Drug Management in Assisted Living Facilities: Dementia, Psychotropics and FAQs

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Focus 2016

Objectives

- Participant will understand current concerns with the overuse of psychotropic medications, especially antipsychotics for behavior management in residents with dementia
- Participant will be able to identify current situations of inappropriate use of psychotropic medications

Objectives

- Participant will be able to identify appropriate techniques to reduce or eliminate inappropriate use of psychotropic medications for dementia behaviors
- Participant will be able to identify FAQs and be able to ask some of their own
Antipsychotics “101”

- Antipsychotics are a group of medications commonly but not exclusively used to treat psychosis
- Antipsychotics work on a variety of chemical and neurotransmitters in brain, but primarily work to decrease dopamine

Antipsychotics “101”

- Conditions for which antipsychotics might be used and are officially indicated to treat include:
  - Schizophrenia
  - Bipolar disorder, including acute mania and depressive symptoms
  - Irritability associated with Autistic Disorder
  - Adjunctive therapy for major depressive disorder

Regulation: DHS 83.02(41)

(41) “Psychotropic medication” means a prescription drug, as given in s. 450.01 (20), Stats., that is used to treat or manage a psychiatric symptom or challenging behavior
Psychotropic vs. Antipsychotic

An antipsychotic medication is a subset of psychotropic medications
- All antipsychotic medications are psychotropic, but not all psychotropic medications are antipsychotics

Psychotropics

- Antipsychotics
- Antidepressants
- Anxiolytics
- Anticonvulsants
- Cognitives; Blood pressure

Regulation: DHS 83.37(1)(h)1&2

- Scheduled Psychotropic medications
  - Quarterly review
  - Desired response and side-effects
  - Documented in resident record
  - Care staff must understand the potential benefits and side-effects
Psychotropic Concerns

- Individuals at greater risk for inappropriate use of psychotropic drugs
- Barriers in communicating symptoms (behaviors) confuse healthcare providers possibly leading to incorrect diagnoses
What is a Black Box?

- FDA alert regarding high risks associated with a drug
- Black Box warnings emphasize significant and serious safety data regarding prescription drugs
- Warnings may include: potential adverse effects, drug interactions, dosing information, monitoring and administration requirements, and at-risk populations

Black Box Warning Antipsychotics

- Increased Mortality in Elderly Patients with Dementia Related Psychosis
  "Elderly patients with dementia-related psychosis treated with atypical antipsychotic drugs are at an increased risk of death compared to placebo. Analyses of seventeen placebo controlled trials (modal duration of 10 weeks) in these patients revealed a risk of death in the drug-treated patients of between 1.6 to 1.7 times that seen in placebo treated patients. Over the course of a typical 10-week controlled trial, the rate of death in drug-treated patients was about 4.5% compared to a rate of about 2.6% in the placebo group. Although the causes of death were varied, most of the deaths appeared to be either cardiovascular (e.g., heart failure, sudden death) or infectious (e.g., pneumonia) in nature. This drug is not approved for the treatment of patients with dementia-related psychosis (See WARNINGS in package insert)."

Black Box on the Billboard
Focus 2012 - Dr. David Gifford

Antipsychotic use in dementia scenario

- Assisted Living Facility is successfully sued for administering an antipsychotic medication to a resident with dementia who suffers a stroke. The ALF contracted with pharmacy to start a program that recommends QQR to physicians and families. Families, Physicians and Nursing staff are very concerned that residents will have a "relapse" of their behavior. The facility documentation for informing families of the risks and -why a QQR is not possible increases dramatically but the rate of antipsychotic use remains unchanged.

Perspective on Psychotropics

- Use for mental illness: Valid
- Use for behaviors related to dementia: Not supported in literature and ineffective

Dr. Gifford-Focus 2012

#1 Challenge: Changing attitudes

- Most families and healthcare providers believe these medications are effective to treat “problem behaviors”
- Behaviors are believed to be a symptom of dementia
-Most behaviors are either normal for a person with cognitive impairment or are modes of communicating an unmet need
- Use of antipsychotics in dementia are mainly a problem in nursing homes
Dr. Gifford: Focus 2012

Effectiveness in Dementia is weak
Meta-Analysis (JAMA 2011)
- Cholinesterase, Receptor and Antidepressant had a small but statistically significant effect (12-20% get better) when compared to placebo
- Quetiapine did not have a statistically significant effect
- Antipsychotic led to an average change/difference on the Neuropsychiatric Inventory (NPI) of
- 35% from a patient's baseline
- 3.41 point difference from placebo group
- 30% change and 4.0 difference is the minimum threshold needed for a clinically meaningful result

Source: JAMA 2011; 305:1399-1407 2011; www.neurology.20 RC/ in dementias

Dr. Gifford: Focus 2012

Effectiveness with Low Dose
Meta-Analysis (Cochrane 2012)
- Low dose Risperidone < 1 mg/d has small positive effective but also has increase risk of adverse events
- Low dose Clozapine (5 mg/d) has no positive effect but does have increase risk of adverse events
- Low dose Aripiprazole and Quetiapine effectiveness are unknown but Quetiapine at normal dose is ineffective

Source: Cochrane Review 2012: Meta-analysis 19 RC/ in dementia

Dr. Gifford: Focus 2012

Evidence based for discontinuing meds at low dose
- RCTs comparing withdrawal of medication to continuing antipsychotics show
- No significant difference in outcomes between placebo group and continued medication group
- Individuals with psychoses (hallucinations & delusions) are more likely to "relapse" and need the medication restarted
- Most individuals with dementia do not have hallucinations or delusions as the reason for their antipsychotic prescriptions
Why Do We Have Behaviors?

- Residents take medications associated with psychotic symptoms
- Residents are at risk for medical disorders commonly associated with psychosis
- Residents are subjected to significant environmental changes

What Are Behaviors?

- Communication
- Medical issue
- Need

Differential Diagnosis

- Medical/Organic Causes
  - Medications
  - Hypo/hyperglycemia
  - Hypo/hyperthyroidism
  - Cushing’s disease
  - Parkinson’s disease
  - Vitamin B/Folate deficiency
  - Infections (UTI)
Differential Diagnosis

- Medical/Organic Causes
  - Electrolyte imbalance
  - AIDS
  - Sleep deprivation
  - Pain
  - CNS lesions
  - Steroid use
  - Alcohol use

- Mental Illness
  - Depression
  - Anxiety
  - Schizophrenia
  - Bipolar disorder
  - Schizoaffective Disorder
  - Delirium
  - Tourette’s
  - Huntington’s

- Dementia
  - Alzheimer’s
  - Lewy body
  - Vascular
  - Frontal lobe
Matching Treatment (TX) to Diagnosis (DX)
- If the cause of behavior/delusion etc. is a drug side-effect then get rid of the offending drug
- If the cause of behaviors is hyperthyroidism treat hyperthyroidism

Matching TX to DX
- If the cause of the behavior is pain - treat pain
- If the cause of the behavior is due to the resident being hot or cold - then adjust the temperature

Valid Use
- Psychiatric illness
- Medical condition
- Behavioral interference on necessary function
**Valid Use**

- Sedation for procedures
- Withdrawal treatment

**Invalid Use**

- Substitute medication use vs. behavioral support
- PRN use without parameters
- Caregiver convenience

**Invalid Use**

- Lack of assessment
- No re-evaluation
- Not getting to root cause
Behavior Management

A medication for behavior management may be necessary, if:
- Other causes are ruled out
- Behavior is persistent
- Behavior is causing harm, and
- Non-pharmacological approaches have been tried and have failed

Non-pharmacological Interventions

- Music and Memory
  - [http://musicandmemory.org/](http://musicandmemory.org/)
- Validation therapy
- Reminiscence therapy

Non-Pharm Interventions

- Light therapy
- Activities
- Aromatherapy
- Snoezelen
**Indications**

- Is there rationale for use?
- Is there rationale to continue?
- Have there been other treatments provided?

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**Psychotropic Medication Use**

- Baseline data
- Plan
- Collect outcome data
- Match data to plan
- If it’s not working, modify it
- Make sure expectations are known

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**Monitoring of the Psychotropic Medications**

- With many medications it is uncertain how they work…but they do
- For many medications no lab is available to check if it is working
- Monitoring often is subjective
- Response may not be complete: partial response…do you add on?
Monitoring of the Psychotropic Medications

- Monitoring for effectiveness: Behavior monitoring sheets
- Moving beyond the behavior monitoring sheet:
  - Is indication clearly identified?
  - Are goals clearly identified?
  - Are the goals measurable?
  - Is the facility collecting that measurable data?
  - Is it consistent with what you are seeing?

Monitoring of the Psychotropic

- Do you know what the medication is for and can you determine that it is working or causing more problems?

Regulation: DHS 83.37(1)(h)1&2

- Scheduled Psychotropic medications
  - Quarterly review
  - Desired response and side-effects
  - Documented in resident record
  - Care staff must understand the potential benefits and side-effects
Regulation

- Must look at desired responses
  - There is documentation somewhere that shows what the desired response is expected to be - Treatment Goal
    Example: less crying with Paxil for depression
  - There must be documentation that shows they are monitoring desired effects
    Example: behavior monitoring sheet showing amounts of crying behavior

Regulation

- Must look at possible side-effects
  - Staff must understand the potential common side-effects
  - There must be means to monitor and document side-effects

Proof

- Documentation that indicates the goals of treatment
- Documentation/interviews that support staff know potential side-effects
- Facility has a process for documenting side-effects and goals
Proof

- Documentation that physician or pharmacist or registered nurse has reviewed the medications
  - Key point...were these individuals provided the data that they need to complete the review. (documentation of side-effects and outcomes)

What are the Requirements for PRN Psychotropics?

PRN Psychotropic

- The resident's individual service plan (ISP) shall include the rationale for use and a detailed description of the behaviors which indicate the need for administration of PRN psychotropic medication

- The administrator or qualified designee shall monitor at least monthly for the inappropriate use of PRN psychotropic medication, including but not limited to, use contrary to the ISP, presence of significant adverse side effects, use for discipline or staff convenience, or contrary to the intended use
PRN Psychotropic

- Documentation in the resident’s record shall include the rationale for use, description of behaviors requiring the PRN psychotropic medication, the effectiveness of the medication, the presence of any side-effects, and monitoring for inappropriate use for each PRN psychotropic medication given.

FAQs

- Can a CBRF have a contingency supply?
- Can the CBRF go to the connected nursing home and use their contingency supply?
- What can go in a contingency supply?
- What about Over-the-Counter (OTC)?
**OTC Contingency**

- For a facility to have OTC contingency supplies of medications, they must do the following per 83.37(1):
  - Have a written order for the OTC medication
  - Keep OTC medications in manufacturer container
  - Place each resident’s name on the label

**Medication Storage**

- Security
  - Access
  - Reconciliation
  - Safety

**Medication Administration**

- Injections - Vaginal, Rectal, Stomal, Enteral, Nebulizers
  - CBRF staff must be delegated by RN or must be self-administered
Medication Administration

- Can the staff take medication out of the pharmacy bottle and put the medications in a medicine reminder box?

Medication Administration

- Can staff give insulin?
- Can staff give Intramuscular (IM) medications B12 or EpiPen shots?
- Can staff administer medications via G-tube, and what are the guidelines?
- Can a CBRF RN delegate IM medications?

Timely Services

- Medication non-availability
  - Manufacturer shortage
  - Insurance formulary change
  - Resident money
  - Weather
  - Prior authorizations
Timely Services Interventions

- Determine if short or long-term
- Determine impact on resident
- Determine if there are alternatives
- Discuss with pharmacist and physician

Medication Diversion

- Controlled substance
- Misappropriation
- Abuse/Neglect

Medication Destruction

- Security
- Accountability
- Environmental
- Resident awareness
Drug Disposal

- Regular
- Hazardous
- Controlled substance
  - Diversion

Medication Destruction Resources

- Dose of Reality Campaign
  - http://doseofrealitywi.gov/
- DNR Resources

Questions

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