Compounded Pain Medications in Community Pharmacy

John Voliva, R.Ph.

President

Hook's Apothecary, LLC

Hook's Apothecary Background

- First Compounding-Only Pharmacy in Indiana
- Cash-only practice no billing of third parties (PBMs) for compounded medications
- Major areas of focus:
 - Women's Health
 - Veterinary Medicine
 - Dermatology
- Compounding for pain:
 - Soft tissue injuries
 - Chronic Pain
 - Hospice

Questions Posed by NASEM

- Common formulations compounded
 - No set "starting point", nor do we have one formulation overwhelmingly more popular than another. Formulation is based on patient need and what the prescriber is wanting to treat.
- Conditions / Indications
 - Wide variety, but the three main areas: soft tissue injuries, chronic pain and hospice
- Information shared with patients regarding risks / appropriate use
 - ▶ When asked for a recommendation, we start with lowest strength we have found clinically relevant and increase strengths after one to four weeks of patient use. We strive to minimize risk at beginning of therapy as much as possible.

Questions Posed by NASEM

- How do we get our prescriptions
 - Primarily in close consultation with the prescriber. Occasionally, the patient will approach us first seeking recommendations for their current concerns.
- How do we choose our ingredients
 - Dependent on the type of pain
- Do we recommend or does prescriber specify ingredients
 - Again, depends on the individual patient. Some prescribers do have greater knowledge than others and will specify their own ingredients / strengths. If they do, we ensure appropriate therapy based on our clinical experience and published information.

Questions Posed by NASEM

- Trends in number of prescriptions we fulfill
 - Steady over the last 10-15 years. We did not participate in the illegal prescription fraud schemes which occurred over the last 5-7 years. Nor do we employ marketing techniques to prescribers outside of informing them of our services and to serve as a resource to help with their patients struggling with FDA approved medications.
- Information regarding dermal penetration
 - ▶ We review the information provided by manufactures and any published literature currently available.
- Amount applied per application / protections against overdose
 - Again, depends on the particular formulation. For formulations at risk of possible overdose, we will unit dose the medication for patient use.

Working with individual patients

- When patients or prescribers turn to us for assistance in treating pain, we are a bit of a last resort.
- In my opinion, compounded pain medications should not be a first line therapy
- Vast majority of prescriptions compounded for pain are for patients who have tried on failed on multiple therapies (usually due to side effects) and/or current FDA approved medications cannot be used on the patient.
- For hospice care, oftentimes compounded medications for pain is the only option available for symptom control.
- It is of upmost importance that these medications are implemented in close consultation between the pharmacist and prescriber. Close patient monitoring for dose response and side effects is an important tool in implementing these therapies in practice.

WB, Chronic Pain

- Injured in late 70s
- Chronic pain in both feet
- Treated for over two decades with opioids and gabapentin to control pain.
- Opioids doses were escalated over the years d/t decrease effectiveness of controlling patient's pain.
- Hook's Apothecary approached in early 2000s to consult on whether compounded medications were appropriate.
- Started patient on: Ketoprofen 10%. Currently on: Amitriptyline 15% / Ketoprofen 15% - Total of 4 different formulations used - Added Amit. In 2007, increased strengths in 2010
- Since 2010, patient has been pain free and no longer taking oral opioids or gabapentin.

EV, Back Pain

- 92 year old patient who suffered several micro-fractions in lower lumbar secondary to a fall
- All oral opioids cause disorientation & hallucinations
- Oral NSAIDs contraindicated
- ▶ Pain controlled on 2 to 3 grams of APAP Q24H even with this, patient was unable to continue physical therapy
- Patient started on Gabapentin 2% / Ketoprofen 20% / Lidocaine 1%with close monitoring (weekly follow—ups) to monitor for adverse effect or drug interactions
- After two days of topical therapy, patient ceased use of APAP, as pain was now tolerable. Three week later, patient was able to resume PT. Patient now on Gabapentin 4% / Ketoprofen 20% / Lidocaine 2% with no side effects or drug interactions.

Conclusion

- Compounded Pain Medications should not be a first line therapy for most cases.
- Formulation considerations depend on many factors: type of pain, experience with previous medications, goals of therapy.
- Important to start low and go slow with dosing recommendations and adjust dose on patient response.
- Patient monitoring by prescriber an/or pharmacist is an important part of this process.
- Compounding is not a one size fits all proposition. Different patients will require different formulations at different strengths to control their pain.

Contact

John Voliva, R.Ph.

President

Hook's Apothecary, LLC

Evansville, IN

john@hooksrx.com

(812) 476-6194