  - ↑ strain on caregiver

JAGS Patient-Centered Care for Older Adults with Multiple Chronic Conditions 2012

Optimizing Therapies and Care Plans

- Prioritize!
  - optimize benefit
  - minimize harm
  - enhance quality of life
- Stop inappropriate medications
- Use nonpharmacologic interventions when possible

FMX

Medication self-administration in challenging populations

- Develop collaborative care plans to address the needs of patients who have poor health literacy or reduced cognitive function, or those patients who have language barriers, in order to foster appropriate self-administration of medications.
- Counsel elderly patients and caregivers about tools, resources, and strategies to aid in the self-administration of medications.

FMX

Low Health Literacy

- Reduces efficacy
- Increases risk of adverse effects

FMX

Health Literacy Interventions

- Simplify information
  - Use illustrations
  - Limit the number of messages
  - Focus on action
- Avoid jargon
- "Teach back" method
- Encourage questions

FMX

Reduced Cognitive Function

- Keep it simple
- Repeat essential information
- Write down instructions
- Involve a caregiver
- Use community resources

FMX

Resources

- Home Healthcare referral
  - HHC nurse can set up medications, help caregiver develop system for administration and monitoring
- Telehealth or disease-state monitoring systems
- Automatic Medication dispenser
- Alarms
  - There's an app for that- lots of them!

FMX

Language Barrier

- Use a trained interpreter
  - Family members may have own agenda or may place interpreter in inappropriate position
  - Untrained staff may misinterpret medical terms
- Provide education in patient's primary language
- Write down instructions
- Avoid metaphors, idioms, colloquialisms

Cultural competence

- Value diversity
- Ask about preferences, customs, and expectations
- Respect male-female role differences
- Keep abreast of major health concerns and issues for ethnically and racially diverse patient populations in your area

Health literacy for older adults

- Simplify the regimen
- Medication reconciliation during transitions
- Educate patients/caregivers
- Use pill box, reminder tools
- Write down instructions
- Be aware of
  - Visual impairment
  - Hearing impairment

Brief Introduction to REMS

Intro to Risk Evaluation and Management Strategies

http://www.fda.gov/downloads/AboutFDA/Transparency/Basics/UCM328784.pdf

- In 2007 the FDA was granted authority to require manufacturers to propose and implement REMS for new or existing meds for which the FDA deems it is necessary
- REMS can consist of any of a number of different strategies including Med Guides, Elements to Assure Safe Use, and Implementation systems
- Free on-demand webinar: http://www.fda.gov/AboutFDA/Transparency/Basics/ucm325201.htm

REMS Elements

• All REMS required for an NDA or BLA must contain a timetable for submission of assessments of the REMS. They may also contain any of the following:

– Medication Guide or Patient Package Insert (required to be dispensed with the drug)
– Communication Plan
– Elements To Assure Safe Use (ETASU)
– Implementation System

http://www.fda.gov/downloads/AboutFDA/Transparency/Basics/UCM328784.pdf

Examples of REMS

Risk Example	Possible REMS Action
Serious infection	Patient education of initial warning signs of infection prior to prescribing
Severe allergic reaction	Healthcare professional must be certified to administer the product
Liver damage	Liver function monitoring while the patient is taking the drug
Severe birth defects	Negative pregnancy test prior to dispensing each prescription

http://www.fda.gov/downloads/AboutFDA/Transparency/Basics/UCM328784.pdf

FMX

REMS Communication Plan

Developed by the drug's sponsor to support implementation of an element of the REMS, and can inform key audiences (health care providers) about the risks of the drug. This could include:

- Sending letters to healthcare providers (e.g., Dear Healthcare Provider letters)
- Disseminating information about the REMS to encourage implementation or to explain certain safety measures
- Disseminating information through professional societies about any serious risks of the drug and any measures to assure safe use

http://www.fda.gov/downloads/AboutFDA/Transparency/Basics/UCM328784.pdf

Examples of Elements to Ensure Safe Use

- Prescribers have specific training/experience or special certifications
- Pharmacies, practitioners or healthcare settings that dispense the drug be specially certified
- Drug be dispensed only in certain healthcare settings (e.g., infusion settings, hospitals)
- Drug be dispensed with evidence of safe-use conditions such as laboratory test results
- Each patient using the drug be subject to monitoring
- Each patient using the drug be enrolled in a registry

http://www.fda.gov/downloads/AboutFDA/Transparency/Basics/UCM328784.pdf

FMX

Practice Recommendations

- Recognize BEERS list medications
- Incorporate patient priorities and prognosis in medication reviews
- Utilize tools to improve self-administration accuracy

FMX

Questions

FMX

Contacts

- Ariel.Cole.MD@FLHOSP.org
- Robert.Vandervoort@FLHOSP.org

FMX

Billing & Coding

When services performed in conjunction with:

Office Visit 992xx *

*Time-based selection documentation criteria:

- Face-to-face time
- greater than 50% spent counseling/coordinating care

Additional tests to confirm or monitor:

99490 Chronic Care Management-20 minutes monthly

FMX

Interested in More CME on this topic?

aafp.org/fmx-internal

FMX