“Managing Diabetes and Other Common Comorbidities in Hospice Care: 2014 and Beyond”.
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Oregon Hospice Association Conference
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Objectives
1. Identify the top 3 co-morbidities seen in hospice care.
2. Define palliative care goals for the top 3 co-morbidities and discuss the medication-therapy-management of each.
3. Discuss the need for hospice formulary management today in light of recent CMS aggression.
4. Define and discuss adverse drug reactions in the hospice patient.

Quality Use of Medicine Framework
1. Ascertain current medications
2. Identify patients at high risk of or experiencing ADE
3. Estimate life expectancy of high risk patients
4. Define overall care goals in context of life expectancy
5. Define and confirm current indications for ongoing treatment
6. Determine the time until benefit for disease modifying medications
7. Estimate the magnitude of benefit versus harm for each medication
8. Review the relative utility of each medication in use
9. Identify drugs which may be discontinued
10. Implement and monitor a drug utilization plan
Hospice MTM

Medication Therapy Management

1. Primary Hospice Diagnosis
2. Secondary Diagnosis
3. Comorbidities

Goals of Hospice MTM

• Improve efficiency and safety of medication use!
  — Hospice Clinical Pharmacist Consultation
• Decrease medication costs
• Patient & Family Education
• "Portmanteau" Medications
• Therapeutic Interchange
• Renal Dosing of Medications
• "You can’t manage what you don’t know!"
  — Medication Utilization Reporting Makes Cents!
• PBM Purchasing Model Options
  • Traditional
  • Mail Order
  • Transparent + Pass Through

Consider

• Time to Benefit
• Time to Harm
• Ask:
  Does an evidence-based consensus exist for using the drug for the indication given in its current dosing rate in this patient’s age group and disability level, and does the benefit outweighs all possible known adverse effects?
Hospice Formulary Management

➢ Hospices have the right to use a medication formulary just like other CMS reimbursed health care providers such as hospitals and Medicare Part D plans!

➢ Hospices should initiate and build a Pharmaco-Therapeutic Support System to allow for needed formulary oversight!

Pharmaco-Therapeutic Support System

3 Components:
• PDL
• Hospice Clinical Pharmacist
• Pharmacy and Therapeutics Committee

Adverse Drug Reactions

• “A reaction that is noxious and unintended, which occurs at dosages normally used in humans for prophylaxis, diagnosis, or therapy” — WHO

• Increases with polypharmacy
• Most frequent drug-related problem in nursing home residents
• Occurs in 5-33% of elderly outpatients

### ADR Predictors

<table>
<thead>
<tr>
<th>Predictors of ADRs in the Elderly</th>
</tr>
</thead>
<tbody>
<tr>
<td>Taking more than four medications*</td>
</tr>
<tr>
<td>Having more than four active medical problems</td>
</tr>
<tr>
<td>Two to four new medications added during a hospitalization</td>
</tr>
<tr>
<td>Alcohol use history</td>
</tr>
<tr>
<td>Older Age*</td>
</tr>
</tbody>
</table>

* Indicates predictors for severe ADRs.


### Preventing ADRs

<table>
<thead>
<tr>
<th>Strategies to Prevent ADRs in the Elderly</th>
</tr>
</thead>
<tbody>
<tr>
<td>Evaluate comorbidities, frailty, and cognitive function</td>
</tr>
<tr>
<td>Evaluate renal function and adjust doses</td>
</tr>
<tr>
<td>Recognize that clinical signs or symptoms can be an ADR</td>
</tr>
<tr>
<td>Adapt treatment to patient’s life expectancy</td>
</tr>
</tbody>
</table>


### ADRs in the Elderly

- Be careful when drugs that alter cognition are prescribed (antipsychotics, benzodiazepines, antiarrhythmics, opioids, etc.)
- Falls can be one of the most damaging ADRs
  - Increase mortality
  - Strong association with benzodiazepines, antidepressants, and antipsychotics

Nonadherence

- Elderly patients are at an increased risk for medication nonadherence
- Barriers to adherence
  - Lack of understanding/provider education
  - Inconvenience
  - Polypharmacy
  - Complex regimens
  - Treatment of asymptomatic conditions
  - Cost


Medication Nonadherence Factors

<table>
<thead>
<tr>
<th>Factor</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>3+ chronic conditions</td>
<td>Living alone</td>
</tr>
<tr>
<td>5+ chronic medications</td>
<td>Recent hospital discharge</td>
</tr>
<tr>
<td>Increased dosing frequency (TID or more than 12 doses/day)</td>
<td>Reliance on a caregiver</td>
</tr>
<tr>
<td>4+ medication changes in the last year</td>
<td>Low literacy level</td>
</tr>
<tr>
<td>3+ prescribers</td>
<td>Medication costs</td>
</tr>
<tr>
<td>Significant cognitive or physical impairments</td>
<td>History of medication nonadherence</td>
</tr>
</tbody>
</table>


Assessing Nonadherence

1. How do you take your medications?
2. How do you organize your medications?
3. How do you schedule your meal and medication times?
4. How do you pay for your medications?
5. How do you think the medications are working for your condition?
6. How many times in the last week/month have you missed a dose?

Improving Adherence

- Patient education
- Making dosing regimens more convenient
- Serial follow-up with patients
- Must keep in mind specific belief-related variables for each patient
  - Personal
  - Cultural


The Top 3 EOL Care Comorbidities

Metabolic Syndrome (Diabetes et al)
COPD
Heart Failure

Metabolic Syndrome

Any 3 criteria from the list below:
- Hyperglycemia
- Hypertension
- Hypertriglyceridemia
- HDL-C (Men < 40 mg/dL; Women < 50 mg/dL)
- Waist circumference > 40” (men) & > 35” (women)
EOL Care of Diabetes

Guidelines: ADA

Does diabetes contribute to terminal prognosis?

EOL Care Goal

Diabetes

Remember: The HBA1C goal is no longer 7% !

Autonomic dysfunction?
Neuropathic Pain?
Renal Function?
Vision?
Initiation of once-daily insulin therapy for type 2 diabetes mellitus
in children and adults

Oral decepeis for the Treatment of Type 2 Diabetes Mellitus

<table>
<thead>
<tr>
<th>Drug Class</th>
<th>Special Precautions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sulfonylureas (1st and 2nd generations)</td>
<td>Severe hypoglycemia, weight gain, dose adjustment in renal impairment</td>
</tr>
<tr>
<td>Short-acting insulin secretagogues</td>
<td>LFT, GGT, and ALT elevation</td>
</tr>
<tr>
<td>Biguanides</td>
<td>Unintended weight loss, lactic acidosis, hypoglycemia, elevated LFTs, dose adjustment in renal and hepatic impairment</td>
</tr>
<tr>
<td>Thiazolidinediones</td>
<td>Fluid retention, weight gain, severe hypoglycemia, dose adjustment in renal and hepatic impairment</td>
</tr>
<tr>
<td>a-Glucosidase inhibitors</td>
<td>Flatulence, diarrhea, abdominal pain, dose adjustment in renal impairment</td>
</tr>
<tr>
<td>Dipeptidyl peptidase-4 (DPP-4) inhibitors</td>
<td>Pancreatitis, dose adjustment in renal impairment</td>
</tr>
<tr>
<td>Pancreatic exocrine insufficiency</td>
<td>Severe hypoglycemia, dose adjustment in renal impairment</td>
</tr>
<tr>
<td>Alpha-glucosidase inhibitors</td>
<td>Edema, hypertension, arrhythmias, dose adjustment in renal impairment</td>
</tr>
<tr>
<td>Sodium-glucose cotransporter 2 inhibitors</td>
<td>Severe hypoglycemia, acute kidney injury, dose adjustment in renal impairment</td>
</tr>
<tr>
<td>Calcium channel blockers</td>
<td>Thoracic aortic aneurysm, dose adjustment in renal impairment</td>
</tr>
<tr>
<td>Dopamine agonists</td>
<td>Severe hypoglycemia, weight gain, dose adjustment in renal impairment</td>
</tr>
</tbody>
</table>
Injectable Agents for the Treatment of Type 2 Diabetes Mellitus

<table>
<thead>
<tr>
<th>Drug Class</th>
<th>Special Precautions</th>
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<tbody>
<tr>
<td>Rapid acting insulin</td>
<td>Hypoglycemia, hypokalemia</td>
</tr>
<tr>
<td>Short acting insulin</td>
<td>Hypoglycemia, hypokalemia</td>
</tr>
<tr>
<td>Intermediate acting insulin</td>
<td>Hypoglycemia, hypokalemia</td>
</tr>
<tr>
<td>Long acting insulin</td>
<td>Hypoglycemia, hypokalemia</td>
</tr>
<tr>
<td>GLP-1 agonists</td>
<td>In order effects, thyroid activity (Bydureon), pancreatitis, avoid use in impaired gastric motility, use not recommended in severe renal impairment</td>
</tr>
<tr>
<td>Amylinomimetics</td>
<td>Avoid use in impaired gastric motility</td>
</tr>
</tbody>
</table>

EOL Care of Hypertension

Guideline: JNC VII

Does Hypertension contribute to the terminal prognosis?

EOL Care Goal:

EOL Care of Hyperlipidemia

Guideline ATP III

Does hyperlipidemia contribute to the terminal prognosis?

EOL Care Goal
EOL Care of Hypertriglyceridemia

Guideline: ATPIII

Does hypertriglyceridemia contribute to the terminal prognosis?

EOL Care Goal:

COPD

Guideline: GOLD

Does COPD contribute to the terminal prognosis?

EOL Care Goal:

??????

Do COPD patients have the minimum required peak inspiratory flow for adequate use of metered-dose inhalers and dry-powder inhalers?
The efficacy of inhaler delivery systems are dependent upon the patients inspiratory flow rate which is compromised in patients with COPD due to diaphragmatic weakness or other physiologic changes.

The minimum required inspiratory flow rate for adequate use of MDI is 25 L/min and for DPI it is 30-60 L/min. (1,4,5,6)

If a patient’s inspiratory flow rate is below the threshold for these delivery systems, the efficacy of the medications they are receiving may be compromised which can lead to suboptimal treatment, acute exacerbations, increase in hospitalizations, and decreased quality of life.

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Global Strategy for Diagnosis, Management and Prevention of COPD

**Therapeutic Options: COPD Medications**

- Beta₂-agonists
  - Short-acting beta₂-agonists
  - Long-acting beta₂-agonists

- Anticholinergics
  - Short-acting anticholinergics
  - Long-acting anticholinergics

- Combination short-acting beta₂-agonists + anticholinergic in one inhaler

- Combination long-acting beta₂-agonists + anticholinergic in one inhaler

- Methylxanthines

- Inhaled corticosteroids

- Combination long-acting beta₂-agonists + corticosteroids in one inhaler

- Systemic corticosteroids

- Phosphodiesterase-4 inhibitors

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Global Strategy for Diagnosis, Management and Prevention of COPD

**Manage Exacerbations: Treatment Options**

- **Oxygen**: Titrate to improve the patient’s hypoxemia with a target saturation of 88-92%.

- **Bronchodilators**: Short-acting inhaled beta₂-agonists with or without short-acting anticholinergics are preferred.

- **Systemic Corticosteroids**: Shorten recovery time, improve lung function (FEV₁) and arterial hypoxemia (PaO₂), and reduce the risk of early relapse, treatment failure, and length of hospital stay. A dose of 40 mg prednisone per day for 5 days is recommended. Nebulized magnesium as an adjuvant to salbutamol treatment in the setting of acute exacerbations of COPD has no effect on FEV₁.
Antibiotics should be given to patients with:

- Three cardinal symptoms: increased dyspnea, increased sputum volume, and increased sputum purulence.
- Who require mechanical ventilation.

Heart Failure

Guideline: American Heart Association

Does heart failure contribute to the terminal prognosis?

EOL Care Goal:
CMS Guidance 18 July 2014

Effective immediately, the only medications that should require a prior authorization from a Part D plan sponsor are medications that are unrelated to the terminal diagnosis and are medications that are usually used to treat pain, nausea, constipation or anxiety.

This means what????

Who Pays for What Medications?

CMS expects that Medicare hospice providers will continue to provide all of the medications that are reasonable and necessary for the palliation and management of a beneficiary’s terminal illness and related conditions.

CMS expects that this will routinely include the drugs in the four categories highlighted by the OIG.
Per CMS: Related, Discontinued Meds

There may be some drugs that were for the treatment of the terminal illness and/or related conditions prior to the hospice election that will be discontinued upon hospice election, as it has been determined by the hospice interdisciplinary group, after discussions with the hospice patient and family, that those medications may no longer be effective in the intended treatment, and/or may be causing additional negative symptoms in the individual.

Related, Discontinued Meds (continued)

These medications would not be covered under the Medicare hospice benefit, as they would not be reasonable and necessary for the palliation of pain and/or symptom management. If a beneficiary still chooses to have these medications filled through his or her pharmacy, the costs of these medications would then become a beneficiary liability for payment and not covered by Part D. These medications would not be covered by Part D because their further coverage is prohibited under Medicare.

Per CMS: Non-Formulary Meds

If a beneficiary requests a drug for his or her terminal illness or related conditions that is not on the hospice formulary and the beneficiary refuses to try a formulary equivalent first; or the drug is determined by the hospice provider to be unreasonable or unnecessary for the palliation of pain and/or symptom management, the beneficiary may opt to assume financial responsibility for the drug. However, no payment for the drug will be available under Part D.
Per CMS
Hospice providers should note that there are drugs that are statutorily excluded from the Part D benefit, including drugs for the symptomatic relief of cough and cold, most prescription vitamins, and nonprescription (i.e., OTC) drugs.

Per CMS
Hospice providers are encouraged to report a beneficiary’s Medicare hospice election to the Part D sponsor and identify any drugs in the four categories determined to be coverable under Part D because the drugs are unrelated to the terminal illness and/or related conditions prior to the submission of a claim. This communication, however, is not a coverage determination or PA request. Rather, the information provided by the hospice can be used by the sponsor to override the beneficiary-level hospice PA at point-of-sale (POS).

Communicate to Part D
Medication information obtained through the assessments, including whether the medications are related or unrelated to the terminal illness and related conditions, should be provided to the Part D sponsor proactively—meaning before a hospice beneficiary presents a prescription for fill—or, failing proactive provision of the information by the hospice, should be provided to the Part D sponsor, after the Part D sponsor contacts the hospice provider during the PA process.
Remember

Hospices are expected to maintain a record of the clinical basis for the statement that the drug is unrelated and provide it upon request.

Provide it to who?

References

- CMS Memorandum 7-18-14; Part D Payment for Drugs for Beneficiaries Enrolled in Medicare Hospice.
- Lee JK, Grace KA, Taylor AJ. Effect of a pharmacy care program on medication adherence and persistence, blood pressure, and low-density lipoprotein cholesterol in a randomized controlled trial. JAMA. 2006;296:2563-2571.
- Guidelines: ADA 2014, JNC VIII, AHA 2013

Questions?

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