Did you know?

Medication-related deaths in the United States outnumbered traffic fatalities (2009)

37,485

Kochanek, 2009

Average American Lifespan

Year

The Elderly Population

AOA, 2011

The Elderly Population

AGE 65 YEARS-OLD

Population(millions)


AOA, 2011

The Elderly Population

AGE 65 YEARS-OLD

Population(millions)


AOA, 2011

Polypharmacy

Polymedicine: the use of multiple medications for treating multiple co-morbid conditions

Polypharmacy: the use of multiple/duplicative medications that cause increased risk for interactions

- Quantity: >5 drugs is considered polypharmacy
- Quality:
  - Inappropriate medication
  - Overmedication
  - Underuse of indicated drugs

Gokula, 2012
Considerations: Medication Selection in the Elderly

Drug Efficacy

Cost

Safety

*PK

Beers Criteria

Adverse Drug Event (ADE) and Adverse Drug Reactions (ADRs)

ADE: injury resulting from the use of a drug, potentially at the time of prescribing and possible due to lack of monitoring, medication errors

ADR: unexpected, unintended, undesired, or excessive response to a drug resulting in negative consequences from normal use of the drug

Emergency Hospitalizations for Adverse Drug Events in Older Americans

Therapeutic category associated with ADEs

- Hematologic agents (hemorrhage)
- Endocrine agents (hypoglycemia)
- Cardiovascular agents (dizziness, syncope)
- Central nervous system agents (fall, altered mental status)

Drugs most commonly implicated in ADEs

- Warfarin (33%)
- Insulin (13.9%)
- Digoxin (3.3%)

Costs of ADRs

Direct Costs
- Health care costs
- Non-health care costs

Indirect Costs

Intangible Costs

Population at Risk

- Age > 85 years old
- Female
- Mediations
  - ≥ 9 drugs
  - ≥ 12 doses of medications daily
  - Prior ADE
- Physiologic
  - Low body weight
  - ≥ 6 or more concurrent chronic diagnoses
  - CrCl<50 ml/min
  - Hepatic impairment
  - Decreased mobility

 Gokula, 2012
 AHRQ, 2001
 AGS, 2012

Intent of the American Geriatric Society (AGS) 2012 Beers Criteria

“[I]mprove care of older adults by reducing their exposure to [potentially inappropriate medications (PIMs)].”

 AGS, 2012

*Reuben, 2011

*Pharmacokinetics

 Budnitz, 2011

 VA Medication Safety, 2006

 VA Medication Safety, 2006

 Budnitz, 2011

 AHRQ, 2001

 AGS, 2012

 Gokula, 2012

 Jacobi, 2012
Case

85 year-old SD presents for annual primary care visit reporting mild hip and knee pain following a fall last week. He also reports recent trouble sleeping.

PMH: Type 2 DM, HTN, BPH, insomnia

Labs: electrolytes WNL, CBC WNL, CrCl 50 mL/min, LDL at goal, A1c is 6.9%

Vitals: 132/80 mmHg and HR 68 (sitting), 118/69 mmHg and 64 (standing), RR 16, 64 in and 167 lbs (BMI = 28.6)

Medications:
- insulin glargine 20 units at bedtime
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- enalapril 40 mg daily
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- acetaminophen 650 mg three times daily as needed for pain
- aspirin 81 mg daily
- pravastatin 20 mg at bedtime
- lorazepam 2 mg at bedtime as needed for sleep

The Beers Criteria

1954 - 2009

Rationale for Development:

Age/Disease Effect on Pharmacokinetic Changes

<table>
<thead>
<tr>
<th>Absorption</th>
<th>Rate/extent unaffected</th>
<th>Achlorhydria, medications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Distribution</td>
<td>↑ In fat:water ratio</td>
<td>↓ protein</td>
</tr>
<tr>
<td>Metabolism</td>
<td>↓ In liver mass/blood flow</td>
<td>Smoking, genotype</td>
</tr>
<tr>
<td>Excretion</td>
<td>Age-related ↓ GFR</td>
<td>Renal impairment</td>
</tr>
</tbody>
</table>

Rationale for Development: Pharmacodynamic changes

- Reported age-effects on drug sensitivities (receptor changes)
- Generalizations difficult
  - Less predictable and often altered drug response at usual or lower concentrations
  - Drug-drug and drug-disease interactions may alter responses
  - Prolonged pain relief with opioids at lower dosages; ↑ sedation and postural instability to benzodiazepines; altered sensitivity to beta-blockers

History of Development

- 2001: Nursing Home Research
- 1999: CMS adopts as Quality Indicator
- 2006: CMS updated; NCQA adopted for HEDIS measures
- 2012: New Partnership with AGS

- 2007: "Most" Geriatric Settings
- 2009: Dr. Beers Dies
### Beers Criteria

<table>
<thead>
<tr>
<th>Pub Date</th>
<th>Organization</th>
<th>Setting</th>
<th>Improvements</th>
</tr>
</thead>
<tbody>
<tr>
<td>1991</td>
<td>30 factors that required minimal clinical data for application (chart review)</td>
<td>Nursing home residents</td>
<td>N/A</td>
</tr>
<tr>
<td>1997</td>
<td>28 PIM criteria &amp; 35 inappropriate drugs in 15 clinical conditions</td>
<td>65+ year old (generally) Nursing home residents Community</td>
<td>PIMs generally Max dosing Clinical conditions &amp; PIMs</td>
</tr>
<tr>
<td>2003</td>
<td>48 PIMs/classes &amp; 20 drug combos inappropriate with specific diagnoses or conditions</td>
<td>65+ year old (generally)</td>
<td>Uniform severity ratings and inclusion of additions conditions and medications</td>
</tr>
<tr>
<td>2012</td>
<td>3 lists compiled from 53 PIMs/classes - Recommendation - Quality of evidence - Strength</td>
<td>All patient-care settings Exclusion Palliative care Hospice</td>
<td>Evidence-based collaboration with AGS Regular updates Clinical data used More PIMs</td>
</tr>
</tbody>
</table>

- **Beers, 1991; 1997**
- **Fick, 2003**
- **AGS, 2012**

### Health Employer (Effectiveness) Data Information Set

- **HEDIS**
  - Contributor to standard assessment of quality in ambulatory care (2006)
  - Care/service provided by health plans
  - Health plan’s effectiveness and member satisfaction
  - Updated in 2012

- **Beers Criteria (2003)**
  - Used to develop HEDIS:
    - Use of high risk medications in the elderly
    - Excluded - Beers “Some Indication” drugs

### HEDIS and Beers

- **Pugh (2006):**
  - Determine rate of PIMs identified by HEDIS
  - Results: 19.8% had at least 1 HEDIS drug (similar to Beers)

- **Albert (2010):**
  - Determine strength of association between PIMs and hospitalization
  - Results: ≥1 PIM on HEDIS or Beers, 2.8x and 1.9x admit

### The American Geriatrics Society (AGS) 2012 Beers Criteria

- **Overview**
  - **Literature search:** 25,549→6,505→2,169 for review
  - **Panel selection:**
    - 11 experts
    - Interdisciplinary - various specialties and settings
  - **53 medications/classes (3 categories):**
    - PIMs to avoid
    - PIMs to avoid with syndromes/diseases
    - PIMs to use with caution

- **Uses of HEDIS:**
  - Third-party payers - reimbursement for services
  - CMS STARs Program - Medication Part D Advantage Plans

- **Update Changes**
  - **Limitations of 2003 Beers Criteria:**
    - Not updated
    - Focused on long-term care, community, and ambulatory care settings
    - Medication potential therapeutic use omitted
    - Lists/organization confusing
    - Not referenced
  - **Improvements on 2003 Beers Criteria:**
    - Patient applications
    - Role as educational/quality assessment tool
    - Scope of medications, therapeutic classes, and disease states
    - Presentation clarity
    - Evidence - grading and strength
Grading System

Adapted from the American College of Physician's Guideline Grading System

Quality of Evidence: Health Outcomes and Population

<table>
<thead>
<tr>
<th>Quality</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>High</td>
<td>Consistent results from ≥2 randomized controlled trials or multiple, consistent observational trials</td>
</tr>
<tr>
<td>Moderate</td>
<td>Sufficient evidence from ≥1 high quality trial with &gt;100 participants, ≥2 high quality trials with some inconsistency, ≥2 lower quality trials with consistent results, or multiple consistent observational trials with flawed methodology</td>
</tr>
<tr>
<td>Low</td>
<td>Insufficient evidence based on small or inadequately powered studies, inconsistent results from large trials, or trials with significant methodological flaws</td>
</tr>
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Case

85 year-old SD presents for regularly scheduled primary care visit reporting mild hip and knee pain following a fall last week. SD also reports recent trouble sleeping.

Medications:
- insulin glargine 20 units at bedtime
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SD's PIMs

According to the AGS 2012 Beers Criteria

- **Sliding-scale insulin**
  - *New inclusion* to the AGS 2012 Beers Criteria
  - Recently added to SD's medications for consistently elevated blood sugars before meals (previous A1c 7.4%)

- **Doxazosin**
  - Alpha-blockers - included in 2003 Beers Criteria
  - Prescribed for SD's BPH

- **Lorazepam**
  - Benzodiazepines (BZDs) - included in 2003 Beers Criteria
  - Prescribed for SD's insomnia

Queale, 1997

- **Design**: single-site, prospective cohort; inpatient setting
- **Purpose**:
  - Identify predictors of hyper/hypoglycemia (<60 mg/dL)
  - Assess effectiveness of sliding scale insulin
- **Results**:
  - Overall, 23% of study patients experienced hypoglycemia
  - Sliding scale regimens associated with 2 times greater risk of hyperglycemia
  - Benefit of glycemic control does NOT outweigh risks

Queale, 1997

ALLHAT, 2000

- **Design**:
  - Multi-center, double-blind RCT
- **Population included**:
  - Age ≥55 years
  - SBP ≥140 and/or DBP ≥90 mmHg
  - Anti-HTN meds + CHD risk factor
- **Consideration**: doxazosin arm discontinued 1/2000
- **Results**: > risk of NEGATIVE outcomes with doxazosin

ALLHAT, 2000
**Alpha-blockers** | **Risk of orthostatic hypotension** | **Avoid (HTN)** | **Moderate quality / Strong recommendation**
---|---|---|---

**ACCF/AHA 2011 Expert Consensus Document on Hypertension in the Elderly**

- **Recommendations:**
  - Doxazosin not first-line anti-HTN in elderly
  - Use with caution in BPH
  - Monitor for orthostatic hypotension
- **Considerations:**
  - Indication for doxazosin (BPH)
  - Afluzosin, doxazosin, tamsulosin, and terazosin considered by AUA equally efficacious

**BZDs** | **↑ Risk of cognitive impairment, delirium, falls, fractures and MV accidents** | **Avoid** | **High quality / Strong recommendation**
---|---|---|---

- **Design:** France, systemic review (10 studies)
  - 9 surveys
  - 1 lab study
- **Objective:** Establish relationship between treatment with hypnotics and risk of postural instability (risk of falls/fractures)
- **Prospective/retrospective:**
  - Lawlor, 2003 - falling prevalence over 12 months if on study drugs = 16.9%; hypnotics/anxiolytics ↑ odds of falling
  - Stenbacka, 2002 - ↑ risk of falls (age >60) with daily use
  - Ensrud, 2002 - BZDs significant predictor of falls in women (p=0.017)
  - Chaimowicz, 2002 - independent association between variable BZD use and falls (age >65)

- **Laboratory results:**
  - Freis, 2002 - significant predictors of falling (inpatient) = previous fall, need for max assistance and BZD use
- **Pharmacoepidemiology results:**
  - Ray, 1989 - BZDs pose risk to elderly (age >65)
  - Allain, 1991 - zopiclone not related to falls (mean age = 52.3)
  - Wang, 2001 - similar significant risk of hip fracture with zolpidem and BZDs (age >65, mean age = 82)
- **Conclusion:** Hypnotics can alter postural instability and equilibrium (↑ risk of falls/hip fractures)
Medicare Modernization Act (2003)
- Medicare Part D
- BZDs excluded

Medicare Improvements for Patients and Providers Act (2008)
- Exclusion of BZDs eliminated
- Effective 2013

Based on 2003 Beers Criteria

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Case Results

- What additional information would be useful in SD’s assessment?
- What do you think is the likely culprit for SD’s fall?
- What recommendations might you include in your plan?

The AGS 2012 Beers Criteria

<table>
<thead>
<tr>
<th>Strengths</th>
<th>Weaknesses</th>
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<tbody>
<tr>
<td>Partnership with AGS Institute of Medicine Standards</td>
<td>Many topics under represented: Duration of use Therapeutic duplication [Some] Drug-drug interactions</td>
</tr>
<tr>
<td>Assessed in large patient samples</td>
<td>Easy to use Inexpensive Drug indication not required</td>
</tr>
<tr>
<td></td>
<td>Does not represent underused (indicated) medications</td>
</tr>
<tr>
<td>Regular update of criteria Evidence-based (referenced)</td>
<td>Not applicable to hospice patients</td>
</tr>
<tr>
<td></td>
<td>Not applicable to palliative care patients</td>
</tr>
</tbody>
</table>

The Bottom Line

- The 2012 AGS Beers Criteria could be potentially useful for prospective considerations of PIMs.
  - Computerized algorithms
  - Potential flagging - new prescriptions
- Not intended to supplement clinical judgment.
  - Lack of efficacy - retrospective studies
  - Does not consider patient-specific nuances
The Pharmacist’s Role

- Formulary development - Pharmacy & Therapeutics Committee
- Medication reconciliation - National Patient Safety Goal (NPSG.03.06.01)
- Patient adherence
- Appropriate prescribing - Quality Assurance
  - Academic detailing
  - Prospective identification of PIMs and recommendations for safer alternatives

Academic Detailing: “Un-advertisement”

- Goal: close gap between best available science and actual prescribing practices
  1. Collect evidence-based guidelines and identify potential barriers to education
  2. Present providers with objective education and value of evidence-based clinical practice
  3. Reassess education level within a set time period (usually 6-12 months)

For Your Information: Beyond Beers

Resources for Pharmacy Practice

Links and Apps

- Quick Reference Sites
  - AGS
    - http://www.americangeriatrics.org/health_care_professionals/clinical_practice/clinical_guidelines_recommendations/2012/Patient_handouts_and_information
  - Duke University
    - https://www.dcri.org/trial-participation/the-beers-list/
  - Medicare Part D Prescription Drug Plan

- iGeriatric App
  - Smart technology (iPhone/iPad and Droid)

Thank you!