Medication Management, Regulations and Resident Centered Care: What Could Possibly Go Wrong?

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Disclosure / Contact

- Jennifer Hardesty is a shareholder at Remedi SeniorCare
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“Welcome to the ISMP *Long-Term Care Advise-ERR*, a medication safety newsletter designed specifically to meet the needs of administrators, nursing directors, and nurses who transcribe medication orders, administer medications, monitor the effects of medications on residents, and/or supervise those who carry out these important tasks.”

http://www.ismp.org/Newsletters/longtermcare/default.aspx
Learning Objectives

At the conclusion of this presentation, the attendee will be able to:

1. Describe three geriatric principles of medication management
2. Discuss the concept of informed consent as it relates to medication management
3. Identify two federal regulations governing nursing homes which address medication management and describe how they support residents’ rights
4. Describe the concept of a resident centered medication pass
Why Regulate Nursing Homes?

Protect the vulnerable

Account for the $$$
Federal Regulations - The Bottom Line

Quality of Care

• If possible, make me better …
• If that’s not possible, keep me stable …
• If that’s not possible, slow my decline …
• Don’t make mistakes that hurt me

Quality of Life

• Keep “me” involved
• Let me say yes … and no
• You’re my partner, not my parent
• Always treat me as a person, not a patient
The Power of Regulatory “Priorities”
The Power of Regulatory “Priorities”
Medication-Related Adverse Events in Nursing Homes (S&C: 15-47-NH - July 17, 2015)

OIG report (2/2014) “ADVERSE EVENTS IN SKILLED NURSING FACILITIES: NATIONAL INCIDENCE AMONG MEDICARE BENEFICIARIES”

- Study time frame: 2008-2012
- Resident stay < 36 days
- “adverse events” (defined as harm resulting from medical care)
- 1 in 3 SNF residents “harmed”
- 37% of adverse events were related to meds
- 2nd most frequent adverse event: excessive bleeding related to anticoagulation

Washington Post article (7/2015) “Popular blood thinner causing deaths, injuries in nursing homes”

- At least 165 residents hospitalized/died due to Coumadin errors

Outcome: Pilot focused surveys med management
Informed Consent

- The physician (not a delegated representative) should disclose and discuss:
  - The diagnosis, if known
  - The nature and purpose of a proposed treatment or procedure
  - The risks and benefits of proposed treatment or procedures
  - Alternatives (regardless of costs or extent covered by insurance)
  - The risks and benefits of alternatives
  - The risks and benefits of not receiving treatments or undergoing procedures

Source: AMA
Informed Consent: Medications

- F154

- §483.10(b)(3) – The resident has the right to be **fully informed** in language that he or she can understand of his or her **total health status**, including but not limited to, his or her **medical condition**;

- §483.10(d)(2) - The resident has the right to be **fully informed in advance** about care and treatment and of any changes in that care or treatment that may affect the resident’s well-being;
Informed Consent: Medications

- How much information is enough?
WARNINGS AND PRECAUTIONS-----------------------

- Cerebrovascular events, including stroke, in elderly patients with dementia-related psychosis. Risperdal® is not approved for use in patients with dementia-related psychosis (5.2)
- Neuroleptic Malignant Syndrome (5.3)
- Tardive dyskinesia (5.4)
- Hyperglycemia and diabetes mellitus (5.5)
- Hyperprolactinemia (5.6)
- Orthostatic hypotension (5.7)
- Leukopenia, Neutropenia, and Agranulocytosis: has been reported with antipsychotics, including Risperdal®. Patients with a history of a clinically significant low white blood cell count (WBC) or a drug-induced leukopenia/neutropenia should have their complete blood count (CBC) monitored frequently during the first few months of therapy and discontinuation of Risperdal® should be considered at the first sign of a clinically significant decline in WBC in the absence of other causative factors. (5.8)
- Potential for cognitive and motor impairment (5.9)
- Seizures (5.10)
- Dysphagia (5.11)
- Priapism (5.12)
- Disruption of body temperature regulation (5.13)
- Antiemetic Effect (5.14)
- Suicide (5.15)
- Increased sensitivity in patients with Parkinson’s disease or those with dementia with Lewy bodies (5.16)
- Diseases or conditions that could affect metabolism or hemodynamic responses (5.16)
“Sometimes it is appropriate and necessary to use antipsychotic medications for patients with dementia related behaviors.”
AMDA, 2011

WARNING: INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS
See full prescribing information for complete boxed warning. Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. RISPERDAL® is not approved for use in patients with dementia-related psychosis. (5.1)
Move Over Antipsychotics ...
Clostridium difficile

- 2011 US Data
- ~ 500,000 infections
- ~ 83,000 at least one reoccurrence
- ~ 29,000 deaths within 30 days of dx
- Two out of every three healthcare-associated C diff infections occur in patients aged 65 years or older
- > 80% of deaths occurred in patients aged 65 years or older
  - Source: CDC

- Informed consent?
Deficiency Data

- F 154 (1/1 → 10/31, 2015)\(^1\)
  - Nationwide: 200
  - PA: 5

\(^1\) [https://data.medicare.gov/](https://data.medicare.gov/)
PA: F 154

• “… the facility failed to informed a resident and/or responsible party of the risk of the use of anti-psychotic medications prior to administration the anti-psychotic medication for two of two residents reviewed.”

• “… that the facility failed to inform the resident that the facility altered the resident's full code status …”

• “… the facility failed to provide a resident with sufficient information to make food choices consistent with a physician prescribed therapeutic diet …”

• “… the facility failed to provide discharge instructions in a language that could be understood …”

• “… the facility failed to inform a resident and/or their responsible party of the need to perform extensive cleaning procedures in the residents' rooms …”
Informed Refusal: Medications

- F 155

- § 483.10(b)(4) - The resident has the right to refuse treatment ... and to formulate an advance directive

- Guidance:
  - If a resident (directly or through an advance directive) declines treatment (e.g., refuses artificial nutrition or IV hydration, despite having lost considerable weight), the resident may not be treated against his/her wishes
Informed Refusal: Medications

- F 155
- § 483.10(b)(4) - The resident has the right to refuse treatment ... and to formulate an advance directive

Guidance:

- A facility may not transfer or discharge a resident for refusing treatment ...
- The resident’s refusal of treatment does not absolve a facility from providing other care that allows him/her to attain or maintain his/her highest practicable physical, mental and psychosocial well-being.
“... She died suddenly in her home, at age 87, most likely of a massive heart attack. It was a painful loss for all of us. Had she taken her medicines at the appropriate doses, she might have survived the heart attack. But then maybe she would have died a slower and more painful death from some other ailment. Her biggest fear had always been ending up dependent in a nursing home, and by luck or design, she was able to avoid that. Perhaps there was some wisdom in her “noncompliance.”

Informed Refusal: Medications

- End of Life Care - The Changing Risk / Benefit Analysis
- Advanced dementia (ABTs)
- Pain / symptom management (opioid dosing)
Self Administration

- F 176
- §483.10(n) Self-Administration of Drugs
- An individual resident may self-administer drugs if the interdisciplinary team, as defined by §483.20(d)(2)(ii), has determined that this practice is safe.
Pharmacy Choice

§483.10 Resident Rights

- The resident has a right to a dignified existence, self-determination, and communication with and access to persons and services inside and outside the facility. A facility must protect and promote the rights of each resident …

- F151

- §483.10(a) Exercise of Rights

- §483.10(a)(1) The resident has the right to exercise his or her rights as a resident of the facility and as a citizen or resident of the United States.

- §483.10(a)(2) The resident has the right to be free of interference, coercion, discrimination, and reprisal from the facility in exercising his or her rights.
Pharmacy Choice

• PA regs (§ 211.9. Pharmacy services)

• “Residents shall be permitted to purchase prescribed medications from the pharmacy of their choice. If the resident does not use the pharmacy that usually services the facility, the resident is responsible for securing the medications and for assuring that applicable pharmacy regulations and facility policies are met.”

• How to operationalize this?
Med Availability - Spontaneous LOA
The Resident Driven Medication Pass

• F 242
• §483.15(b) - Self-Determination and Participation
• The resident has the right to:
  ▪ Choose activities, schedules, and health care consistent with his or her interests, assessments, and plans of care;
  ▪ Make choices about aspects of his or her life in the facility that are significant to the resident.
The Resident Driven Medication Pass

- Flexibility
- Limited institutional footprint
- Expanded home-like environment
- Evidenced based medication administration
  - Critically evaluate current “standards” (one hour before/after)
  - Expand administration window (“upon rising”)
  - Decrease dosing
  - Evaluate monitoring
  - Maintain strict times as needed (pain, Parkinson’s)
  - Plan for exceptions (impromptu LOAs)
The Resident Driven Medication Pass

- Consistent with federal regulations

- **Risks** vs. **Benefits**
Final Thoughts

- Evidenced based
- Risk / Benefit
- Resident / Surrogate involvement
Medication Management Principles

- Basic Geriatric Principles
- Unnecessary Meds F329
- Medication timing
- Creating a resident-centered program for medication management
Basic Geriatric Principles
Influencing Medication Management

- Medical conditions in geriatric patients are commonly chronic, multiple, and multifactorial

- Reversible and treatable conditions are often under-diagnosed and under-treated in geriatric patients

- Iatrogenic illnesses are common and many are preventable
  - Drug Interactions, Adverse Drug Reactions, Prescribing Cascades

- Functional ability and quality of life are critical outcomes - and sometimes critical limitations

- Geriatric care is multidisciplinary!!
Basic Geriatric Principles

Start Low, and Go Slow……

………But Go!

Unnecessary Medications - AKA F329

General.- Each resident’s drug regimen must be free from unnecessary drugs. An unnecessary drug is any drug when used:

(i) In excessive dose (including duplicate therapy); or
(ii) For excessive duration; or
(iii) Without adequate monitoring; or
(iv) Without adequate indications for its use; or
(v) In the presence of adverse consequences which indicate the dose should be reduced or discontinued; or
(vi) Any combinations of the reasons above.

Antipsychotic Drugs- Based on a comprehensive assessment of a resident, the facility must ensure that:

(i) Residents who have not used antipsychotic drugs are not given these drugs unless antipsychotic drug therapy is necessary to treat a specific condition as diagnosed and documented in the clinical record; and
(ii) Residents who use antipsychotic drugs receive gradual dose reductions, and behavioral interventions, unless clinically contraindicated, in an effort to discontinue these drugs.
F 332/F333 - Medication Errors

• **Guidance: Medication Error definition**
  - Order
  - Manufacturer’s specifications
  - Accepted professional standards and principles

• **Significance**
  - Resident Condition
  - Drug Type (Narrow Therapeutic Index)
  - Frequency of Error

“The relative significance of medication errors is a matter of professional judgment”
Resident-Centered Medpass

Critical Elements:

I. Develop Nomenclature and Definitions:
- “Upon rising” “With lunch” “At bedtime”
- Once Daily Dosing = Upon Rising or Bedtime as defined by the resident
- Twice Daily Dosing = Upon Rising and Bedtime as defined by the resident
- Three Times Daily = Upon rising, afternoon, and bedtime as defined by the resident
- With Meals = with meals as defined by resident

II. Clinical Review of Medication Regimen:
- Clinical need for continuation of medication
- Potential areas of poly-pharmacy concern
- Review of resident goals and health management history (how the resident has managed his/her medications and health in the past)
- Clinical contraindications for flexible scheduling of medications
Individualized Resident Review

Careful Clinical Review of Medication Regimens:

• Review medications administered ≥TID
• Review Residents with < 2 hours between Med-passes
• Convert to medications that have extended release formulations
• Identify medications that require:
  • Critical Timing
  • Taken with Food
  • Taken on Empty Stomach
Resident-Directed Medpass
Critical Elements

III. Exemptions:
Identify medications which are not eligible for scheduled dosing times, either in general or in specific clinical applications.

These are medications that require exact or precise timing of administration based on:
- Diagnosis type
- Treatment requirements
- Therapeutic goals
- Pharmacokinetics of the prescribed medication
- Patient risk factors

There are very few absolutes!
Examples of potentially time-critical medications:

- Antibiotics
- Anticoagulants
- Insulin
- Anticonvulsants
- Immunosuppressants
- Pain Medications (ATC)
- Bisphosphonates
- Parkinson’s Medications
- Medications Prescribed more frequently than every 4 hours
- Medications prescribed for administration within a specified period of time
- Medications that must be administered apart from other medications for optimal therapeutic effect
Medication Errors - Timing

- Ex: Proton Pump Inhibitors
  - Drug
  - Food
  - Symptom/ Type of Reflux

<table>
<thead>
<tr>
<th>Proton Pump Inhibitors</th>
<th>Take WITH FOOD</th>
<th>EMPTY STOMACH</th>
<th>Without Regard to Meals</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dexlantoprazole (Dexilant®)</td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Esomeprazole (NexIUM ®)</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lantoprazole (Prevacid ®)</td>
<td>X</td>
<td></td>
<td></td>
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<tr>
<td>Omeprazole (Prilosec ®)</td>
<td></td>
<td>X</td>
<td></td>
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<tr>
<td>Pantoprazole (Protonix ®)</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>RABEprazole (Aciphex ®)</td>
<td></td>
<td>X</td>
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</tbody>
</table>

Count a wrong time error if the medication is administered 60 minutes earlier or later than its scheduled time of administration, BUT ONLY IF THAT WRONG TIME ERROR CAN CAUSE THE RESIDENT DISCOMFORT OR JEOPARDIZE THE RESIDENT’S HEALTH AND SAFETY”[1]

Identifying Target Drugs

Develop specific facility guidelines that follow goal Med-pass times for drugs that may have problematic timing, numerous daily doses, or duplicative action.

<table>
<thead>
<tr>
<th>Drug</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>Levothyroxine</td>
<td>Calcium and Iron</td>
</tr>
<tr>
<td>Bisphosphonates</td>
<td>APAP</td>
</tr>
<tr>
<td>Warfarin</td>
<td>Cranberry Caps</td>
</tr>
<tr>
<td>Proton Pump Inhibitors</td>
<td>Natural Tears</td>
</tr>
<tr>
<td>Vitamins/Minerals</td>
<td>Senna &amp; Docusate</td>
</tr>
</tbody>
</table>

- The Clinical Team (Medical director, Prescribers, DON, NPs, nurses, Consultant RPh) can identify and propose standards for the target drugs.

- Reports can be created to identify and evaluate residents on target drugs.
Target Drugs: Clinical Aspects

- **PPIs and Empty stomach**
  - Empty stomach - omeprazole, lansoprazole, esomeprazole → move to afternoon or HS
  - Without regard to food - pantoprazole, rabeprazole, dexlansoprazole

- **Levothyroxine**
  - Package insert ‘Administered as a single daily dose, preferably one-half to one-hour before breakfast’
  - TSH stable, documentation is appropriate

- **Bisphosphonates**
  - Weekly or monthly dosing available

- **Multivitamins, Stress-tabs, Vitamin C, Ocuvite etc.**
  - Duplicate therapies - Can we condense?
  - Dietician involvement
Target Drugs: Clinical Aspects

- **Warfarin**
  - Nurse vs. medication aid administration
  - Timing: HS Med-pass?

- **Calcium, Iron**
  - Is TID necessary? (1,500mg total from all sources)
  - Dietary factors

- **Senna, Senna-S, and Colace**
  - Is TID necessary?
  - Duplications (i.e. Senna and Senna-S)
  - Efficacy of Colace

Target drugs assist with evaluation and implementation of initiatives
Medications that should be taken with Food

- Allopurinol
- Carbamazepine
- Carvedilol
- Cefuroxime
- Cimetidine
- NSAIDs
- Divalproex
- Fenofibrates
- Glyburide
- Azole Antifungals
- HIV meds
- Macrobid

- Prednisone
- Renvela
Medications that should be taken on Empty Stomach

- Alendronate
- Ibandronate
- Risedronate
- Captopril
- Ampicillin
- Metronidazole
- Mycophenolate
- Rifampin
- Sucralfate
- Tetracycline
- Sustiva
- Accolate
Now where’s that little white one?
Thank You

time for questions