Out with the old, in with the new: what essential updates in geriatrics should you learn in 60 minutes?

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I have no actual or potential conflicts of interest to disclose

Disclaimer

This presentation is based on the current literature and practice guidelines available at the time of slide preparation. I am not here as a representative of the VA and any opinions expressed are my own and do not necessarily represent the views of the Department of Veterans Affairs or the United States of America.

Learning Objectives for Pharmacists

1. Explain the basics of the Beers criteria such as the organization that compiles it, where to access it, and available companion papers.
2. Describe recent key changes to Beers criteria with focus on evidence and recommendations for nitrofurantoin, digoxin, proton pump inhibitors, insomnia medications, drug-drug interactions, and renal dosing tables.
3. Review recent changes to the pneumonia vaccination recommendations for older adults.

Learning Objectives for Pharmacy Technicians

1. Explain the basics of the Beers criteria such as the organization that compiles it, where to access it, and available companion papers.
2. Identify recent key changes to the Beers criteria.
3. Recognize recent changes to the pneumonia vaccination recommendations for older adults.

Beers Criteria History

Original Beers Criteria – 1991

– Explicit criteria for determining inappropriate medication use in nursing home residents

1997

– Expanded to all adults older than 65 years

2003

2012

– American Geriatrics Society took ownership

2015

What is the purpose of the 2015 Beers Criteria?

- Identify potentially inappropriate medications that should be avoided in many older adults
- Reduce adverse drug events and drug related problems
- Improve medication selection in older adults
- Designed for use in any clinical setting; also used as an educational, quality, and research tool
  - Not applicable to hospice and palliative care

Key Changes with Updates

2012 Update

- Rigorous evidence based approach
- Major expansion of drug-disease interactions
- Drugs to use *with caution*

2015 Update

- Dose adjustments based on renal function
- Drug-Drug Interactions
- Companion Papers
  - How to use the Beers criteria
  - Alternatives

2015 Criteria Literature Search

Initial search identified 20,748 citations

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Preliminary abstract review 6,719 citations

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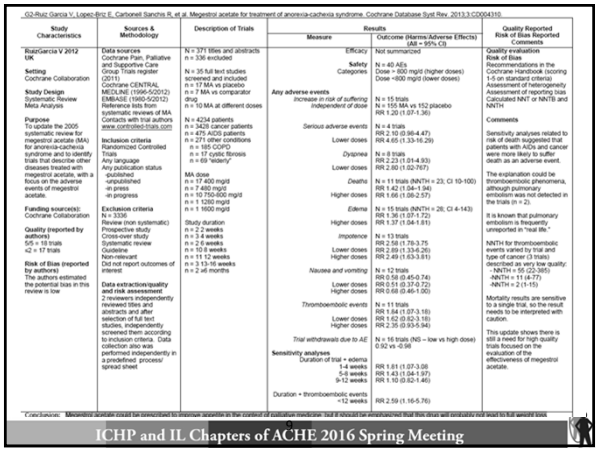
Reviewed by co-chairs 3387 citations

↓

Full panel review 1188 citations

↓

Creation of evidence tables 342 citations



Oz-Ruiz Garcia V, Lopez-Briz E, Carbonell Sanchis R, et al. Megestrol acetate for treatment of anorexia-cachexia syndrome. Cochrane Database Syst Rev. 2013;3:CD004310.

Study Characteristics	Sources & Methodology	Description of Trials	Results: Measure	Results: Outcome (Harms/Adverse Effects) (All + 95% CI)	Quality Reported Risk of Bias Reported Comments
RuizGarcia V 2012 UK **Setting** Cochrane Collaboration **Study Design** Systematic Review Meta Analysis **Purpose** To update the 2005 systematic review for megestrol acetate (MA) for anorexia-cachexia syndrome and to identify trials that describe other diseases treated with megestrol acetate, with a focus on the adverse events of megestrol acetate. **Funding source(s):** Cochrane Collaboration **Quality (reported by authors)** 5/5 = 18 trials +2 = 17 trials **Risk of Bias (reported by authors)** The authors estimated the potential bias in this review is low	**Data sources** Cochrane Pain, Palliative and Supportive Care Group Trials register (2011) Cochrane CENTRAL MEDLINE (1966-5/2012) EMBASE (1960-5/2012) Reference lists from systematic reviews of MA Contacts with trial authors www.controlled-trials.com **Inclusion criteria** Randomized Controlled Trials Any language Any publication status -published -unpublished -in press -in progress **Exclusion criteria** N = 3336 Review (non systematic) Prospective study Cross-over study Systematic review Guideline Non-relevant Did not report outcomes of interest **Data extraction/quality and risk assessment** 2 reviewers independently reviewed titles and abstracts and after selection of full text studies, independently screened them according to inclusion criteria. Data collection also was performed independently in a predefined process/ spread sheet	N = 371 titles and abstracts n = 336 excluded N = 35 full text studies screened and included n = 17 MA vs placebo n = 7 MA vs comparator drug n = 10 MA at different doses N = 4234 patients n = 3428 cancer patients n = 475 AIDS patients n = 271 other conditions n = 185 COPD n = 17 cystic fibrosis n = 69 "elderly" MA dose n = 17 400 mg/d n = 7 480 mg/d n = 10 750-800 mg/d n = 1 1280 mg/d n = 1 1600 mg/d Study duration n = 2 2 weeks n = 3 4 weeks n = 2 6 weeks n = 10 8 weeks n = 11 12 weeks n = 3 13-16 weeks n = 2 ≥6 months	*Efficacy* **Safety** *Categories* **Any adverse events** *Increase in risk of suffering independent of dose* *Serious adverse events* *Lower doses* *Dyspnea* *Lower doses* *Deaths* *Higher doses* *Edema* *Higher doses* *Impotence* *Lower doses* *Higher doses* *Nausea and vomiting* *Lower doses* *Higher doses* *Thromboembolic events* *Lower doses* *Higher doses* *Trial withdrawals due to AE* **Sensitivity analyses** Duration of trial + edema 1-4 weeks 5-8 weeks 9-12 weeks Duration + thromboembolic events <12 weeks	Not summarized N = 40 AEs Dose > 800 mg/d (higher doses) Dose <800 mg/d (lower doses) N = 15 trials N = 155 MA vs 152 placebo RR 1.20 (1.07-1.36) N = 4 trials RR 2.10 (0.96-4.47) RR 4.65 (1.33-16.29) N = 8 trials RR 2.23 (1.01-4.93) RR 2.60 (1.02-767) N = 11 trials (NNTH = 23; CI 10-100) RR 1.42 (1.04-1.94) RR 1.66 (1.06-2.57) N = 15 trials (NNTH = 28; CI 4-143) RR 1.36 (1.07-1.72) RR 1.37 (1.04-1.81) N = 13 trials RR 2.58 (1.78-3.75 RR 2.89 (1.33-6.26) RR 2.49 (1.63-3.81) N = 12 trials RR 0.58 (0.45-0.74) RR 0.51 (0.37-0.72) RR 0.68 (0.46-1.00) N = 11 trials RR 1.84 (1.07-3.16) RR 1.62 (0.82-3.18) RR 2.35 (0.93-5.94) N = 16 trials (NS – low vs high dose) 0.92 vs -0.96 RR 1.81 (1.07-3.08 RR 1.43 (1.04-1.97) RR 1.10 (0.82-1.46) RR 2.59 (1.16-5.76)	**Quality evaluation** **Risk of Bias** Recommendations in the Cochrane Handbook (scoring 1-6 on standard criteria) Assessment of heterogeneity Assessment of reporting bias Calculated NNT or NNTB and NNTH **Comments** Sensitivity analyses related to risk of death suggested that patients with AIDs and cancer were more likely to suffer death as an adverse event. The explanation could be thromboembolic phenomena, although pulmonary embolism was not detected in the trials (n = 2). It is known that pulmonary embolism is frequently unreported in "real life." NNTH for thromboembolic events varied by trial and type of cancer (3 trials) described as very low quality: - NNTH = 55 (22-385) -NNTH = 11 (4-77) - NNTH = 2 (1-15) Mortality results are sensitive to a single trial, so the result needs to be interpreted with caution. This update shows there is still a need for high quality trials focused on the evaluation of the effectiveness of megestrol acetate.

Conclusions: Megestrol acetate could be prescribed to improve appetite in the context of palliative medicine, but it should be emphasized that this drug will probably not lead to full weight look.

Key Tables in the 2015 Criteria

- Table 2 – Potentially inappropriate drugs
  - Organized by organ system and therapeutic category
- Table 3 – Drug-Disease or Drug-Syndrome
- Table 4 – Medications to use with caution
- Table 5 – Drug-Drug Interactions (NEW)
  - Non anti-infectives
- Table 6 – Renal dosing table (NEW)
  - Non anti-infectives

Beers Criteria Changes - Nitrofurantoin

Organ System, Therapeutic Category, Drugs	Rationale	Recommendation	Quality of Evidence/ Strength of Recommendation
Anti-infective -Nitrofurantoin	Potential for pulmonary toxicity, hepatic toxicity and peripheral neuropathy	AVOID in patients with CrCl <30 ml/min AVOID long-term suppression 2012 Criteria: CrCl < 60 ml/min	Low/Strong

Beers Criteria Changes – Cardiovascular Drugs

Organ System, Therapeutic Category, Drugs	Rationale	Recommendation	Quality of Evidence/ Strength of Recommendation
Cardiovascular -Dronaderone	Worse outcomes reported in patients who have permanent atrial fibrillation, severe or recently decompensated heart failure	AVOID	Low/Strong
-Digoxin	For A. Fibrillation – may be associated with increased mortality	AVOID as first line therapy in atrial fibrillation	Moderate/Strong

Beers Criteria Changes - Digoxin

Organ System, Therapeutic Category, Drugs	Rationale	Recommendation	Quality of Evidence/ Strength of Rec.
Cardiovascular -Digoxin	Use in Heart Failure: ? Effects on risk of hospitalization and maybe associated with increased risk of mortality Higher doses – no additional benefit and may increase risk of toxicity Decreased renal clearance, may lead to ↑ risk of toxicity	AVOID as first line therapy for heart failure If used for A. Fib or heart failure, avoid >0.125 mg/d	Low/Strong Moderate/ Strong

Beers Criteria Changes – Antiarrhythmics

Organ System, Therapeutic Category, Drugs	Rationale	Recommendation	Quality of Evidence/ Strength of Rec.
Cardiovascular -Amiodarone	Amiodarone is effective for maintaining sinus rhythm but has greater toxicities than other antiarrhythmics	AVOID as first line unless patient also has heart failure or sig. LVH	High/ Strong
Antiarrhythmic drugs (Class Ia, Ic, III) : Avoid use as 1st line agents for A. Fib - 2012 Criteria. Removed in 2015 criteria, because new evidence and guidelines that suggest rhythm control may have equal or favorable outcomes compared with rate control.			

Assessment Question

- Which of the following is a medication related update in the 2015 Beers criteria?

A.) Amiodarone is definitely inappropriate to use in atrial fibrillation

B.) Nitrofurantoin can be considered for use if CrCl >30ml/min

C.) Digoxin should be avoided as 2nd line therapy for heart failure

D.) Digoxin should be avoided as 2nd line therapy for atrial fibrillation

Beers Criteria Changes – Non-Benzodiazepine Sedative Hypnotics

Organ System, Therapeutic Category, Drugs	Rationale	Recommendation	Quality of Evidence/ Strength of Rec.
CNS Medications: Nonbenzodiazepine, benzodiazepine receptor agonist hypnotics -Eszopiclone -Zolpidem -Zaleplon	Adverse events similar to those of BZDs in older adults (e.g., delirium, falls, fractures) Increased emergency room visits/hospitalizations Motor vehicle crashes Minimal improvement in sleep latency and duration	AVOID	Moderate/ Strong
Beers Criteria 2012: Avoid chronic use (>90 days) Also added to Table 3 to avoid with dementia or cognitive impairment			

Beers Criteria New Addition – PPI's and Desmopressin

Organ System, Therapeutic Category, Drugs	Rationale	Recommendation	Quality of Evidence/ Strength of Rec.
Gastrointestinal: Proton-pump inhibitors	Risk of C difficile infection , bone loss and fractures	Avoid use for > 8 weeks unless patient is considered high risk (corticosteroids or chronic NSAID use, Barrett's esophagitis, pathological hypersecretory condition, need for maintenance tx).	High/Strong
Genitourinary: Desmopressin	High risk of hyponatremia; safer alternative treatments	Avoid for treatment of nocturia or nocturnal polyuria	Moderate/ Strong

Beers Criteria Changes – SSI and Megestrol

Organ System, Therapeutic Category, Drugs	Rationale	Recommendation	Quality of Evidence/ Strength of Rec.
Insulin, Sliding scale	Higher risk of hypoglycemia without improvement in hyperglycemia management. Short or rapid acting insulins: Not to be used as a sole agent to manage hyperglycemia in the absence of basal or long-acting insulins	AVOID	Moderate/ Strong
Megestrol	Minimal effect on weight; Increases risk of thrombotic events and possible death	AVOID	Moderate/ Strong

Beers Criteria Changes – Drug-Disease Interactions

Disease or Syndrome	Drug(s)	Rationale	Recommendation Quality of Evidence/ Strength of Rec.
Delirium	Anticholinergics Antipsychotics BZDs Chlorpromazine Corticosteroids H2-receptor antagonists Meperidine Sedative hypnotics	-Potential to induce or worsen delirium -Avoid antipsychotic use for behavioral problems of dementia or delirium unless nonpharmacological interventions failed or not possible and the older adult is threatening substantial harm to self or others -Increased risk of CVA and mortality	AVOID Moderate/Strong

Beers Criteria Changes – Drug Disease Interactions

Disease or Syndrome	Drug(s)	Rationale	Recommendation Quality of Evidence/ Strength of Rec.
History of falls or fractures	Anticonvulsants Antipsychotics BZDs Nonbenzodiazepine, benzodiazepine receptor agonist hypnotics TCAs SSRIs Opioids	-May cause ataxia, impaired psychomotor functions, syncope, additional falls -Short-acting BZDs are not safer than long-acting BZDs Consider reducing use of other CNS active meds	-AVOID unless safer alternatives are not available -AVOID anticonvulsants except for seizure and mood disorders -AVOID opioids unless acute pain mgmt. due to fractures or joint replacement

Assessment Question

- Which psychotropic medication has recently been linked to the highest number of ED visits amongst older adults?

A.) Lorazepam
B.) Quetiapine
C.) Citalopram
D.) Zolpidem

Table 5: Drug-Drug Interactions

Object Drug/Class	Interacting Drug/Class	Rationale	Recommendation	Quality of Evidence/ Strength of Rec.
Alpha-1 blockers, peripheral	Loop Diuretics	↑ risk of urinary incontinence in older women	Avoid in older women, unless condition warrants both drugs	Moderate/ Strong
ACEIs	Amiloride or Triamterene	↑ hyperkalemia	Avoid routine use; reserve for hypokalemia on ACEI	Moderate/ Strong
Anticholinergic	Anticholinergic	↑ risk of cognitive decline	Avoid, minimize # of anticholinergic meds	Moderate/ Strong
Corticosteroids	NSAIDS	↑ risk of peptic ulcer disease / GI bleed	Avoid; if not possible, provide GI protection	Moderate / Strong

Table 5: Drug-Drug Interactions

Object Drug/Class	Interacting Drug/Class	Rationale	Recommendation	Quality of Evidence/ Strength of Rec.
Antipsychotic	2 or more other CNS drugs	↑ risk of falls	Avoid 3 or more CNS drugs, minimize # of CNS drugs	Mod. / Strong
Benzos and benzo receptor agonists	2 or more other CNS drugs	↑ risk of falls	Avoid 3 or more CNS drugs, minimize # of CNS drugs	High / Strong
Opioid Analgesics	2 or more other CNS drugs	↑ risk of falls	Avoid 3 or more CNS drugs, minimize # of CNS drugs	High / Strong
Antidepressant	2 or more other CNS drugs	↑ risk of falls	Avoid 3 or more CNS drugs, minimize the number of CNS drugs	Mod./ Strong

Table 5: Drug-Drug Interactions

Object Drug/Class	Interacting Drug/Class	Rationale	Recommendation	Quality of Evidence/ Strength of Rec.
Warfarin	Amiodarone	↑ risk of bleeding	Avoid when possible; monitor INR closely	Mod. / Strong
Warfarin	NSAIDS	↑ risk of bleeding	Avoid when possible; if used together – monitor closely for bleeding	High / Strong
Theophylline	Cimetidine	↑ theophylline toxicity	Avoid	Mod. / Strong
Lithium	ACEIs and Loop Diuretics	↑ toxicity	Avoid, monitor lithium concentrations	Mod./ Strong

Table 6: Renal Dosing Table

Medication	CrCl (ml/min) at which action is required	Rationale	Recommendation	Quality of Evidence / Strength of Rec.
Apixaban	<25	Increased bleeding	Avoid	Moderate/Strong
Dabigatran	<30	Increased bleeding	Avoid	Moderate/Strong
Rivaroxaban	30-50	Increased bleeding	Reduce dose	Moderate/Strong
	<30		Avoid	
Edoxaban	30-50	Increased bleeding	Reduce dose	Moderate/Strong
	<30 or >95	↑Bleed / ↓efficacy	Avoid	
Enoxaparin	<30	Increased bleeding	Reduce dose	Moderate/Strong
Fondaparinux	<30	Increased bleeding	Avoid	Moderate/Strong

Table 6: Renal Dosing Table

Medication	CrCl (ml/min) at which action is required	Rationale	Recommendation	Quality of Evidence/ Strength of Rec.
Duloxetine	<30	GI SE's (nausea, diarrhea)	Avoid	Moderate/ Weak
Gabapentin	<60	CNS SE's	Reduce dose	Moderate / Strong
Levetiracetam	≤80	CNS SE's	Reduce dose	Moderate / Strong
Pregabalin	<60	CNS SE's	Reduce dose	Moderate / Strong
Tramadol	<30	CNS SE's	IR: reduce dose; ER: avoid	Low / weak
H2 blockers (ranitidine, famotidine etc.)	<50	Mental status changes	Reduce dose	Moderate / strong

Table 6: Renal Dosing Table

Medication	CrCl (ml/min) at which action is required	Rationale	Recommendation	Quality of Evidence / Strength of Rec.
Amiloride	<30	Increased K+, Decreased Na+	Avoid	Moderate / Strong
Triamterene	<30	Increased K+, Decreased Na+	Avoid	Moderate / Strong
Spironolactone	<30	Increased K+	Avoid	Moderate / Strong
Colchicine	<30	GI, neuromuscular and bone marrow toxicities	Reduce dose; monitor for adverse effects	Moderate / Strong
Probenacid	<30	Loss of efficacy	Avoid	Moderate / Strong

Assessment Question

- According to the Beers criteria, which of the following is an accurate threshold in which action is required to dose adjust based on renal function?

A.) Ranitidine when CrCl <50ml/min
B.) Edoxaban when CrCl <60ml/min
C.) Pregabalin when CrCl <30ml/min
D.) Levetiracetam when CrCl <60ml/min

How much do you like the 2015 Beers Criteria?

- Completely and totally fabulous!
- Pretty Good
- Good, but I have some issues with them
- Don't like them!

New Document

DRUGS & PHARMACOLOGY

Alternative Medications for Medications in the Use of High-Risk Medications in the Elderly and Potentially Harmful Drug–Disease Interactions in the Elderly Quality Measures

Joseph T. Hanlon, PharmD, MS,[a,b,c,d,e,f,g,h] Todd P. Semla, MS, PharmD,[i,j,k] and Kenneth E. Schmader, MD[l,m]

Alternatives to High Risk Medications

Therapeutic Class	High-Risk Medications	Alternatives
1st Generation Anti-histamine	Diphenhydramine (OTC) Hydroxyzine Doxylamine (OTC) Chlorpheniramine (OTC)	Intranasal normal saline 2nd generation antihistmane (e.g. cetirizine, loratadine, fexofenadine), Intranasal steroids (now OTC)
Parkinson's Disease	Benztropine, Trihexyphenidyl	Carbidopa/Levodopa
TCA's	Amitriptyline, Imipramine etc.	For depression – SSRI (except paroxetine), SNRI, bupropion For neuropathic pain – SNRI, gabapentin, pregabalin, lidocaine patch, capsaicin
Barbiturates	Phenobarbital, Butalbital, Pentobarbital etc.	For epilepsy – other anticonvulsants (e.g. lamotrigine, levetiracetam)

Alternatives to High Risk Medications

Therapeutic Class	High-Risk Medications	Alternatives
Non benzodiazepine sedative hypnotics (e.g. "Z" drugs)	Eszopiclone Zaleplon Zolpidem	None! Non-pharm interventions cited
Sulfonylureas, long-duration	Glyburide	Short acting sulfonylureas (e.g. glipizide), metformin
Skeletal Muscle Relaxants	Cyclobenzaprine, Methocarbamol, Carisoprodol, Metaxalone etc.	Acute mild-mod pain: APAP, non-acetylated salicylate (salsalate), propionic acid derivatives (ibuprofen, naproxen) if no HF or eGFR >30ml/min and given with PPI if used >7 days
Specific NSAIDS	Indomethacin, Ketorolac	See above for skeletal muscle relaxants
Opioids	Meperidine, Pentazocine	Tramadol, morphine, oxycodone

Alternatives to Meds in Drug-Disease Interactions

Disease	High-Risk Medications	Alternatives
Falls	Anticonvulsants	For epilepsy: lamotrigine, levetiracetam + Calcium/Vitamin D ± bisphosphonate; For neuropathic pain: SNRI, gabapentin, pregabalin, capsaicin, lidocaine patch
	Benzodiazepines; Non-Benzodiazepine hypnotics ("Z" drugs)	For anxiety: buspirone, SNRI For sleep: sleep hygiene
Falls or Dementia	TCA's, SSRI's (falls only)	For depression: SNRI, bupropion For neuropathic pain: SNRI, gabapentin, pregabalin, capsaicin, lidocaine patch
Falls or Dementia	Antipsychotics	For delirium: short term use if considered risk to self or others after non-pharm interventions fail For dementia: non-pharm approaches; low dose non-anticholinergic agent (risperidone or quetiapine) for short duration

Alternatives to Meds in Drug-Disease Interactions

Disease	High-Risk Medications	Alternatives
Dementia	H2 blockers	PPI
	Anticholinergics - e.g. 1st generation antihistamines and anti-parkinson agents	For allergies: 2nd generation antihistamine, nasal steroid For Parkinson's: levodopa / carbidopa
	Benzodiazepines	For anxiety: buspirone, SSRI, SNRI For sleep: sleep hygiene
	Non-benzodiazepine hypnotics ("Z" drugs)	Sleep hygiene
CKD (eGFR <30ml/min)	All non-aspirin NSAIDS (including COX-2 selective)	APAP, SNRI, topical capsaicin, topical lidocaine patch

Assessment Question

- Which of the following is an accurate pairing of an alternative to a high risk medication in the Beers criteria?

A.) Zaleplon instead of Lorazepam
B.) Acetaminophen instead of Cyclobenzaprine
C.) Fluoxetine instead of Venlafaxine
D.) Risperidone instead of Quetiapine

New Document

CLINICAL INVESTIGATIONS

How to Use the American Geriatrics Society 2015 Beers Criteria—A Guide for Patients, Clinicians, Health Systems, and Payors

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7 Key Principles

The most important take home message is:

Use clinical common sense!

Key Principles

Medications in the AGS 2015 Beers Criteria are *potentially* inappropriate, not *definitely* inappropriate

- Unfavorable balance of benefits and harms for many older adults
  - Particularly in light of available alternatives
- But, there are some older adults in which use of Beers criteria meds can be appropriate

Key Principles

Read the rationale and recommendations statements for each criterion. The caveats and guidance listed there are important

- Medication appropriateness is not black or white
- Meds may be considered potentially inappropriate only in certain circumstances
- Example: digoxin in heart failure as a 1st line agent

Key Principles

Understand why medications are included in the criteria and adjust your approach to those medications accordingly

- Look at the "rationale" statements
  - This can help guide how stringent we should be in avoiding it
  - Example – medication that increases risk of falls
- Allows us to individualize decision making based on anticipated risk
  risk

Key Principles

Optimal application of the criteria involves …offering safer nonpharmacological and pharmacological therapies

- See alternative therapy document
- Often, the best alternatives involve non-pharmacologic strategies
  - Patient counseling and lifestyle changes

Key Principles

Access to medications included in the Beers criteria should not be excessively restricted by prior authorization and/or health plan coverage policies

- Judicious use through insurance design can be reasonable
- Onerous restrictions can disrupt care and hinder access to meds for patients that need them
- Programs that restrict access to meds should be carefully targeted and give clinicians efficient opportunities to justify use

Application of Key Principles - Clinicians

- Think of the Beers criteria as a *warning light*
  - Potentially unfavorable balance of benefits and harms
  - Why is the patient taking the drug?
  - Is this medication truly needed?
  - Are there safer or more effective alternatives?
  - Does this patient have characteristics that increase or mitigate the risk of this medication?
- This highlighted awareness should continue over time and prompt ongoing monitoring
- This highlighted awareness should continue over time and prompt ongoing monitoring

Application of Key Principles - Clinicians

- Actively inquire about symptoms that could be adverse drug effects, and assess whether these could be related to medications
- Don't automatically defer to colleagues
  - Just because another clinician prescribed a Beers criteria medication doesn't mean it is safe and effective
  - Use the opportunity to discuss with colleagues whether that medication is right for the patient

Beers Criteria Conclusions

- The success of the AGS 2015 Beers criteria depends on being applied in a thoughtful manner
- Utilizing these key principles and application strategies are intended to improve outcomes while minimizing unintended harms

To access all AGS 2015 Updated Beers Resources Visit

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Updates in Pneumococcal Vaccinations as Recommended by the Advisory Committee on Immunization Practices (ACIP) and the Center for Disease Control and Prevention (CDC)

Epidemiology of Pneumonia in Older Adults

- ~4,000 deaths and ~300,000 hospitalizations per year
- 2013 – estimated 13,000 cases of invasive pneumococcal disease (IPD) in elderly
  - ~10x more likely in older adults
- 20-25% of IPD cases and 10% of community acquired pneumonia cases are caused by vaccine preventable serotypes

Pneumococcal Vaccines

23-valent pneumococcal polysaccharide *(PPSV23)*	13-valent pneumococcal conjugate *(PCV13)*
• 1st marketed in 1983 • Protects against 23 serotypes – 12 also in PCV13 + 11 others • Most effective in adults and does not generate immunity in children under 2 years old	• 1st used in children in 2010 – expanded from PCV7 vaccine • Protects against 13 serotypes – 1 that is not in PPSV23 • Give before PPSV23 for better immune response

PCV13

- 0.5ml IM in deltoid x 1 lifetime dose
- Adverse effects: pain at injection site, redness, swelling at injection site, fatigue, headache
- Supplied: pre-filled syringe that does not contain latex

Timeline of PCV13

- FDA approved **2010** for children aged 6 weeks through 71 months (replaced PCV7)
- **Dec 2011** – FDA approved for prevention of pneumonia and invasive disease in adults >50 y/o
- **June 2012** – ACIP recommended for adults (≥19 y/o) with immunocompromising conditions with high risk of pneumococcal disease
- **August 2014** – ACIP recommended use for immunocompetent older adults
- **June 2015** – ACIP updates interval for the PCV13 → PPSV23 sequence for immunocompetent older adults

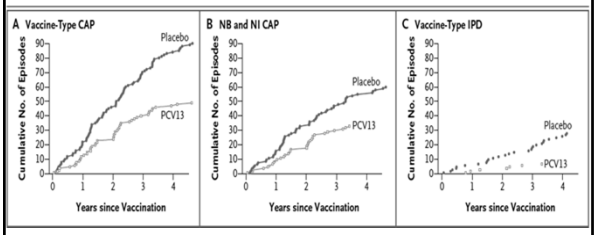
Immunogenicity Studies

- Adults 60-64 y/o with no prior vaccine hx.
  – PCV13 antibody titers to the 12 common serotypes comparable to or higher than PPSV23
- Adults ≥70 y/o with previous PPSV23 vaccine
  – PCV13 titers comparable for 2 and higher for 10 common serotypes

Immunogenicity Studies

- PCV7 → PPSV23 – better immune response than PPSV23 → PCV7
- PCV13 → PPSV23 – better immune response at 2, 6, and 12 months and at 3-4 years
  – 2nd vaccine given 1 year after 1st vaccine
- No study evaluated optimal interval between vaccines

CAPITA Trial



NB = Non-bacteremic
NI = Non-invasive

Indications for Vaccine

Indications for PCV13 and PPSV23 Administration for Adults Age 19 to 64 Years by Risk Group
Source: Centers for Disease Control and Prevention (CDC)[1]

Risk Group	Underlying Medical Condition	PCV13	PPSV23	
		Recommended	Recommended	Revaccination 5 years After First Dose
Immunocompromised persons*	Congenital or acquired immunodeficiency[†]	✔	✔	✔
	HIV	✔	✔	✔
	Chronic renal failure	✔	✔	✔
	Nephrotic syndrome	✔	✔	✔
	Leukemia	✔	✔	✔
	Lymphoma	✔	✔	✔
	Hodgkin disease	✔	✔	✔
	Generalized malignancy	✔	✔	✔
	Iatrogenic immunosuppression**	✔	✔	✔
	Solid organ transplant	✔	✔	✔
	Multiple myeloma	✔	✔	✔

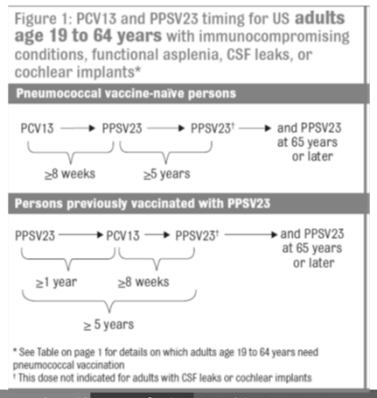
Indications for Vaccine

Indications for PCV13 and PPSV23 Administration for Adults Age 19 to 64 Years by Risk Group
Source: Centers for Disease Control and Prevention (CDC)[1]

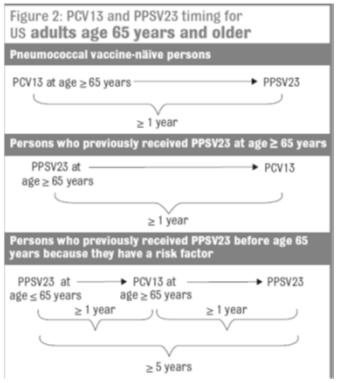
Risk Group	Underlying Medical Condition	PCV13	PPSV23	
		Recommended	Recommended	Revaccination 5 years After First Dose
Persons with functional or anatomic asplenia*	Sickle cell disease/other hemaglobinopathy	✔	✔	✔
	Congenital or acquired asplenia	✔	✔	✔
Immunocompetent persons*	Cerebrospinal fluid leak	✔	✔	
	Cochlear implant	✔	✔	
Immunocompetent persons	Chronic heart disease[†]		✔	
	Chronic lung disease[§]		✔	
	Diabetes mellitus		✔	
	Alcoholism		✔	
	Chronic liver disease, cirrhosis		✔	
	Cigarette smoking		✔	

Every Adult ≥ 65 y/o should get both PCV13 AND PPSV23!

Vaccine Intervals



Vaccine Intervals



So What Changed in 2015?

PCV13 → PPSV23

Age Groups	Underlying Conditions	2014 Interval Recs	2015 Interval Recs
≥ 19 years	• High-risk immunocompetent (CSF leak, cochlear implants) • Functional or anatomic asplenia • Immunocompromised	≥ 8 weeks	No change
≥ 65 years	N/A	6-12 months (minimum 8 weeks)	≥ 1 year

Why the Change?

- Confusion among healthcare providers
- Challenges in programming reminders in computerized programming
- CMS Policy
  - Medicare will only cover a different second pneumococcal vaccine after 1 year
- ACIP re-reviewed immunogenicity studies

Can I give PCV13 with Influenza Vaccine?

- Yes!
- The PCV13 labeling states that administration with inactivated flu vaccine was associated with diminished PCV13 antibody responses
  - Clinical significance of this data is unknown
- CDC still endorses giving at the same time

Let's Close with a Case!

- BD is a 66 y/o male with a PMH of COPD, DM, and HTN who received a PPSV23 vaccine 3 years ago. What pneumococcal vaccine(s) is he appropriate to receive and in what timeframe?
  - A.) PCV13 now only
  - B.) PCV13 now, then PPSV23 in 1 year
  - C.) PCV13 now, then PPSV23 in 2 years
  - D.) PPSV23 now, then PCV13 in 1 year

Questions??

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