

Updated Surveyor Guidance
on Medications: F329

Steve Levenson, MD, CMD

1

OVERVIEW

2

Medication Benefits and Risks

- Medications can stabilize or improve outcome, quality of life, and function
- Any medication can have adverse consequences
- Potential to increase risk of adverse consequences
 - Without adequate indications
 - Excessive dose
 - Excessive duration
 - Without adequate monitoring

3



Scope of the Problem

- Medications are well-known public health problem
 - Described in the medical, nursing, and pharmacology literature for many decades
 - Discussed repeatedly in the mass media
 - Relevant in every setting

4



- Source: Parade Magazine, March 12, 2006

5



Why Focus on Problematic Drugs?

- J Amer Bd of Family Practice, 95; 8:195-205, Ackerman et al.
 - "It is safe to assume that many of our nursing home patients are suffering from drug side effects, drug interactions, or both."
 - "Careful review and pruning of the medication list could be the single most important service the clinician can provide to his or her nursing home patients"

6

ADRs Increase With Number of Medications



7

Medications Elsewhere

- From 13 papers
 - Median percentage of preventable drug-related admissions to hospital was 3.7% (range 1.4–15.4)
- From nine papers
 - Majority (51%) of preventable drug-related admissions involved either antiplatelets (16%), diuretics (16%), nonsteroidal anti-inflammatory drugs (11%) or anticoagulants (8%)

8

Medications Elsewhere

- Five studies
 - Median proportion of preventable drug-related admissions associated with prescribing problems was 30.6% (range 11.1–41.8)
 - Adherence problems 33.3% (range 20.9–41.7)
 - Monitoring problems 22.2% (range 0–31.3)

9



Medications Elsewhere

- R. L. Howard, A. J. Avery, S. Slavenburg, S. Royal, G. Pipe, P. Lucassen, M. Pirmohamed (2007)
- Which drugs cause preventable admissions to hospital? A systematic review
- British Journal of Clinical Pharmacology 63 (2), 136–147.

10



Mistaking ADRs for Medical Illnesses

- Elderly woman with frequent dizziness and falling
- On diuretic and ACE inhibitor for hypertension
- Despite lack of convincing evidence, cardiologist places pacemaker

11



Mistaking ADRs for Medical Illnesses

- Patient has trouble with rehabilitation, feels lightheaded
- Lightheadedness persists despite stopping diuretic and ACE inhibitor
- After Sinemet dose cut from 25/250 t.i.d. to 10/100 t.i.d., lightheadedness stops and function improves to enable discharge

12



PDR: Sinemet

- "Symptomatic postural hypotension has occurred when SINEMET is added to the treatment of a patient receiving antihypertensive drugs."

13



Not Recognizing Risk

- Elderly woman falls at home and fractures hip
- Treated on orthopedic service
- Medical consult obtained at beginning of stay; lytes OK, no further monitoring done
- Left on Aldactone throughout hospital stay, despite minimal evidence of serious history
- Arrives at SNF for rehab, but is delirious
- Repeat labs: sodium 111, K 2.0

14



Not Knowing or Believing Precautions

- Elderly patient with atrial arrhythmia placed on amiodarone 200-400 mg. / day
- No monitoring of pulmonary, liver, thyroid, or eye function
- Overall condition deteriorates
- Signs of heart failure appear
- Patient given additional medications

15



Unnecessary Drugs: F329

Overview and Interpretive Guidelines

16



INTENT: (F329) 42 CFR 483.25(l)

- Each resident's entire drug/medication regimen is managed and monitored to achieve certain goals

17



INTENT: (F329) 42 CFR 483.25(l)

- An individual receives only medications clinically necessary to treat assessed condition(s)
 - Appropriate doses for appropriate duration
- Non-pharmacologic interventions considered and used instead of, or in addition to, medication when indicated
 - For example, behavioral interventions for dementia-related behavioral symptoms

18

INTENT: (F329) 42 CFR 483.25(l)

- Medication or combination helps promote or maintain highest practicable physical, functional, and psychosocial well-being
- Risks for adverse consequences or negative outcome(s) due to medication(s) are minimized

19

INTENT: (F329) 42 CFR 483.25(l)

- If individual experiences decline or newly emerging or worsening symptoms
 - Change is recognized promptly
 - Medication regimen evaluated as potential contributing or causative factor
 - Changes made as appropriate

20

Factors Affecting Medication Utilization

- Important considerations
 - Underlying condition / current signs and symptoms
 - Identification of root causes of symptoms
- Diagnosis alone may not warrant treatment with medication

21



MEDICATION MANAGEMENT

22



Purpose of F329 Surveyor Guidance

- Help surveyor determine whether the facility has a system for medication management that promotes key objectives regarding medications

23



Guidance To Surveyors

- Guidance applies to all categories of medications including antipsychotic medications
- Surveyor's review of medication use not intended to constitute practice of medicine
 - However, surveyors are expected to investigate basis for decisions and interventions

24



Key Considerations

- Indications for use
- Dosage
- Duration
- Monitoring for effectiveness and adverse consequences
- Tapering / gradual dose reduction
- Preventing, identifying, and responding to adverse consequences

25



Medication Management System Objectives

- Select medications based on assessing relative benefits and risks to individuals
- Evaluate underlying cause(s) of signs and symptoms, including those due to adverse medication consequences
- Use of medications in doses and for duration appropriate to individual's clinical conditions, age, and underlying causes of symptoms

26



Medication Management System Objectives

- Use of non-pharmacologic interventions as indicated to
 - Minimize need for medications
 - Permit use of the lowest possible dose or allow medications to be discontinued, to extent possible
- Monitoring of medications for efficacy and side effects
 - Especially, medications associated with risk of clinically significant adverse consequences

27

Medication Management Principles

- Based in the care process including
 - Recognition or identification of the problem/need
 - Assessment of details
 - Diagnosis/cause identification
 - Management/treatment
 - Monitoring including revising interventions, as warranted

28

Medication Management Principles

- Attending physician has key role in developing, monitoring, and modifying medication regimen
 - In conjunction with
 - Resident / patient and/or representatives
 - Other professionals and direct care staff

29

Role of Other IDT Members

- Identify, assess, address, monitor, and communicate signs and symptoms, needs, and changes in condition
- Support individuals with limited ability to understand, communicate, or make decisions
- Consider resident / patient wishes, preferences, etc when selecting medication and non-pharmacological interventions

30



Indications

- A pertinent patient evaluation helps
 - Identify patient needs, comorbid conditions, and prognosis
 - Determine causes and contributing factors affecting signs, symptoms and test results
 - Select pertinent interventions
 - Define clinical indications
 - Provide baseline data to enable subsequent monitoring

31



Evaluation Addresses Important Questions

- Do target symptoms and/or related causes warrant medication therapy?
- Are non-pharmacologic interventions relevant?
- Is a particular medication pertinent to managing symptoms or condition?
- Do intended or actual benefits justify risk(s) or adverse consequences?

32



Circumstances For Possible Medication Evaluation

- Admission or readmission
- Clinically significant change in condition/status
- New, persistent, or recurrent clinically significant symptom or problem
- Worsening of existing problem or condition

33

Circumstances For Possible Medication Evaluation

- Otherwise unexplained decline in function or cognition
- Non-specific symptom not otherwise attributable to underlying cause
- New medication order
- Renewal of orders
- Irregularity identified in consultant pharmacist's monthly MRR

34

Monitoring

- Key objectives for monitoring medications
 - Track progress towards therapeutic goal(s)
 - Detect emergence or presence of adverse consequences

35

Adverse Consequences

- Common enough to warrant serious attention and close monitoring
- Study (published in 2005)
 - 338 (42%) of 815 adverse drug events judged preventable
 - Common omissions
 - Inadequate monitoring
 - Lack of response or delayed response to signs or symptoms or laboratory evidence of medication toxicity

36



Adverse Consequences

- Any medication can cause adverse consequences
- Some occur quickly or abruptly
 - Others more insidious; develop over time
- May become evident
 - Shortly after initiating medication
 - Change in dose
 - By tapering or discontinuing a medication

37



Follow-Up

- Review
 - Is medication regimen promoting or maintaining highest practicable level of function?
 - Are therapeutic goals being met?
 - Is individual experiencing adverse consequences?
 - Are current medications and doses still appropriate, or should they be reduced, changed, or discontinued?

38



Tapering / Gradual Dose Reduction (GDR)

- Possible indications for tapering any medication dose
 - Individual's clinical condition has improved and/or declined
 - Medication no longer beneficial or indicated
 - Continued use of a medication may be considered excessive dose
- Example
 - Discontinue cough, cold, and allergy medications after acute upper respiratory symptoms resolved

39



Duration

- Periodic re-evaluation of medication regimen
 - To determine need for prolonged or indefinite use of a medication
- Many conditions require treatment for extended periods
- Others may resolve and no longer require medication therapy
 - Examples: nausea and/or vomiting, acute pain, psychiatric or behavioral symptoms, itching, cough and cold symptoms

40



What Can the Physician Do?

41



F329: Compliance Strategies

- Understand the issues
- Recognize the risks
- Know what is expected
- Use medications carefully
- Perform adequately detailed assessments
- Base decisions on evidence
 - Including results of careful assessments
- Justify long-term use

42



F329: Compliance Strategies

- Monitor closely
 - Effectiveness
 - Adverse consequences
 - Be on the lookout for adverse consequences
 - Rule out adverse drug consequence when
 - New symptoms occur
 - Existing symptoms don't stabilize or improve

43



F329: Compliance Strategies

- Act promptly when adverse consequences suspected or identified
- Provide relevant patient-specific documentation to explain decisions

44



Ultimate Responsibility

- Physicians have primary responsibility to
 - Make appropriate decisions about medications
 - Identify, anticipate, and manage medication-related problems
 - Based on input from others and own reviews

45

Minimizing Risk of Adverse Consequences

- Considerations prior to prescribing
 - Safety
 - Tolerability
 - Ease of dosing
 - Potentially troublesome medication-medication interactions
- Often, but not always, can be anticipated or prevented
 - Or, negative effects can be minimized

46

Avoiding Adverse Consequences: Strategies

- Follow relevant clinical guidelines
- Recognize and take seriously warnings and recommendations for dosage, duration, and monitoring
- Always consider adverse consequences as a possible source of new, worsening, or unrelieved symptoms and condition changes

47

Adverse Consequences: Evidence

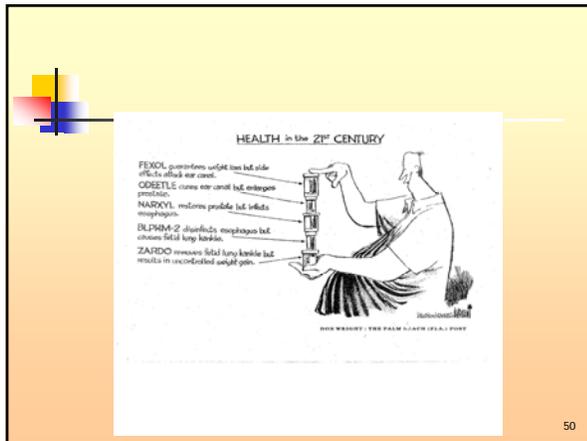
- Study of 18 community-based nursing homes
- 50 percent (276/546) of adverse consequences considered preventable
- 72 percent of fatal, life-threatening, or serious adverse consequences were preventable
- Gurwitz JH, Field TS, Avorn J, et al.. Incidence and preventability of adverse drug events in nursing homes. *American Journal of Medicine.* 2000;109:87-94

48

Adverse Consequences: Evidence

- Studied 2 academic-based NHs
- Identified frequent causes of preventable adverse consequences
 - Inadequate monitoring / failure to act
 - Errors in ordering
 - Including wrong dose, wrong medication
 - Medication-medication interactions
- Gurwitz JH, Field TS, Judge J, et al. The incidence of adverse drug events in two large academic long-term care facilities. *American Journal of Medicine*. 2005;118:251-258

49



50

The "Cascade Effect"

- Medications may be part of a cascade of problems
 - Medication → lethargy → decreased oral intake → fluid/electrolyte imbalance → further lethargy → weight loss → skin breakdown
 - Pneumonia → confusion → medication → lethargy → skin breakdown

51



Diagnosis and Treatment

- Treating symptoms may not address the underlying cause
- Underlying causes may not be correctable
- Treating underlying cause should be relevant to desired outcomes
- Sometimes, underlying causes should not be treated

52



Example: Not Knowing, Believing, Responding to ADR

- Elderly patient being treated with 0.3 mg. clonidine patch
- No significant fluctuations in BP
- Becomes more listless, food intake declines and individual loses weight
- Referred for dietitian consult and MD places on appetite stimulant

53



PDR: Clonidine

- Most frequent side effects (which appear to be dose-related): “. . . dry mouth, occurring in about 40 of 100 patients; drowsiness, about 33 in 100; dizziness, about 16 in 100; constipation and sedation, each about 10 in 100.”

54



Other Examples

- Elderly patient put on large doses of Darvocet and narcotics in hospital, becomes confused and then put on Haldol; comes to NF with delirium
- Elderly patient appears depressed; placed on Elavil, raised gradually to 75 mg. hs; maintained for years
- Elderly patient with low back pain, placed on muscle relaxant without physician assessment; medication continued for months

55



Other Examples

- Elderly patient has stroke, placed on large dose of Depakote for prophylaxis, already on Neurontin for other reasons; remains lethargic after postacute placement; no change made in medications

56



Other Examples

- Elderly patient w/ dementia and incontinence placed on Detrol; maintained despite continued incontinence; mental status worsens over time; referred to psychiatrist; only improves after Detrol stopped
- Elderly patient w/ dementia taking Aricept; remains confused and intermittently agitated; appetite declines and patient loses weight; MD refers to dietitian and prescribes Megace

57

Physician Implications

- We must take ADRs very seriously
- Abundant real-life examples in all settings
- Physicians order most medications
 - Therefore, could significantly impact these problems
 - Must be vigilant
 - Must be aware of major possibilities
 - Not an MD problem alone – we are pressured to prescribe!

58



59

Physician Responsibilities

- Be aware of medications commonly associated with geriatric syndromes
- Perform adequate medical assessment
- Request or find enough information to characterize symptoms concisely
- Refrain from responding automatically to symptoms
- Always place medications in context

60



Physician Responsibilities

- Take ADRs very seriously
- Be suspicious of ADRs in most cases
- Be prepared to taper or stop medications, at least temporarily, unless life-sustaining
- Encourage others to monitor and report ADRs
- Don't take feedback about ADRs as a personal affront

61



Physician Implications

- Insist on considering **intermediate steps** (problem definition, cause identification, identify problem/cause relationship) before shifting into treatment mode, especially in the frail elderly

62



Documentation And Care Process

- What should be documented?
- In the aggregate, enough to answer:
 - How did we identify the symptom?
 - How did we decide that the symptom reflected a problem?
 - How did we decide the problem or symptoms required a treatment?
 - How did we identify a cause (or decide a cause could not be identified)?

63

Documentation And Care Process

- In the aggregate, enough to answer:
 - How did we decide the cause could (or could not) be treated?
 - How did we decide that the cause should (or should not) be treated?
 - Why did we decide that the treatment needed to include a medication?

64

Documentation And Care Process

- Why did we decide that a high-risk medication was indicated?
- How did we decide that an existing high-risk medication could not be discontinued or tapered?
- How did we try to prevent an ADR?
- How did we show that we were monitoring for a potentially significant ADR?

65

The Care Process And Medications

- A vital process can be identified that
 - Is based on key medical and geriatrics principles
 - Covers essential steps
 - Maximizes possibilities for successful outcome
 - Demonstrates basis for clinical decision making
 - Incorporates evidence and consensus
 - Minimizes process contribution to negative outcomes

66
