Updated Surveyor Guidance on Medications: F329

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OVERVIEW

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
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

Source: Parade Magazine, March 12, 2006

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"
**ADRs Increase With Number of Medications**

![Graph showing the relationship between percentage of patients with adverse drug reactions and the number of medications prescribed.](image)

**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%)

**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)
Medications Elsewhere

- Which drugs cause preventable admissions to hospital? A systematic review
- British Journal of Clinical Pharmacology 63 (2), 136-147.

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

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
PDR: Sinemet
- “Symptomatic postural hypotension has occurred when SINEMET is added to the treatment of a patient receiving antihypertensive drugs.”

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

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
Unnecessary Drugs: F329
Overview and Interpretive Guidelines

INTENT: (F329) 42 CFR 483.25(l)
- Each resident’s entire drug/medication regimen is managed and monitored to achieve certain goals

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
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

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

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
Purpose of F329 Surveyor Guidance

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

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
Key Considerations

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

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

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
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

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

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
**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

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**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?

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**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
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

Monitoring

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

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
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

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?

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
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

What Can the Physician Do?

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
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

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

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
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

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

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

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-medicatin interactions

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
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

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

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.”
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

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

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
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!

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
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

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

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)?
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?

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?

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
Regarding Medications, Good Intentions Alone Are Not Enough

Sure, lots of well-intended people think they can fix nursing homes. But that's why they say the road to Hell never lacks for paving materials.