

Medication Monitoring: A Critical Step in the Care Process

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Disclosure

- This speaker has no conflict of interest to disclose but may discuss the off-label use of medications.

Outline

- Medication Use Process in Long Term Care Settings
- Overview of Regulatory Requirements with respect to Medication Management
- Why is Medication Monitoring so important?
- Application of Medication Monitoring to the Use of Antipsychotics
- Resources and Tools to Assist with Medication Monitoring

MEDICATION USE PROCESS IN LONG TERM CARE

Medication Use Process

- 1. Prescribing**
 - Evaluate resident
 - Determine need for medication
 - Select appropriate medicine
- 2. Documenting/Transcribing**
 - Write order in chart to transcribe verbal order
 - Transmit order to pharmacy
 - Transcribe order to MAR
- 3. Dispensing**
 - Receive, review, and confirm order at pharmacy
 - Prepare and dispense medication to facility
 - Transport medications to facility
- 4. Administering**
 - Review MAR
 - Critically think through administration of med
 - Administer the right medication, at the right dose or rate, by the right route, at the right time to the right patient
 - Record administration in MAR
- 5. Monitoring**
 - Assess patient's response to medicine
 - Report and document outcomes
 - Role of consultant pharmacists

Ref: 2008 National Patient Safety Foundation Patient Safety Conference

OVERVIEW OF REGULATORY REQUIREMENTS WITH RESPECT TO MEDICATION MONITORING

Historical Perspective Of Pharmacy Responsibilities in Long Term Care

- 1974 – Monthly pharmacist-conducted Drug Regimen Review (DRR) in SNFs
- 1980 – Indicators for Surveyor Assessment of DRR
- 1987 – DRR in ICFs
- 1990 – Implementation of OBRA 1987
 - Appropriate use of antipsychotics
 - Unnecessary drugs
 - DRR Indicators updated and expanded
- 1999 – Interpretive Guidelines changes
 - Drug therapy guidelines (Beer's Criteria)
 - Medication error defined
 - DRR Indicators updated and expanded
- December 18, 2006 – Updated Guidance within the SOM
- Starting January 2013: Medication Therapy Management and Comprehensive Medication Reviews in Long Term Care

State Operations Manual: Appendix PP – Guidance to Surveyors for Long Term Care Facilities

- §483.60 Pharmacy Services (Tag F425)
- §483.60(d) Labeling and Storage of Drugs and Biologicals (Tag F431)
- §483.60(c)(1)(2) Medication Regimen Review (Tag F428)
- §483.25(l) Unnecessary Drugs (Tag F329)

These new FTags apply to LTC residents of all ages, not just residents older than 65 years, for whom federally-mandated DRR is currently required.

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Synopsis of Regulation F428

- Drug Regimen Review
 - (1) The drug regimen of each resident must be reviewed at least once a month by a licensed pharmacist.
 - A more frequent review may be necessary depending upon the resident's condition and the risks for adverse consequences related to current medications.
 - (2) The pharmacist must report any irregularities to the attending physician and the director of nursing, and these reports must be acted upon.

The new FTags take a holistic approach to medication management stressing the importance of the whole care process – medication use is just one component of the care process and plan of care.

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Medication Regimen Review

- The essential components of the MRR are unchanged but the scope has increased to include:
 - Identification of irregularities through review of:
 - Medication administration records (MAR), prescribers' orders, progress, nursing and consultants' notes, Resident Assessment Instrument (RAI), laboratory and diagnostic test results, and behavioral monitoring information.
 - Pharmacist consideration of whether physician and staff have:
 - Documented indications for use (not just an indication on the chart)
 - Identified allergies, potential side effects, and medication interactions
 - Documented progress toward, or maintenance of, goals of medication therapy
 - Acted upon laboratory results and diagnostic studies
 - Acted upon possible medication-related causes of worsening in the residents' condition.

The focus has shifted to achievement of measurable outcomes.

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F428 MRR Conditions Requiring Identification of Irregularities

Changes that may be related to medication use that need to be evaluated by the consultant pharmacist during MRR include:

- | | |
|--|--|
| • Anorexia | • Evidence of impaired coordination |
| • Behavioral changes | • Gastrointestinal bleeding |
| • Bowel Function changes | • Generalized aching or pain |
| • Confusion, cognitive decline | • Rash, pruritis |
| • Dehydration, fluid/electrolyte imbalance | • Seizure activity |
| • Depression, mood disturbances | • Spontaneous or unexplained bleeding, bruising |
| • Dysphagia, swallowing difficulty | • Unexplained decline in functional status (e.g. ADLs, vision) |
| • Excessive sedation, sleep disturbances | • Urinary retention or incontinence |

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2013---CMR by a Consultant Pharmacist = Added value



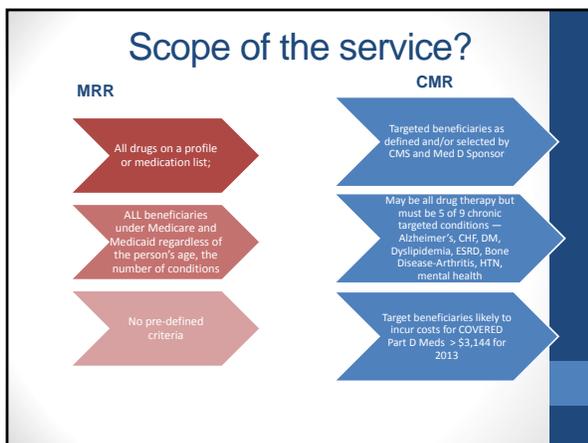
"We agree that LTC consultant pharmacists would be a valuable resource for the delivery of CMRs.....and also acknowledge that the potential overlap between the DRR reviews required in LTC settings and Part D MTM reviews could possibly result in conflicting reviews. To maximize efficient use of healthcare resources, we encourage plan sponsors to consider making arrangements that include the LTC consultant pharmacist in conducting Part D MTM services for targeted beneficiaries in LTC"

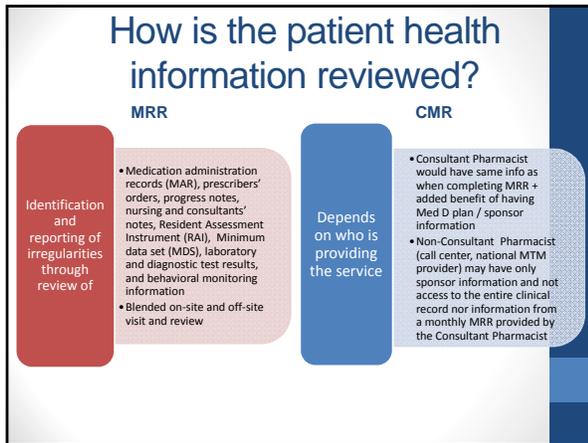
[CMS Final Call Letter](#)

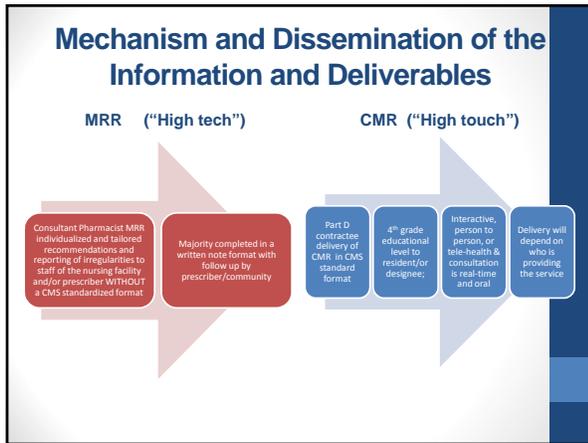
Compare & Contrast MRR to CMR

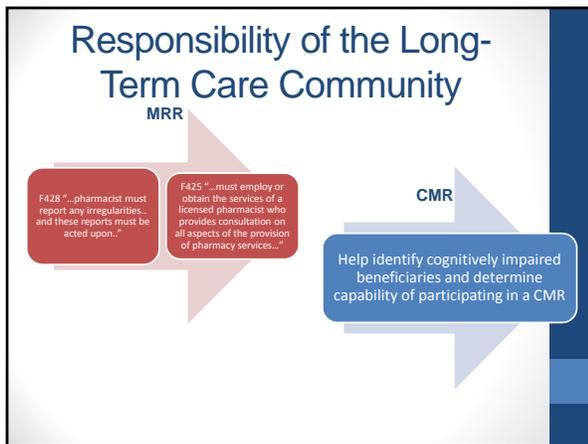
- Who provides the service?
- Who is the audience?
- How is the information reviewed?
- Communication/dissemination of the CMR?
- Responsibility of the long-term care community?
- Responsibility of the Consultant Pharmacist?
- What is the scope of the service?













Similarities of MRR & CMR

- Promote the safe and effective use of medications
 - Education or counseling to the beneficiary and/or caregiver(s) for safe and appropriate medication use
 - Deliverables required for clinical documentation support
 - Process and dissemination of the information is tailored to meet the needs of the participant (person-centered)
 - Utilize and requires strong communication skills by the service provider
- Both value and recognize the Pharmacist as the optimal service provider for medication management services!!



Take Home Points

- Numerous Opportunities for evaluation of ALL medications,
 - Consultant Pharmacist's Medication Regimen Review or comprehensive medication review
 - MD's visit or signing of orders
 - During quarterly MDS review
- Suggested items to evaluate:
 - Resident's target symptoms and the effect of the medication on symptoms (e.g., severity, frequency)
 - Changes in resident's function (e.g., MDS)
 - Whether resident experienced any medication-related adverse consequences

“As older patients move through time, often from physician to physician, they are at increasing risk of accumulating layer upon layer of drug therapy, as a reef accumulates layer upon layer of coral.”

Jerry Avorn, MD 2004



WHY IS MEDICATION MONITORING SO IMPORTANT?

Did you know?

- 10.7% of hospital admissions in older adults are associated with adverse drug events(ADE)¹
- Approximately 100,000 emergency hospitalizations a year are due to ADEs²
 - 48% of hospitalizations occur in adults 80 years of age or older
 - 66% were due to unintentional overdoses

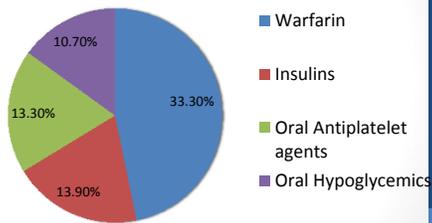
Kongkaew C, et al. Annals of Pharmacotherapy 2008; 42:1017-1029
Budnitz et al. N Engl J Med 2011;365:2090-2098

Top Five Problematic Medication Classes leading to ED

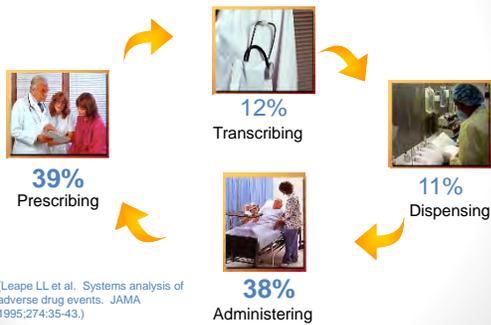
- 1. Hematologic
- 2. Endocrine agents
- 3. Cardiovascular agents
- 4. Central Nervous System Agents
- 5. Anti-infective

Budnitz et al. N Engl J Med 2011;365:2000-12.²

Top Offending Medications (67% of cases)



Where Do Medication Errors Occur?



Medical Error Statistics

- Within hospitals and skilled nursing facilities, one out of five medications are administered in error
- More people die in a given year as a result of medical errors than from motor vehicle accidents, breast cancer or AIDS.
- For every dollar spent on drugs in nursing facilities
 - \$1.33 is consumed in treatment of drug related morbidity and mortality
 - amounting to 7.6 billion dollars dollars for the nation as a whole
 - of which 3.6 billion is estimated to be avoidable

Barker KN, et al. Medication errors observed in 36 health care facilities. Arch Intern Med 2002;162(16):1897-903. Institute of Medicine. To err is human: building a safer health system. Washington, DC: National Academies Press; 2000.

Error Stage for Preventable Adverse Drug Events

N=421 preventable ADEs

Category	Number	Percentage
Prescribing	246	58.4%
Filling	8	1.9%
Monitoring	256	60.8%
Patient adherence	89	21.1%

Gurwitz JH, et al. JAMA. 2003;289:1107-16.

Staff Education

- LTC medication errors tend to be due to
 - knowledge deficits
 - drug information
 - patient information
 - performance deficits
 - fatigue
 - interruptions
 - failure to follow the 5 rights

Pelletier PL. Medication errors: A lesson from long-term care. Nursing Management. 2001;32(11):49-50.

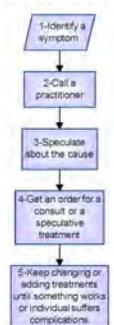
APPLICATION OF MEDICATION MONITORING TO THE USE OF ANTIPSYCHOTICS

Clinical Problem Solving Process

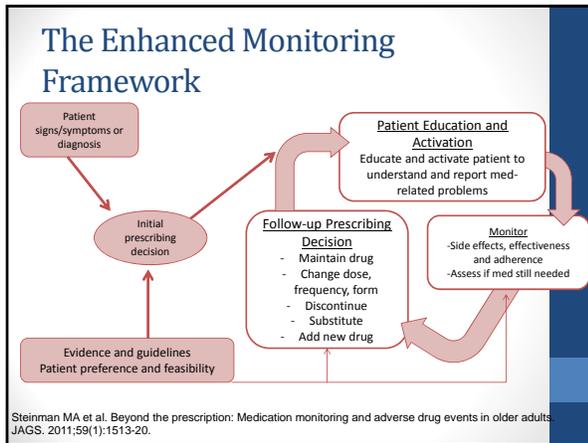


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The Misguided Care Process



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Antipsychotics and Nursing Homes

- “Today, Centers for Medicare & Medicaid Services (CMS) Acting Administrator Marilyn Tavenner announced the Partnership to Improve Dementia Care, an initiative to ensure appropriate care and use of antipsychotic medications for nursing home patients. This partnership – among federal and state partners, nursing homes and other providers, advocacy groups and caregivers – has set a national goal of **reducing use of antipsychotic drugs in nursing home residents by 15 percent by the end of 2012.**” (6/9/12)

CASE DISCUSSION

Case Scenario

NK is an 89 yr old woman admitted to the nursing home within the last 2 months. The facility staff are concerned about her "sundowning."

PMH:

- Osteoporosis
- Hypertension
- Alzheimer's Disease for 6 years

Case Continues

- **SH:** Lived with her husband in their apartment within the retirement community for 8 years but moved to the nursing home after a recent hospitalization for a urinary tract infection. Per the history from the husband, he was unable to handle her due to her agitation with him.
- **Functional Capacity:**
 - Dependent in toileting, dressing and bathing
 - Now wheelchair dependent
 - Of note, been falling more and staff notes she is especially drowsy in the morning with breakfast

Case Continues

- **Medications:**
 - Olanzapine (Zyprexa) 5mg at bedtime for dementia related behaviors
 - Lorazepam (Ativan) 0.5mg twice daily for anxiety
 - Citalopram (Celexa) 20mg daily for depression/irritability
 - Enteric Coated Aspirin 81mg daily for heart health
 - Calcium 600mg/Vitamin D 400IU 1 tablet daily for bone health
 - Lisinopril 10mg in the morning for hypertension
 - Rivastigmine (Exelon) 6mg twice daily for Alzheimer's Disease
 - Memantine (Namenda) 10mg twice daily for Alzheimer's Disease

Pertinent Objective Data:

- Available from the last 48 hours:
- BP = 120/74 sitting HR = 72 bpm
- Ht = 5'2" Wt = 50 kg
- Estimated CrCl = 32 ml/min
- UA: negative
- CBC and BMP: WNL

Let's Walk through the Care Process: Application of F329

- For each resident receiving an **antipsychotic** the following may need to be considered to assess if it is an unnecessary medication:
 - Indication for use
 - Informed consent/discussion
 - Dosage
 - Monitoring to determine effectiveness
 - Monitoring for adverse consequences
 - Duration or Gradual Dose Reduction (GDR)

Indications for Antipsychotics: "On vs. Off Label" Discussion

- Schizophrenia
- Schizo-affective disorder
- Schizophreniform disorder
- Delusional disorder
- Mood disorders (e.g., bipolar disorder, severe depression w/ psychotic features)
- Psychosis in the absence of dementia
- Medical illnesses with psychotic symptoms (e.g., neoplastic disease or delirium) and/or treatment related psychosis or mania (e.g., high-dose steroids)
- Tourette's Disorder or Huntington disease
- Hiccups
- Nausea and vomiting associated with cancer or chemotherapy
- Behavioral or Psychological Symptoms of Dementia (BPSD)

Informed Discussion

- **Resident Choice** – A resident and/or representative(s) has the right to be informed about the resident's condition; treatment options, relative risks and benefits of treatment, required monitoring, expected outcomes of the treatment; and has the right to refuse care and treatment.
 - If a resident refuses treatment, the facility staff and physician should inform the resident about the risks related to the refusal, and discuss appropriate alternatives such as offering the medication at another time or in another dosage form, or offer an alternative medication or non-pharmacological approach, if available.

Standardized Forms for Dementia Residents on Antipsychotics for Behavioral Symptoms

Prescriber "Documentation of Therapy" Form

- Indication
- Target Behavior(s)
- Risk Vs Benefit justification
- Regulatory Language
- Dose Reduction plan

Patient/Guardian Consent Form

- Indication
- Benefit
- Expected patient consequences if medication is not given
- Alternatives/ non-drug therapy
- Side effects/ black-box warning
 - Example within: <http://www.bjmp.org/content/it-s-time-require-written-informed-consent-when-using-antipsychotics-dementia>

Sample Consent Form



Dosage for Use in Dementia Related Behaviors

Generic Name	Maximum Total Dosage (mg) per day
First Generation or Typical Agents	
chlorpromazine	75
fluphenazine	4
haloperidol	2
loxapine	10
molindone	10
perphenazine	8
thioridazine	75 *
thiothixene	7
trifluoperazine	8
Second Generation or Atypical	
aripiprazole	10
clozapine	50
olanzapine	5
quetiapine	150
risperidone	2
zucrasidone	**
paliperidone	**
asenapine	**
loperidone	**
lurasidone	**

Monitoring for Effectiveness

- What would we monitor in this case?
- How often?
- What tools?
- Who is the responsible party?

Case

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Monitoring for Toxicities

- **The facility assures that residents are being adequately monitored for adverse consequences such as:**
 - **General:** anticholinergic effects, falls, excessive sedation
 - **Cardiovascular:** cardiac arrhythmias, orthostatic hypotension
 - **Metabolic:** increase in total cholesterol and triglycerides, unstable or poorly controlled blood sugar, weight gain
 - **Neurologic:** akathisia, neuroleptic malignant syndrome (NMS), parkinsonism, tardive dyskinesia, cerebrovascular event (e.g., stroke, transient ischemic attack (TIA)) in older individuals with dementia
 - If the antipsychotics are identified as causing or contributing to adverse consequences as identified above, the facility needs to act upon this.

Gradual Dose Reduction

- Within the first year in which a resident is admitted on an antipsychotic medication or after the facility has initiated an antipsychotic medication, the facility must attempt a GDR in two separate quarters (with at least one month between the attempts), unless clinically contraindicated. After the first year, a GDR must be attempted annually, unless clinically contraindicated.
- For any individual who is receiving an antipsychotic medication to treat behavioral symptoms related to dementia, the GDR may be considered clinically contraindicated if:
 - The resident's target symptoms returned or worsened after the most recent attempt at a GDR within the facility; and
 - The physician has documented the clinical rationale for why any additional attempted dose reduction at that time would be likely to impair the resident's function or increase distressed behavior.

Relapse Risk after Discontinuation of Risperidone in Alzheimer's Disease

- **Target Population:**
 - outpatients or residents of ALFs or NHs
 - 50-95 years of age
 - Met criteria for probable Alzheimer's Disease
 - Score on Neuropsychiatric Inventory (NPI) of 4 or more on the delusions or hallucinations subscale (agitation score) or agitation-aggression subscale (aggression score)
 - MMSE 5-26(outpts) and 2-26 (NHs)
- **Intervention:** risperidone 0.25mg – up to 3mg/day versus placebo
- **Outcome Measures**
 - Primary End Point: measure of relapse utilizing NPI or Clinical Global Impression of Change Scores
 - Secondary Outcomes: Assessment of Adverse effects (such as EPS, function, cognition)

Study Results

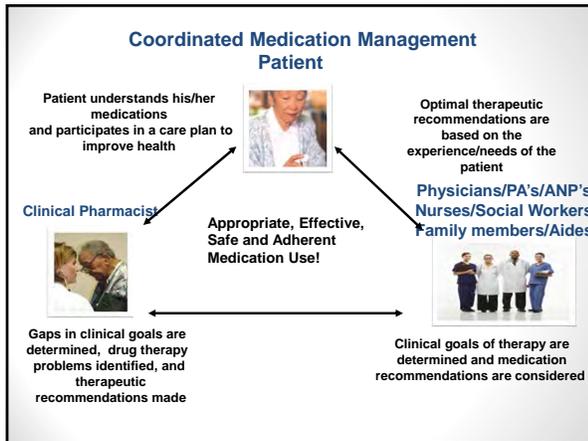
Phase A: 180 received risperidone 112 had a response (62%) and 110 underwent randomization (mean dose 0.97mg)		
Group 1: 32 cont risp for 32 weeks At Wk 16: 14 had a relapse 1 Died 4 Discontinued early 2 had unacceptable side effects 2 nd 16 week phase: 13 cont Yet only 10 completed	Group 2: 38 cont risp for 16 weeks followed by placebo for 16 weeks At Wk 16: 8 had a relapse 3 Discontinued early 2 nd 16 week phase: 27 cont Yet only 14 completed Of note 13 had a relapse	Group 3: 40 placebo for 32 weeks At Wk 16: 23 had a relapse 3 Discontinued early 2 nd 16 week phase: 13 cont Yet only 10 completed Of note 2 had a relapse

Take Home Points

- Increased risk of relapse noted within the study
 - **1st 16 weeks:** 24/40 (60% in group 3) compared to 23/70 (groups 1&2) meaning 6.5 vs 3.0 relapses per 100 patient weeks of follow-up
 - **2nd 16 weeks:** 13/27 (48% in group 2) versus 2/13 (15%) in group 1 meaning 4.3 vs 1.1 relapses per 100 patient weeks of follow-up.

Key points: despite increased risk of relapse important to note that risperidone had limited clinical effectiveness as noted by dropouts despite treatment (38% total cohort in Part A, 68% in group 1, 29% in group 2)

Differences in adverse effects did not differ among the group yet small sample size.



RESOURCES AND TOOLS TO ASSIST WITH MEDICATION MONITORING

The top of the slide features a horizontal strip of various medication packaging, including blister packs and boxes in different colors (yellow, red, white, blue). Below this is a white box with a blue border containing the title 'RESOURCES AND TOOLS TO ASSIST WITH MEDICATION MONITORING'.

Useful Resources for Clinicians

- Medication Management**
 - American Society of Consultant Pharmacy: www.ascp.com
 - American Pharmacist Association: <http://www.pharmacist.com/MTM>
 - Med Management for Older Adults: www.medmanagement.umaryland.edu
- Adherence**
 - WHO Adherence to long-term therapies: evidence for action [report]. Geneva, 2003. http://www.who.int/chp/knowledge/publications/adherence_report/en/
 - National Council on Patient Information and Education (NCPIE) Medication Use Safety Training (MUST) Program: <http://www.mustforseniors.org>
 - Center for Connected Health: <http://www.connected-health.org/programs/medication-adherence.aspx>
- Identifying Potentially Inappropriate Medications**
 - American Geriatrics Society: Beers Criteria 2012: http://www.americangeriatrics.org/health_care_professionals/clinical_practice/clinical_guidelines_recommendations/2012
 - Gallagher P. STOPP (Screening Tool of Older Person's Prescriptions) and START (Screening Tool to Alert doctors to Right Treatment). Consensus validation. *Int J Clin Pharmacol Ther.* 2008;46:72-83. <http://www.ncbi.nlm.nih.gov/pubmed/18218287>

Steinman MA, Hanlon JT. Managing medications in clinically complex elders: "There's got to be a happy medium". *JAMA.* 2010;304(14):1592-601

AGS 2012 BEERS CRITERIA

Specific Aims AGS 2012 Beers Criteria

specific aim – update 2003 Beers Criteria using a comprehensive, systematic review and grading of evidence

Strategy:

1. Incorporate new evidence
2. Grade the evidence
3. Use an interdisciplinary panel
4. Incorporate exceptions

Beers Criteria- 3 Main Tables

- 1) Table 2: Medications or medication classes that *should be avoided* in persons 65 years or older
- 2) Table 3: Medications that should not be used in older person known to have specific medical diseases or conditions.
- 3) Table 4: Medications that should be used with caution

Beers Criteria: Table 2 Results

- 34 potentially inappropriate medications/classes to avoid in older adults independent of diagnoses or conditions.
- Notable mentions:
 - Sliding Scale Insulin
 - Antipsychotics for Behavioral Health issues associated with dementia
 - Non benzodiazepine Hypnotics
 - Megestrol

Antipsychotics

Organ System/Therapeutic Category/Drug(s)	Rationale	Recommendation	Quality of Evidence	Strength of Recommendation	References
Antipsychotics, first-(conventional) and second-(atypical) generation (see Table 8 for full list)	Increased risk of cerebrovascular accident (stroke) and mortality in persons with dementia.	Avoid use for behavioral problems of dementia unless non-pharmacologic options have failed and patient is threat to self or others.	Moderate	Strong	Dore 2009 Maher 2011 Schneider 2005 Schneider 2006a Schneider 2006b Vigen 2011

Timely addition with the increased focus on safety and efficacy in patients on these medications especially within the nursing home setting.

Beers Criteria: Table 3 Notable Mentions

Disease/Syndrome	Drug/Drug Class	Rationale
History of falls or fractures	Anticonvulsants Antipsychotics Benzodiazepines Nonbenzodiazepine hypnotics <ul style="list-style-type: none"> • Eszopiclone • Zaleplon • Zolpidem TCAs and Selective serotonin reuptake inhibitors.	Ability to produce ataxia, impaired psychomotor function, syncope, and additional falls; shorter-acting benzodiazepines are not safer than long-acting ones
Delirium	All TCAs Anticholinergics Benzodiazepines Chlorpromazine Corticosteroids H ₂ receptor antagonists. Meperidine Sedative hypnotics Thioridazine	Avoid in older adults with or at high risk of delirium because of inducing or worsening delirium in older adults; if discontinuing drugs used chronically, taper to avoid withdrawal symptoms.

Beers Criteria: Table 4 Notable Mentions

Drug	Rationale	Recommendation
ASA for Primary Prevention of cardiac events	Limited data in individuals ≥ 80	Use with caution in adults ≥ 80
<ul style="list-style-type: none"> • Antipsychotics • Carbamazepine • Carboplatin • Chlorpropamide • Cisplatin • Mirtazapine • SNRIs • SSRIs • TCAs • Vincristine 	May exacerbate or cause SIADH or hyponatremia; need to monitor sodium level closely when starting or changing dosages in older adults due to increased risk	Use with caution

Beers Criteria only Part of Quality Prescribing

Quality prescribing includes:

- Correct drug for correct diagnosis
- Appropriate dose (label; dose adjustments for comorbidity, drug-drug interactions)
- Avoiding underuse of potentially important medications (e.g., bisphosphonates for osteoporosis)
- Avoiding overuse (e.g., antibiotics)
- Avoiding potentially inappropriate drugs
- Avoiding withdrawal effects with discontinuation
- Consideration of cost

Resources Available Online

www.americangeriatrics.org

For the Health Professional

- Downloadable or laminated pocket card
- Online Evidence tables
- Smartphone application (iGeriatrics)

For the Layperson

- Summary in lay language
- Q & A on what to do if one of your drugs is on the Beers list
- Medication diary & tips for safe use of meds



Frequency of Monitoring

Medication	Laboratory Monitoring Parameter	Interval (Months)
ARBs (e.g., losartan, valsartan)	Serum potassium levels	6
ACE-I (e.g., captopril, lisinopril, enalapril)	Serum potassium levels	6
Amiodarone	Serum liver function and Thyroid-stimulating hormone level	6
Digoxin	Serum blood urea nitrogen, Serum creatinine level, and Trough serum digoxin level	6
Diuretics (e.g., furosemide, HCTZ, spironolactone)	Serum sodium and potassium level	3
Statins (e.g., lovastatin, simvastatin)	Serum liver function tests	6

Handler SM et al. Frequency of laboratory monitoring of chronic medications administered to nursing facility residents: Results of a national internet-based study. *The Consultant Pharmacist*. 2008;23(5):387-95.

General Resources

- Appropriate Prescribing for Elderly People
- Disposal of Drugs
- Drug-Drug Interaction Identifiers
- Health Directory
- Medication Safety



www.medmanagement.umaryland.edu

Take Home Points

- Medication Monitoring takes a team!
- It needs to be patient centered.
- Most importantly, monitoring needs to be evaluated on an ongoing basis.