

Dr. Bill Arcurie

Director of Consulting Services
Trinity Pharmacy Services
3910 Adler Place Suite 210
Bethlehem Pa, 18017
Office Phone: 484 - 860 - 3130
Cell Phone: 570 - 815 - 7086

Newsletter – 12th edition



Please note the information contained in this emailed is privileged and is protected under HIPAA's privacy rule. It is intended only for the use of the individuals or entities named in this email and others who have been specifically authorized to receive it. If you are not the intended recipient, you are hereby notified that any distribution, dissemination, or copying of this communication is strictly prohibited.

Tramadol Linked to Hospitalization for Hypoglycemia

A new report has linked tramadol use with an increased risk of serious hypoglycemia. Researchers conducted a population-based (UK) observational study of patients receiving new tramadol or codeine prescriptions for non-cancer pain. The study included about 28,000 new users of tramadol and 306,000 new users of codeine, with an average follow-up of 5 years. Compared with codeine, tramadol was linked with a 52% increased risk of hospitalization for hypoglycemia. The risk was particularly elevated during the first 30 days of use. The mechanism for tramadol-induced hypoglycemia is thought to involve the drug's effects on serotonin pathways as well as opioid receptors.

Whether tramadol should be avoided in patients who take hypoglycemic drugs is unclear. However, healthcare providers should be aware of this rare (approximately 0.07% per year) but potentially life-threatening complication.

REFERENCE:

1. Fournier JP, et al. JAMA Intern Med. Published online December 8, 2014
2. www.rxconsultant.com

Who has Pain Symptoms, is being treated for Pain or who has the Potential for Pain Symptoms Related to Conditions or Treatments.

Recognition and Management of Pain

1. In order to help a resident attain or maintain his or her highest practicable level of well-being and to prevent or manage pain, the facility, to the extent possible:

- a. Recognizes when the resident is experiencing pain and identifies circumstances when pain can be anticipated
- b. Evaluates the existing pain and the cause(s)
- c. Manages or prevents pain, consistent with the comprehensive assessment and plan of care, current clinical standards of practice, and the resident's goals and preferences.
- d. Identify an Adverse drug reaction (ADR): a form of adverse consequences. It may be either a secondary effect of a medication that is usually undesirable and different from the therapeutic effect of the medication or any response to a medication that is noxious and unintended and occurs in doses for prophylaxis, diagnosis, or treatment.
- e. The term "side effect" is often used interchangeably with ADR; however, side effects are but one of five ADR categories, the others being hypersensitivity, idiosyncratic response, toxic reactions, and adverse medication interactions. A side effect is an expected, well-known reaction that occurs with a predictable frequency and may or may not constitute an adverse consequence.
- f. Pain is an unpleasant sensory and emotional experience that can be acute, recurrent or persistent. Persistent Pain or Chronic Pain refers to a pain state that continues for a prolonged period of time or recurs more than intermittently for months or years.

Overview of Pain Recognition and Management

1. Have an effective pain recognition and management plan: It requires an ongoing facility-wide commitment to resident comfort, to identifying and addressing barriers to managing pain, and to addressing any misconceptions that residents, families, and staff may have about managing pain.
2. The resident's needs and goals as well as the etiology, type, and severity of pain are relevant to developing a plan for pain management. It should be noted that while analgesics can reduce pain and enhance the quality of life, they do not necessarily address the underlying cause of pain. It is important to consider treating the underlying cause, where possible. Addressing underlying causes may permit pain management with fewer analgesics, lower doses, or medications with a lower risk of serious adverse consequences.
3. Those who cannot report pain may present with nonspecific signs such as grimacing, increases in confusion or restlessness or other distressed behavior. Effective pain management may decrease distressed behaviors that are related to pain. However, these nonspecific signs and symptoms may reflect other clinically significant conditions (e.g., delirium, depression, or medication-related adverse consequences) instead of, or in addition to, pain. To distinguish these various causes of similar signs

and symptoms, and in order to manage pain effectively, it is important to evaluate (e.g., touch, look at, move) the resident in detail, to confirm that the signs and symptoms are due to pain.

Care Process for Pain Management

Processes for the prevention and management of pain include:

1. Assessing the potential for pain, recognizing the onset or presence of pain, and assessing the pain
2. Addressing/treating the underlying causes of the pain, to the extent possible
3. Developing and implementing interventions/approaches to pain management, depending on factors such as whether the pain is episodic, continuous, or both
4. Identifying and using specific strategies for different levels or sources of pain or pain-related symptoms, including
 - a. Identifying interventions to address the pain based on the resident-specific assessment, a pertinent clinical rationale, and the resident's goals
 - b. Trying to prevent or minimize anticipated pain
 - c. Considering non-pharmacological and CAM ("Complementary and Alternative Medicine") interventions
 - d. Using pain medications judiciously to balance the resident's desired level of pain relief with the avoidance of unacceptable adverse consequences
 - e. Monitoring appropriately for effectiveness and/or adverse consequences (e.g., constipation, sedation) including defining how and when to monitor the resident's symptoms and degree of pain relief
 - f. Modifying the approaches, as necessary.

Pain Recognition:

1. A resident may avoid the use of the term "pain." Other words used to report or describe pain may differ by culture, language and/or region of the country. But may use descriptions that may include heaviness or pressure, stabbing, throbbing, hurting, aching, gnawing, cramping, burning, numbness, tingling, shooting or radiating, spasms, soreness, tenderness, discomfort, pins and needles, feeling "rough," tearing or ripping. Verbal descriptions of pain can help a practitioner identify the source, nature, and other characteristics of the pain.
2. Nonverbal indicators which may represent pain need to be viewed in the entire clinical context with consideration given to pain as well as other clinically pertinent explanations. Examples of possible indicators of pain may include, but are not limited to the following:
 - a. Negative verbalizations and vocalizations (e.g., groaning, crying/whimpering, or screaming)
 - b. Facial expressions (e.g., grimacing, frowning, fright, or clenching of the jaw); Changes in gait (e.g., limping), skin color, vital signs (e.g., increased heart rate, respirations and/or blood pressure), perspiration
 - c. Behavior such as resisting care, distressed pacing, irritability, depressed mood, or decreased participation in usual physical and/or social activities

- d. Loss of function or inability to perform Activities of Daily Living (ADLs), rubbing a specific location of the body, or guarding a limb or other body parts
 - e. Difficulty eating or loss of appetite;
 - f. Difficulty sleeping (insomnia).
3. Sleep cycle, change in mood, decline in function, unstable condition, weight loss, and skin conditions can be potential indicators of pain. Any of these findings may indicate the need for additional and more thorough evaluation.
 4. Many medical conditions may be painful such as pressure ulcers, diabetes with neuropathic pain, immobility, amputation, post- CVA, venous and arterial ulcers, multiple sclerosis, oral health conditions, and infections.
 5. Moving a resident or performing physical or occupational therapies or changing a wound dressing may be painful. Understanding the underlying causes of pain is an important step in determining optimal approaches to prevent, minimize, or manage pain.
 6. Observations at rest and during movement, particularly during activities that may increase pain (such as dressing changes, exercises, turning and positioning, bathing, rising from a chair, walking) can help to identify whether the resident is having pain.
 7. Nursing assistants may be the first to notice a resident's symptoms; therefore, it is important that they are able to recognize a change in the resident and the resident's functioning and to report the changes to a nurse for follow-up.
 8. Other staff, e.g., Nursing assistants, dietary, activities, therapy, housekeeping, who have direct contact with the resident may also report changes in resident behavior or resident complaints of pain.

Management of Pain

The interdisciplinary team and the resident collaborate to arrive at pertinent, realistic and measurable goals for treatment, such as reducing pain sufficiently to allow the resident to ambulate comfortably to the dining room for each meal or to participate in 30 minutes of physical therapy. Depending on the situation and the resident's wishes, the target may be to reduce the pain level, but not necessarily to become pain-free.

The basis for effective interventions includes several considerations, such as the resident's needs and goals; the source(s), type and severity of pain (recognizing that the resident may experience pain from one or more sources either simultaneously or at different times) and awareness of the available treatment options.

Non-pharmacological interventions:

Non-pharmacologic interventions may help manage pain effectively when used either independently or in conjunction with pharmacologic agents.

Examples of non-pharmacologic approaches may include, but are not limited to:

1. Altering the environment for comfort (such as adjusting room temperature, tightening and smoothing linens, using pressure redistributing mattress and positioning, comfortable seating, and assistive devices)
2. Physical modalities, such as ice packs or cold compresses (to reduce swelling and lessen sensation), mild heat (to decrease joint stiffness and increase blood flow to an area), neutral body alignment and repositioning, baths, transcutaneous electrical nerve

- stimulation (TENS), massage, acupuncture/acupressure, chiropractic, or rehabilitation therapy
3. Exercises to address stiffness and prevent contractures
 4. Cognitive/Behavioral interventions (e.g., relaxation techniques, reminiscing, diversions, activities, music therapy, coping techniques and education about pain).
 5. The list of Complementary and Alternative Medicine (CAM) options is evolving, as those therapies that are proven safe and effective are used more widely. Because CAM can include herbal supplements, some of which potentially can interact with prescribed medications, it is important that any such agents are recorded in the resident's chart for evaluation by the physician and consultant pharmacist.

Pharmacological interventions:

The interdisciplinary team (nurses, practitioner, pharmacists, etc.) is responsible for developing a pain management regimen that is specific to each resident who has pain or who has the potential for pain, such as during a treatment.

The regimen considers factors such as the causes, location, and severity of the pain, the potential benefits, risks and adverse consequences of medications; and the resident's desired level of relief and tolerance for adverse consequences.

The resident may accept partial pain relief in order to experience fewer significant adverse consequences (e.g., desire to stay alert instead of experiencing drowsiness/confusion).

It is important to follow a systematic approach for selecting medications and doses to treat pain. Developing an effective pain management regimen may require repeated attempts to identify the right interventions. General guidelines for choosing appropriate categories of medications in various situations are widely available.

Analgesics may help manage pain; however, they often do not address the underlying cause of pain.

Examples of different approaches for administering pain medications may include, but are not limited to:

1. Administering lower doses of medication initially and titrating the dose slowly upward
2. Administering medications "around the clock" rather than "on demand" (PRN)
3. Combining longer acting medications with PRN medications for breakthrough pain.

Recurrent use of or repeated requests for PRN medications may indicate the need to reevaluate the situation, including the current medication regimen. Some clinical conditions or situations may require using several analgesics and/or adjuvant medications (e.g., antidepressants or anticonvulsants) together. Documentation helps to clarify the rationale for a treatment regimen and to acknowledge associated risks.

Monitoring, Reassessment, and Care Plan Revision:

Monitoring the resident over time helps identify the extent to which pain is controlled, relative to the individual's goals and the availability of effective treatment.

Adverse consequences related to analgesics can often be anticipated and to some extent prevented or reduced. For example, opioids routinely cause constipation, which may be minimized by an appropriate bowel regimen.

If pain has not been adequately controlled, it may be necessary to reconsider the current approaches and revise or supplement them as indicated.

If pain has resolved or there is no longer an indication or need for pain medication, the facility works with the practitioner to discontinue or taper (as needed to prevent withdrawal symptoms) analgesics.

Criteria for Compliance with F309 for a Resident with Pain or the Potential for Pain:

For a resident with pain or the potential for pain (such as pain related to treatments), the facility is in compliance with F309 Quality of Care as it relates to the recognition and management of pain, if each resident has received and the facility has provided the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the comprehensive assessment and plan of care

Example: The facility:

1. Screened residents on admission
2. Recognized and evaluated the resident who experienced pain to determine (*to the extent possible*) causes and characteristics of the pain, as well as factors influencing the pain
3. Developed and implemented interventions for pain management for a resident experiencing pain, consistent with the resident's goals, risks, and current standards of practice; or has provided a clinically pertinent rationale why they did not do so
4. Recognized and provided measures to minimize or prevent pain for situations where pain could be anticipated
5. Monitored the effects of interventions and modified the approaches as indicated
6. Communicated with the health care practitioner when a resident was having pain that was not adequately managed or was having a suspected or confirmed adverse consequence related to the treatment.
7. Revised the approaches as appropriate or verified their continued relevance.
8. Pharmacy services (*were medications and treatments required to manage a resident's pain were available and administered as indicated and ordered at admission and throughout the stay*).
9. Did the facility comprehensively assess the resident's physical, mental, and psychosocial needs to determine underlying causes of the resident's pain?

Some Pain Scales for Residents that are Non Cogitative

1. **Faces** pain scale;
2. **Pain Assessment Checklist for Seniors with Limited Ability to Communicate (PACSLAC)**,
3. **Doloplus 2 Scale**, and
4. **PAINAD** (*from American Academy of Hospice and Palliative Medicine*). Review the MDS for the pain indicators *as well*

Reference: CMS Regulations

Insomnia

By: Maria J. Minielly, PharmD and CGP
Consultant Pharmacist for Trinity Pharmacy

Insomnia can be classified as having trouble falling asleep (sleep onset/latency) or having trouble staying asleep (sleep maintenance). Individuals that suffer from insomnia may not feel rested by a night's sleep, poor sleep quality.

It can be a short-term problem due to a physical or emotional stressor or it can be a chronic problem due to some other underlying cause such as depression, anxiety, pain, sleep apnea, restless leg syndrome or poor sleep habits. Chronic insomnia is defined as insomnia occurring nightly for more than six months.

We can overlook some common every day culprits such as caffeine, alcohol, nicotine and daytime napping. Using our beloved electronic devices such as iPads and smartphones right before bed can also cause alterations to our sleep cycles.

Certain medications can cause insomnia; the most common classes of these medications are stimulants, corticosteroids, allergy medications, antihypertensive and antidepressants. It is important to remember that over the counter products such as weight loss supplements, cough and cold preparations and analgesics may contain ingredients such as caffeine that can also increase the risk of insomnia.

Insomnia becomes more common with age making residents in the long term care setting more vulnerable. The elderly not only experience changes in health and physical activity, but changes in their "internal clocks." As one ages, his or her "internal clock" advances, causing the early to bed, early to rise phenomenon. But the elderly need just as much sleep as the young.

It is important to look at all these potential causes before starting a medication, especially in the long term care setting. Most of the agents to treat insomnia can be found on the Beer's List and are considered high risk per CMS Quality Measure and Star Ratings Measure.

Without question, first line therapy is non drug, lifestyle modifications or behavior therapy; this can include sleep restriction, stimulus control, sleep hygiene, cognitive therapy and relaxations training. Sleep restriction limits the amount of time spent in bed to the actual number of hours spent sleeping. Contrary to that is stimulus control which limits the amount of time spent awake in bed. This will hopefully help one re-associate his or herself with the bed and bedroom being only used for sleep.

Sleep hygiene generally isn't used alone to help treat insomnia and can be combined with sleep restriction and stimulus control. Sleep hygiene looks at environmental factors such as light and temperature, food, alcohol and caffeine consumption, napping and exercise. Making adjustments to known non-hygienic factors can greatly reduce the likeness of insomnia.

Cognitive therapy examines a person's beliefs and attitudes about sleep and looks to alter any false or unrealistic expectations about his or her sleeping patterns. Often times these unrealistic expectations can cause an increase in stress or anxiety which can increase the risk of insomnia. Thus, a vicious cycle is created; so cognitive therapy helps on break this cycle.

Much of the research out there shows that relaxation is essential for not only initiating but maintaining sleep. Some common relaxation techniques include deep breathing, muscle relaxation, visualization and guided imagery. These techniques can not only be practiced before bedtime, but throughout the day and during the night should one awaken.

Treating an underlying chronic condition can also help eliminate insomnia and the need for a hypnotic:

1. Keep the resident busy during the day and not just put them in the hall way and expect them to stay awake (make sure activities are involved along with social workers to help).
2. If the resident wants to sleep during the day, don't assume that they need a medication to help sleep at night (i.e. check their past history, did they work the late shift, did they stay up at night to watch television, did they read late into the night, etc.)
3. A good Sleep Hygiene program (combining what the resident did in the past to get ready for bed), should always be part of the care plan and changed to fit the needs or change in condition of the resident.
4. However, when nothing else work or any of the above are ineffective, choosing the appropriate drug therapy is key. In general, the side effect profile for hypnotics is greater in the geriatric population:
 - a. So it is important to start at the lowest effective dose,
 - b. Assess for effectiveness
 - c. Side effects and
 - d. Then reassess the need for the hypnotic therapy, whether it be on a routine or PRN basis.
 - e. The majority of treatment options are not recommended for use greater than 7 to 10 days on a routine basis; according to the CMS regulations.

The following is a comparison of the treatment options for insomnia.

Nonprescription (OTCs):

Diphenhydramine (Benadryl, Nytol, Sominex, etc.) – Should avoid use in the elderly; because Anticholinergic side effects, Poor efficacy data, often contain a pain reliever (APAP, IBU), and increased risk of tolerance.

Doxylamine – Should avoid use in the elderly; because potent anticholinergic, poor efficacy data, and High risk of tolerance

Antidepressants:

Doxepin (Silenor) 3mg – Better choice if this medication is needed to be used. Improves sleep maintenance, but may still have Anticholinergic side effects, not to be taken w/in 3 hours of a meal. At **doses of 10mg or higher** it is an Off-label use with a Narrow therapeutic window, Dose-dependent CV and anticholinergic ADRs.

Trazodone – Should start at the lowest possible effective dose. Still an off-label use of the medication, Low anticholinergic ADRS, but Limited efficacy data

Benzodiazepines: Should not be used for more than seven days on a routine basis; according to the CMS regulations, and they have to be evaluated every quarter, to very effectiveness and need for continued use.

Lorazepam (Ativan) – Should start at the lowest possible effective dose. Off-label use for secondary insomnia due to anxiety/stress, may improve sleep maintenance, not sleep onset and there is an increased risk of impaired cognition, falls with use.

Oxazepam (Serax) – Should start at the lowest possible effective dose. Off-label use: may be effective for sleep onset

Temazepam (Restoril) – Should start at the lowest possible effective dose. Short-term treatment only, improves sleep onset and maintenance, it is a better **Benzodiazepine** option in elderly when dosed appropriately.

Non-Benzodiazepine Hypnotics:

Eszopiclone (Lunesta) – Should start at the lowest possible effective dose. Improves sleep onset and maintenance, avoid chronic use, not to be taken with or immediately after a meal = delayed onset

Ramelteon (Rozerem) – Improves sleep onset, not limited to short-term use, not a controlled substance, Duration 8 hours. Not to be taken with or immediately after a meal = delayed onset

Zolpidem/Zolpidem ER (Ambien/Ambien CR) – Should not exceed 5mg/day or 6.25mg CR/day. Improves sleep onset, Lower risk of dependence compared with benzodiazepines. Should not to be taken with or immediately after a meal = delayed onset.

Zaleplon (Sonata) – **Should** not exceed 5mg/ day. Improves sleep onset, has a lower risk of dependence than benzodiazepines. Should not to be taken with or immediately after meal = delayed onset

References: Pharmacist Letter, Lexi Comp, Mayo Clinic, Neurotherapeutics (2012) 9:717-727

Considerations in Insulin Therapy

By: Tom Corwin

Consultant Pharmacist for Trinity Pharmacy

Insulin therapy is a part of many residents complex medication regimen. The storage and management of this portion of the medication regimen is important to ensure maximum desired effectiveness and minimize adverse medication events.

The attached chart contains some important information for most common insulins. Storage requirements between insulins vary between different products and distribution devices (vials vs pens).

Suggestions regarding Insulin storage guidelines:

1. Unopened insulin vials/preloaded pens should be stored in the main body of the fridge at 35.6 to 46.4 degrees F (2 to 8 degrees C). If stored in this way the insulin remains useable up until its expiry date
2. Insulin in use should be stored at room temperature. Stored in this way, the insulin remains stable and useable for 28 days or longer (see chart)
3. Partly used insulin pens should never be returned to the fridge to be reused. They should be discarded appropriately.
4. **Note** - Write date of expiration on vials i.e. 28 days from the day you remove from the fridge

The decision regarding insulin choice should be based on individual patient response, insurance coverage and response to ongoing monitoring and testing to maximize results through dose adjustment.

The administration of short acting and rapid acting insulins can cause a hypoglycemic episode if food is not administered immediately after administration unless it is being used to address an elevated blood glucose level.

In most cases patients are maintained on a long acting basal insulin such as Lantus or Levemir. During adjustment periods sliding scale insulin administration is helpful in determining and adjusting basal insulin dose; but long term use of sliding scale insulin dosing in most cases can cause an increase in the prevalence of hypoglycemic events.

The chart below contains information regarding the onset, peak and duration of many insulin products so you can relate signs and symptoms of hypoglycemic events to the last administered dose of insulin. It can also be used to evaluate and track trends with blood sugar readings.

Economics of insulin therapy and monitoring:

A rule of thumb would be that if a patient is using less than 30 units per day of any insulin, then it would be more economical to consider administration with an insulin pen. Even though pens cost more there is less waste when you consider the storage requirements and the fact you have to discard the remainder of the unused vial after 28 days.

The negative outcome of long term insulin admin is also associated with a higher incidence of hypoglycemic events. Determination for deciding the need to use ongoing sliding scale insulin can be made by evaluating HgA1C.

Short Acting				
Insulin	Onset	Peak	Duration	Storage at room temp

Humulin R (vial)	30-60 Min	2-4 Hrs	5-8 Hrs	28 Days
Novolin R (vial)	30 Min	2.5-5 hrs	8 hrs	42 days below 77 degrees

Rapid Acting				
---------------------	--	--	--	--

Apidra Vial	15-30 Min	0.5-2.5Hr	5 hrs	up to 28 days
Apidra solostar (Pen)	15-30 Min	0.5-2.5Hr	5 hrs	up to 28 days
Humalog (vial)	15-30 Min	0.5-2.5Hr	5 hrs	up to 28 days
Humalog (pen)	15-30 Min	0.5-2.5Hr	5 hrs	up to 28 days
Novolog (vial)	10-20 min	1-3 hrs	3-5 hrs	up to 28 days
Novolog (Pen)	10-20 min	1-3 hrs	3-5 hrs	up to 28 days

Intermediate acting				
----------------------------	--	--	--	--

Humalog 70/30 vial	15-30 Min	0.5-2.5Hr	up to 24 hrs	up to 28 days
Humalog (pen)	15-30 Min	0.5-2.5Hr	up to 24 hrs	up to 10 days
Novolog 70/30 (vial)	10-20 min	2.4 Hrs.	up to 24 hrs	up to 28 days
Novolog (70/30) (pen)	10-20 min	2.4 Hrs.	up to 24 hrs	up to 14 days
Humulin N (vial)	1-2 hrs	2-8 hrs	14-24 hrs	up to 28 days
Humulin N (vial)	1-2 hrs	2-8 hrs	14-24 hrs	up to 14 hrs
Novolin N (vial)	1.8 hrs	4-12 hrs	24 hrs	up to 42 hrs

Long acting				
--------------------	--	--	--	--

Lantus (vial)	1.5 hrs	NONE	24 hrs	up to 28 days
Lantus solostar (pens)	1.5 hrs	NONE	24 hrs	up to 28 days/pen
Levemir (vial)	1.6 hrs	flat	up to 24 hrs	up to 42 days
Levemir flexpen	1.6 hrs	flat	up to 24 hrs	up to 42 days

References:

<http://firstport/sites/hai/Control%20of%20Infection%20Manual/Forms/Home%20Page.aspx>

NHS Lanarkshire (2003), Risk Assessment for Insulin Administration in the Community.

<http://www.DiabetesHealth.com>

Beers, H. Mark, "Explicit Criteria for Determining Potentially Inappropriate Medication Use by the Elderly" Archives of Internal Medicine, vol. 157, July 28

Disclaimer to the Newsletter: This information is intended for general education purposes and the information has been cited, where previously noted. Any of the trademarks, design rights or similar rights mentioned, used or cited in the articles here-in, are the property of their respective owners and I take no credit in their original design or writing.