

# Geriatric Safety

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## Reviewing the Update to the AGS 2023 Beers Criteria®

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# Disclosure

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- I have no actual or potential conflict of interest in relation to this program/presentation.

# Learning Objectives

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- Have a better understanding of the aging population and their physical changes
- Identify medications that are considered potentially inappropriate
- Select a safer medication regimen reducing adverse drug events
- Understand the rationale behind the recommendations in the AGS Beers® Criteria update

# Age Related Changes

- Pharmacokinetic changes

- Absorption
- Distribution
- Metabolism
- Elimination

- Pharmacodynamic changes

- Decreases in receptors

	Change	Result
<b>A</b>	↓ Active transport ↓ First pass	Unpredictable bioavailability
<b>D</b>	↓ Total body water ↑ Total body fat	↓ Vd for water soluble drugs ↑ Vd for fat soluble drugs
<b>M</b>	↓ Phase I metabolism ↓ Hepatic blood flow	↓ Metabolism = ↑ t <sub>1/2</sub>
<b>E</b>	↓ Renal elimination	↑ t <sub>1/2</sub>

# Physical Changes in Elderly



- ↓ Brain Volume (Cortical Volume)
- ↓ Cerebral Blood Flow
- ↓ Number of Synapses (Synaptic Density)
- ↑ Neurofibrillary tangles and senile plaques
- ↑ Energy expenditure
- ↓ Working memory
- ↓ Executive Function
- ↓ Processing Speed
- ↓ Attention



- ↑ LV wall thickness
- ↑ LA size
- ↓ end diastolic volume (Cardiac Output)
- ↑ myocyte hypertrophy
- ↓ number of cardiomyocytes
- ↑ collagen content
- ↑ fibrosis (Arterial Stiffness)
- ↓ Heart Rate Modulation
- Myocardial Hypertrophy
- Impaired endothelial function
- Conduction abnormalities



- ↓ GFR
- ↑ Glomerulosclerosis
- ↑ Interstitial fibrosis
- ↑ Tubular atrophy
- ↑ Arteriosclerosis
- ↓ number of nephrons
- ↓ kidney volume
- ↓ Renal Mass
- ↓ Drug clearance
- Hyalinisation of renal vasculature

# Physical Changes in Elderly



- ↓ alveolar surface area
- ↓ Elastic recoil
- ↓ diffusion capacity
- ↑ alveolar-arterial oxygen gradient
- chest wall compliance (Ventilation-perfusion inequality)
- ↓ FEV1 / FVC
- ↓ Lung Volume
- ↓ airway clearance



- ↓ muscle mass
- ↓ muscle quality
- ↑ myosteatosis
- Altered muscle energetics
- ↑ fracture risk
- ↓ Bone mineral density
- ↓ Strength and Power



- ↓ Volume
- ↓ Blood Flow
- ↓ First-pass metabolism
- ↓ Drug clearance



- ↓ Acid secretion
- ↓ Drug Absorption



# 2023 AGS Beers Criteria®

What is it and Why does it Matter

# How did it Begin

Developed by late Mark Beers, MD and colleagues at the University of California Los Angeles with the purpose to identify medications for which potential harm > expected benefit and should be avoided in nursing homes

1991

Criteria was updated by an interprofessional group

2003

7th overall update and 4th since AGS took over as the criteria's steward

2023

1997

Criteria was expanded to all older adults

2010

American Geriatrics Society takes over stewardship





# The Literature

- **Search dates:**
  - PubMed from June 1, 2017, to May 31, 2022
- **Search terms for each criterion:**
  - individual drugs, drug classes, specific conditions, and combinations thereof
  - focus on “adverse drug events” and “adverse drug reactions,” specific focus defined by the expert panel
- **Searches targeted:**
  - controlled clinical trials, observational studies, systematic reviews, meta-analyses
  - filters for human participants, 65 years old and older, and the English language.
  - Clinical reviews and guidelines (to provide context)
  - Excluded: Case reports, case series, letters to the editor, and editorials
- **Searches identified:**
  - 33,965 references and 7352 abstracts (sent to panelists for review)
  - 1574 references were selected for full-text review
  - 451 manuscripts were abstracted into evidence tables
  - 148 were included as background reports

# Strengths and Limitations

## Limitations of the study

- evidence available - small number of clinical trials in older adults; lack of inclusion of a sufficient number of older adults to conduct an age specific analysis; lack of studies for evidence of harm
- lack of diversity in study populations
- criteria includes only medications available in the United States

## Strengths (panel and staff)

- highly experienced; most have participated in updating the criteria since 2012, and some since 2003.
- Familiar with the process and modified Delphi technique
- Included ad hoc members from important stakeholders (Centers for Medicare and Medicaid, the National Committee for Quality Assurance, and the Pharmacy Quality Alliance, who provided valuable insight and feedback throughout the process.
- Robust internal review and external public comment processes

# Definitions

## Avoid

- “the medication should be avoided except under unusual circumstances”
  - When a safer alternative did not achieve the desired therapeutic outcome
  - Should be chosen infrequently after careful considerations of benefit vs risk
- Not defined as an absolute contraindication unless specified in the medications label
- Caveats are provided about when choosing a PIM may be reasonable

## Use with Caution

- Highlights medications that raise some cause for concern, but not to the level of “avoid”
- Evidence for the concern lacks consistency or is limited
- Degree of harm relative to alternative therapies is not high enough to warrant an “avoid” recommendation
- Extenuating clinical circumstances are often present

# Categories of Medications

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MEDICATIONS  
CONSIDERED  
**POTENTIALLY  
INAPPROPRIATE**



MEDICATIONS  
**POTENTIALLY  
INAPPROPRIATE  
IN PATIENTS  
WITH CERTAIN  
DISEASES OR  
SYNDROMES**



MEDICATIONS  
TO BE **USED  
WITH  
CAUTION**



POTENTIALLY  
INAPPROPRIATE  
**DRUG-DRUG  
INTERACTIONS**



MEDICATIONS  
WHOSE  
**DOSAGES  
SHOULD BE  
ADJUSTED  
BASED ON  
RENAL  
FUNCTION**

## Tables and Boxes

- **Table 2** → 2023 American Geriatrics Society Beers Criteria ® for potentially inappropriate medication use in older adults
- **Box 1** → Synthesis of anticoagulation recommendations
- **Table 3** → 2023 American Geriatrics Society Beers Criteria ® for potentially inappropriate medication use in older adults due to drug-disease or drug-syndrome interactions that may exacerbate the disease or syndrome
- **Table 4** → 2023 American Geriatrics Society Beers Criteria ® for potentially inappropriate medication: drugs to be used with caution in older adults
- **Table 5** → 2023 American Geriatrics Society Beers Criteria ® for potentially clinically important drug-drug interactions that should be avoided in older adults
- **Table 6** → 2023 American Geriatrics Society Beers Criteria ® for medications that should be avoided or have their dosages reduced with varying level of kidney function in older adults
- **Table 7** → Drugs with strong anticholinergic properties

# Key Principals of the AGS BEERS Criteria®

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- Medications that are *potentially* inappropriate, not *definitely* inappropriate
- Each criterion has rationale and recommendation statements – pay attention to caveats and guidance listed
- Understand why the medications are included and adjust the approach to those medications accordingly
- Optimal application involves offering safer non-pharmacologic and pharmacologic therapies



# Key Principals of the AGS BEERS Criteria®

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- A starting point for comprehensive process - identifying and improving medication appropriateness and safety
- Access should not be excessively restricted by prior authorization and/or health plan coverage policies
- Primarily based on medications available in the United States (not equally applicable to all countries)

# Keep in Mind...

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- Criteria is intended to be applied to:
  - adults 65 years old and older (ambulatory, acute, and institutional settings)
    - Age cut off are provided when evidence is specific to that age group
  - **Exceptions: hospice, end-of-life care settings**
- Primary target audience:
  - practicing clinicians (all areas of practice)
- Drug related harms:
  - more pronounced in:
    - “old-old” than in the “young-old”
    - persons with complex multimorbidity and frailty

# In the end remember...

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- The AGS Beers Criteria®
  - support, not contradict, common sense and good clinical care – **USE CLINICAL COMMON SENSE**
  - Follow the key principles and application strategies set forth
    - outcomes improved
    - unintended harm minimized
  - Expresses the known concern for significant barriers to the use of alternatives as a continuing factor in individualized decision making
    - including high out-of-pocket drug costs
    - Formulary/financial restrictions

# Now for the Update

What has changed for the 2023 AGS Beers Criteria

# Changes since 2019 AGS Beers Criteria®

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- Table 8 → Medications/criteria removed since 2019 American Geriatrics Society Beers Criteria ®
  - Still considered to be PIMs (unless specified otherwise) but which are now moved off of Tables 2-7 on account of having low usage in the US, not currently available in US, or for other reasons
- Table 9 → Medications/criteria added since 2019 American Geriatrics Society Beers Criteria ®
- Table 10 → Medications/criteria modified since 2019 American Geriatrics Society Beers Criteria ®

# Noteworthy changes to PIMS for older adults

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- **BOX 1** Synthesis of anticoagulation recommendations has been added
  - Summarizes criteria for anticoagulants (warfarin, rivaroxaban, and dabigatran)
- **Tables 2,3,5** – the rationale for anticholinergic drugs to avoid has been expanded to recognize the risks associated with concurrent use (cumulative anticholinergic burden)



# Box 1 Anticoagulation Recommendations

BOX 1. Synthesis of anticoagulation recommendations

Background	Recommendations
The current standard recommendations for the treatment of nonvalvular atrial fibrillation (NVAF) are based on the results of the Atrial Fibrillation Treatment with Oral Anticoagulants (AF-TOC) trial, which compared the results of warfarin and direct-acting oral anticoagulants (DOACs). The results of this trial are consistent with the results of other studies, which have shown that DOACs are associated with a lower risk of major and gastrointestinal bleeding compared with warfarin.	Anticoagulation with a DOAC is preferred to treatment with warfarin for the prevention of stroke and systemic embolism in patients with NVAF. DOACs are preferred to warfarin for the prevention of stroke and systemic embolism in patients with NVAF, particularly in older adults and those with a history of major or gastrointestinal bleeding.
When used as a long-term treatment, DOACs are preferred to warfarin for the prevention of stroke and systemic embolism in patients with NVAF, particularly in older adults and those with a history of major or gastrointestinal bleeding.	When used as a long-term treatment, DOACs are preferred to warfarin for the prevention of stroke and systemic embolism in patients with NVAF, particularly in older adults and those with a history of major or gastrointestinal bleeding.

## DOACs for long term treatment of NVAF and VTE

- Pradaxa – use with caution over other DOACs for long term treatment
- Xarelto previously recommended to “use with caution”
- New recommendation for Xarelto: “avoid”
  - observational studies and network meta-analyses find that this drug confers a higher risk of major and gastrointestinal bleeding in older adults than other direct-acting oral anticoagulants (DOACs), particularly apixaban, but also dabigatran

## Warfarin

- Added to Table 2 → avoid when starting initial therapy for VTE or nonvalvular atrial fibrillation
- Warfarin should be used only when alternatives (e.g., DOACs) are contraindicate or there are substantial barriers to the use of an alternative

## Reduced Kidney Function (Table 6)

- Apixaban → criterion has been removed given the evidence for its safe use in patients with end-stage renal disease.
- Rivaroxaban → the criteria recommends referring to the product labeling

# Aspirin

- Use of aspirin for primary prevention of cardiovascular disease
  - Previously listed as “use with caution”
  - New recommendation → avoid initiating aspirin for the primary prevention of cardiovascular disease in older adults (in agreement with the U.S. Preventive Services Task Force’s recommendation).
    - The USPSTF concludes with moderate certainty that initiating aspirin use for the primary prevention of CVD events in adults 60 years or older has no net benefit.
  - **Older adults already taking aspirin for primary prevention – deprescribing should be considered**

# Antiplatelet

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- Ticagrelor
  - Recommendation added:
    - use with caution, particularly among adults 75 years old and older because of concerns of major bleeding.

# Estrogen (Oral and Transdermal)

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- Estrogen in postmenopausal women
  - Regarding initiation and continuation
    - Initiation of oral and transdermal estrogen is to be avoided in older women – those that are already taking, deprescribing should be considered
    - Topical vaginal estrogen remains appropriate for its major indications of symptomatic vaginal atrophy or urinary tract infection prophylaxis

# Sulfonylureas

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- Sulfonylureas as first or second-line monotherapy or add on-therapy
  - Previously focused on long-acting but has now been expanded to **ALL** sulfonylureas
    - associated with a higher risk of cardiovascular events, all-cause mortality, and hypoglycemia vs. alternative choices
    - short-acting ones pose less risk of hypoglycemia than long-acting [ADA 2018]
    - second-generation (longer half-life) are associated with a high risk of hypoglycemia [Holstein 2010; WHO 2018]; recommendation to use newer generations [Davies 2018; WHO 2018]; avoid first generation all together [AGS 2013]

# SGLT2 Inhibitors

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- A new criterion was added
  - used with caution because of the increased risk of urogenital infection and euglycemic diabetic ketoacidosis, and recommends monitoring early during treatment
  - Recommends actively monitoring for possible adverse effects.
  - Panel recognizes the value of SGLT2-inhibitors
    - CVD-REAL 2 (observational study)
      - associated with a lower risk of death, hospitalization for HF , MI, and stroke [Kosiborod 2018]



# Disease State Updates

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- **Criteria: PIMs to avoid in older adults with a history of falls or fractures**
  - Level of evidence for antidepressants has been lowered to “moderate.”
- **Criteria for Delirium, Dementia, and Parkinson disease**
  - Modifications and clarifications were made to existing criteria
  - Opioids added to the list of drugs that can exacerbate delirium.
  - Continued emphasis on avoiding antipsychotics and other medications for behavioral problems of dementia and delirium
  - Behavioral interventions and modifiable triggers for behavior remains the preferred management
  - Antipsychotics and other medications listed in these criteria should be a last resort (in collaboration/with shared decision-making)

# Drug-Disease Interactions

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- Heart Failure

- combination drug dextromethorphan-quinidine (Neudexta®) was added to the list of drugs to avoid

# Drug-Drug Interactions

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- Important Drug-Drug interactions were consolidated and clarified (Table 5)
- Emphasis on
  - use of multiple agents with anticholinergic activity
  - concurrent use of  $\geq 3$  CNS-active drugs from specific therapeutic categories (which now include skeletal muscle relaxants)
  - addition of SSRIs to the list of warfarin drug–drug interactions

# Renal Dysfunction

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- Addition of Baclofen
  - Recommended to avoid use when eGFR is  $<60$  mL/min (increased risk for encephalopathy in older adults)
- NSAIDs by patients with a CrCl  $<30$  mL/min was moved from Table 3 to Table 6 for consistency of presentation.

# Question 1

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Throughout the AGS Beers Criteria® there is a constant reminder for clinicians to do the following:

- A – use for every patient over the age of 65
- B – use clinical common sense when applying the guidelines
- C – use only when reviewing patient from a skilled nursing facility
- D – use in patients that are under the age of 65 but present as old-old

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## Question 2

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Patient JP, a 76-year-old male admitted to the hospital for exacerbation of heart failure. While there the patient develops a DVT, is placed on heparin x 7 days and the Resident wants to change to oral therapy for discharge. What would you recommend as the pharmacist?

- A – Dabigatran 75 mg BID
- B – Ticagrelor 90 mg BID
- C – Apixaban 5 mg BID
- D – Rivaroxaban 10 mg Daily

Pertinent Information on discharge:

- CrCl 35 ml/min
- SCr 1.12 mg/dL
- BMI 28.6 kg/m<sup>2</sup>



## Question 2

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## Question 3

Patient KG, is an 80-year-old female admitted to the ICU with pneumonia. PMx of CKD3, Asthma, HTN, and NSTEMI. Home medications include aspirin EC 81 mg daily, Ventolin HFA 2 puffs Q4h PRN, and metoprolol succinate 50 mg daily. Which of the following statements regarding KG's medication regimen would you recommend as the rounding ICU pharmacist on the team? *Vitals/Labs: Potassium 5.2; BP 101/62, SPO2 94% on 2L*

- A – start Singulair 5 mg to help control the patient's asthma
- B – discontinue Aspirin based on KG's past medical history
- C – consider adding Dabigatran over apixaban for VTE prophylaxis
- D – add Lisinopril taken before each HD session

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- A – start Singulair 5 mg to help control the patient's asthma
- **B – discontinue Aspirin based on KG's past medical history ← primary prevention**
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# References



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# Additional References

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# Questions?

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