Use and Mis-Use of Controlled Substances and Other Medications in Eyecare

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1

Disclosures Joe DeLoach, OD, FAAO

I Have Received Honoraria From or Served as a Consultant for: (Partial Listing)

- Vision Source
- Alcon Laboratories
- Carl Zeiss Meditec
- Optos
- Diopsys
- Kowa
- Optovue
- AllDocs
- OfficeMate
- Marco
- TSO
- NVision
- Cleinman Partners
- Vision Trends
- Konan
- Essilor of America
- SNAPP
- AACO
- Vision West
- UHCO, NOVA, RSO, UAB, Berkley, *and other optometry schools*

Over half the state optometric associations in the United States

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2

Why and How of this Course

This course is designed to meet the requirement issued by the Texas Legislature that all optometry TG license holders complete a two-hour controlled substances course by September 1, 2021.

Since…

- ✓ This topic has been presented in a prior PR course already
- ✓ It overlaps with the required Opioid course
- ✓ The State has mandated content requirements

Please understand much of the material you have already seen!

Hang in there, this is a one-time requirement!

3

Soup de jour

- What are controlled substances
- Classification systems
- What are the problems with controlled substances
- Some "Do's and Don'ts" of prescribing
- General guideline for drug prescribing
- Alternatives to drug therapy
- "Physician heal thyself?"

4

Controlled Substances

- Controlled substances are defined by the Drug Enforcement Agency at the Federal level but most States have their own controlled substance classifications
- Federal law applies when State laws do not exist
- Texas has its own controlled substance definition and classification system – defined by the Texas Controlled Substances Act under the Health & Safety Code, Chapter 481
- Drug classifications are updated and new drugs added once a year with the new classification typically release in February

5

What are controlled substances?

Here is the biggest misconception…

Controlled substances are just narcotics that require special prescriptions and optometrists in Texas cannot prescribe them anyway….So we don't have to worry about any of this. ***RIGHT?***

6

Controlled Substances

- The Texas Legislature felt otherwise!
- Controlled substances are ANY prescription deemed by the Drug Enforcement Agency or applicable State agency to have ***"the potential for abuse that can lead to physical or psychological dependence"***
- Controlled substances are NOT just Schedule I and II narcotic agents. **There are controlled substances in every Schedule – I through V**
- ***HOPEFULLY – our scope is getting ready to change. This will all become MUCH MORE important***

7

Schedule I Controlled Substances

- These are the drugs with the MOST potential for dependency
- There are actually thousands of them
- The common ones would be heroin, LSD, marijuana and potent, often experimental, psycho-active agents – NEVER an application to primary eye care or most any healthcare for that matter

8

Schedule II Controlled Substances

- This is the category receiving the most attention in the US right now. There is a SEVERE issue with opioid narcotic over-use that predominantly stems from opioid narcotic over-prescribing.
- While ODs in Texas have not / can not legally contribute to this problem under existing law, it is essential we understand the problem and how we can help solve the problem.

9

Schedule II Controlled Substances

- **Narcotics** - Opium and opiate derivatives
  - The main culprits – morphine and morphine derivatives (meperidine/Demerol, methadone, fentanyl); oxycodone (Oxycotin, Percocet, Percodan); hydrocodone (Vicodin, Norco, Lortab, Lorcet, Norcet, Lorcet)
- **Stimulants** – mainly from the amphetamine family but also includes cocaine
- **Depressants** – mainly from the barbiturate family
- **Hallucinogens**

10

A word about cocaine…

(JJ Cale and Eric Clapton said "it don't lie"…but that's three words)

Cocaine has application as a diagnostic agent in evaluation of pupil anomalies. Texas ODs have right to possess and administer cocaine for diagnostic use

BUT….really

- The regulations are stifling
- The legal issues are stifling
- Storage and reporting issues are complicated
- There are "almost as good" alternatives

11

We will get back to the problems and solutions of controlled substance abuse in a bit…

12

Schedule III Controlled Substances

- **Narcotics** - Opium and opiate derivatives
  - The main culprit is codeine: aspirin or acetaminophen + codeine (#2 – 15mg codeine; #3 – 30mg codeine; #4 – 60mg codeine)
- **Depressants** – barbiturate family with less dosage than Schedule II
- **Anabolic steroids and hormones**

13

Schedule IV Controlled Substances

- **Non-narcotic pain medications**
  - Ultram (tramadol)
- **Stimulants** – just a few
- **Depressants** – tons of them
  - Common culprits include: Xanax (alprazolam); Klonopin (clonaxepam); Valium (diazepam); Ativan (lorazepam); Ambien (zolpidem); Centrax (prazepam); Dalmane (flurazepam)

14

Schedule V Controlled Substances

- A plethora of drugs that would rarely or never be used in eyecare – most common application is cough suppressants
- Does include some synthetic codeine preparations (low dose dihydrocodeine) that have pain moderating effects but are used more for their anti-tussive properties

15

Why should you care about any of this…most of all this rarely applies to eye care

While true, being aware and involved is important because:

- ✓ ODs can help identify problems with addictive patients
- ✓ ODs can help identify problems with addictive colleagues
- ✓ We can prescribe some of these medications now
- ✓ We hopefully will change the current law to allow more access to needed medications

16

Texas Prescription Monitoring Program (PMP)

- Implemented in 2008 – only for Schedule I and II reporting
- Amended in 2016 to include all Schedules with required reporting requirements for all Texas pharmacists and any physician prescribing opioid derivatives, benzodiazepine (many sedatives), barbiturate or carisoprodol (Soma) – regardless of the Schedule
- This means under current law we are required to use the PMP with any prescription for codeine or tramadol containing medications

17

Side point…

Every licensed practitioner has a profile in PMP accessible by any pharmacist in Texas. It's a bit like social media…your prescribing patterns are being recorded and monitored whether you elect to participate in the PMP program or not.

More information on the Texas Prescription Monitoring Program can be found at: www.pharmacy.Texas.gov

18

How do I participate?

- First, register
  https://texaspmpaware.net
- Instructions are easy – you will need a DEA number to register

Wait, I have to have a DEA?

✓ You do to register for the PMP
✓ You do if you want your patient's prescriptions filled without additional hassle

19

Then….

IT'S JUST THAT EASY….

- Before writing any applicable prescription you must login and check the registry regarding the patient's history
- Then make a determination if you want continue with the prescribed medication based on:
  - The prescription data and history related to the patient, if any, contained in the Prescription Monitoring Program
  - A determination whether the planned decision would constitute a potentially harmful prescribing pattern or practice.

20

Problems with prescribing medications, especially controlled substances

- Unnecessary and overuse of opioid narcotics
  - Abuse
- Unnecessary and overuse of antibiotics
  - Resistance
- Unnecessary and overuse of medications in general
  - Cost burden to healthcare system

21

Opioid Overuse / Abuse

22

Landmarks in History of Opioids

- It all started with opium – **3,400 BC**. Sumerians labeled the opium poppy "**the joy plant**"
- Production and **trading escalates after 15th century**
- Before the **1800s**, opioids **used to treat everything** from a toothache to pain at death
- **1806** – Friedrich Serturner isolates morphine from opium (named after **Morpheus** – "god of dreams").
- **1853** – **hypodermic needle** invented. Game changer spawned **massive use** esp. during Civil War
- **1898** – Bayer isolates **heroin** from morphine. Given as the "non-addictive alternative to morphine"

FROM THERE IT ALL STARTED DOWNHILL

23

Opioids – 20th century and forward

- 1900-1985: Creation of **Food and Drug Administration** in **1906** and **Harrison Narcotic Control Act** in 1914 attempt to curb physician prescribing of opioids
- Around **1990**, medical and scientific world focus on what as considered a "**massive undertreatment of pain**". **Use of opioid analgesics skyrockets** – considered a **standard of care** issue in pain management
- **2012** – FDA approves **extended release opioid analgesics** - opioid use peaks with consumption of **365,000 pounds** in the US alone and widespread opioid addiction
- **2016 - *OOPS*…**medical community focuses on **increased physician education** and decreasing use of opioid analgesics

24

How Bad Is It Now?

National Institute on Drug Abuse (latest data)

- 2018 – **128** people in US **died** from opioid overdose – **PER DAY**
- **21-29%** of patients prescribed opioids for pain management **mis-use** them
- Texas has 5th lowest death rate. South Dakota has lowest - West Virginia and Delaware have the highest. Ohio has highest percentage increase over past three years. Only Missouri has a decrease over the past three years.
- Significant **acceleration of problem during COVID** crisis (81,000 deaths from drug overdose in 2020 – overall 29% increase but some states reported as high as 98% increase from 2019)

25

How Bad Is It?

National Institute on Drug Abuse (latest data)

- Adjusted for 2019, opioid addition and abuse resulted in **$101 BILLION** burden from crime, loss of productivity and health care related costs
- Social complications from opioid abuse include short and long term physical health problems, short and long term mental health problems, accidents, increased suicide rate, family conflict, work performance issues, financial problems, increase involvement in criminal activities
- **Studies show most all attempts to reverse addiction have limited success and the best course of action is PREVENTION**

26

But we only prescribe for very short periods of time…addiction not an issue?

*"It takes a **couple of weeks** to become physically dependent on an opioid, but that varies by individual. If you take an opioid for a day or two, it should not be a problem and, generally, you will not become addicted. However, **some studies show even the first dose of an opioid can have physiological effects**."*

https://www.hopkinsmedicine.org/opioids/science-of-addiction

27

Who Uses Them?

- As expected, most prevalent in **Metropolitan and fringe areas** (except in West Virginia)
- Problem in **all age groups**, all **ethnicities**, all **genders**, all **socio-economic** backgrounds
- Tendency toward **lower income** groups
- Groups with **largest death rate** - **African descent** 45-65 years old and **non-Hispanic whites** 25-35 years old
- WebMD – **14% age 12-17** stated **had used** opioid narcotics

28

Five tips to spotting the "addicted" patient

1. **Inconsistencies** in reported symptoms or history
   - **Over-rated explanations** of injuries;
   - **Symptoms persisting** well beyond injury;
   - **Over-rated pain** in relation to cause
2. **Unusual behaviors**
   - Patient is **obsessive, agitated, irritable**,
   - **Fails to keep appointments** then wants in for "emergency" care,
   - **Overly complimentary** of physician

29

Five tips to spotting the "addicted" patient

3. **Lack of correlation between symptoms and signs** from examination
4. **Failure to accept non-narcotic recommendations**
   - "I tried that before, it didn't work…***but Vicodin did***!"
5. Request for **dosages or refills in excess** of the problem
   - losing prescriptions

30

Opioid Misuse

It's common…look for it!

Risk assessment tools
http://core-rems.org/opioid-educational/tools/

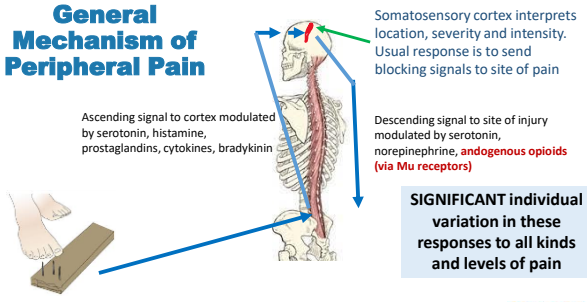
31

Assessing Patients in Pain

- Pain is **one of the most common reasons** a patient will present for care
- The ability to decrease or eliminate pain is considered **one of the most significant powers of a physician**
- **Failure to provide options** for pain control, which may include many things, **will often result in loss of patient confidence**

32

General Mechanism of Peripheral Pain



33

Pain Classification

In General

- Acute
  - Most common ocular pain
- Chronic
  - Most common opioid problem

34

Significant New Term – directly applies to eye care

Chronic, non-cancer pain (CNCP)

- Defined as **chronic** pain **lasting >2-3** months **NOT** the result of **cancer** or cancer treatment
- A **major issue contributing to** opioid use crisis

35

Ocular Pain

- **Acute pain** due to injury
  - **Cornea** most common site
- **Acute or chronic** presentations due to:
  - **Dry eyes** or other chronic external eye disease
  - "**Eyestrain**"
  - Ocular presentation from **external disease**
  - Ocular manifestation of **remote disease**
  - **I feel….in the corner, behind the eye, above the eye, , around the eye, in the library with a candlestick…**

36

So, a word about corneal pain

- Corneal and ocular pain can be / is often VERY severe
- Pain medications, even Schedule II narcotics, have minimal effect on curbing this pain
- Bandage lenses have far more pain controlling power than narcotics
- Does the ibuprofen/acetaminophen cocktail work?
- Sure fire method…

37

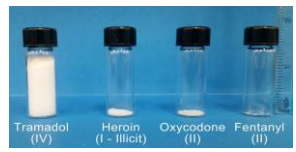
Pain Management Plans

Key Points

- Organism's **recognition of ACUTE pain is vital** for survival
- **CHRONIC pain serves no beneficial** physiologic or psychologic function
- Common problem with pain, especially chronic, is the ***"fix it NOW"*** expectation
- **People experience pain** – health care providers must offer solutions

38

Opioid Narcotic Choices



- meperidine (Demerol)
- methadone
- fentanyl ← 2015-2019: 540% increase in overdose deaths
- **oxycodone (OxyContin, Percocet, Percodan)**
- hydromorphone (Dilaudid)
- hydrocodone (Vicodin, Norco, Lortab, Lorcet, Norcet, Lorcet)
- codeine

39

Long-Acting Opioids – The Big Problem

- morphine ER (Kadian)
- morphine SR (MS Contin)
- buprenorphine (Subutex)
- **buprenorphine/naloxone (Suboxone)** ←
- fentanyl patch (Duragesic)
- methadone (Metadol)
- oxycodone controlled release (OxyNeo, Targin)
- hydromorphone (Hyrdomorph Contin)

40

When To Consider Opioids

- *Typically* **ONLY in moderate to severe** nociceptive or neurologic pain
- *Typically* **ONLY after non-opioid alternatives have failed** to produce desired response
- ALWAYS - only when the **benefits outweigh the risks**

41

Non-Opioid Pain Medications

- tramadol
- gabapentin
- antihistamines
- Topicals (anesthetics, capsaicin)
- Non-steroids
  - acetaminophen
  - ibuprofen
  - naproxen
  - Does the **acetaminophen/ibuprofen** bomb work?

42

NSAID and Toxic Doses

Which is better and why?

- acetaminophen has far more hepatic toxicity
- acetaminophen does NOT reduce inflammation
- ibuprofen is a VERY powerful anti-inflammatory agent

Toxic doses ibuprofen = naproxen > aspirin > acetaminophen

- acetylsalicylic acid (Aspirin) – 4,000 mg / 24 hours
- acetaminophen (Tylenol) – 4,000 mg / 24 hours
- ibuprofen (Advil) – 1,200 mg / 24 hours
- naproxen (Aleve) – 660 mg / 24 hours

43

Antibiotic Overuse

44

Overuse of Antibiotics

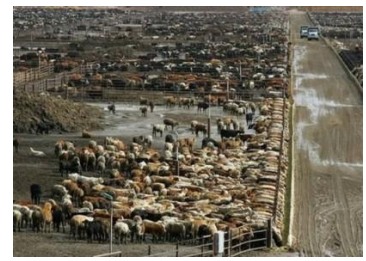
Per CDC (www.mayoclinic.org/healthy-lifestyle/consumer-health/in-depth/antibiotics/art-20045720)

- Antibiotic resistance is **one of the world's most pressing health problems.**
- According to the Centers for Disease Control and Prevention, up to **one-third to one-half of antibiotic use in humans is unnecessary or inappropriate.**

Per NIH (www.ncbi.nlm.nih.gov/pmc/articles/PMC4378521/)

- Problem complicated by use as growth supplements in livestock

45



Actually, they have to give them antibiotics because it is the only way they can survive being raised in their own sewage.

But I digress…

46

Google it….

You will find as many articles on the problems with over-use of antibiotics as you will find on the problem with opioid addiction

47

Consequences of Antibiotic Overuse

- Resistance – in past few years the development of antibiotic resistance has outpaced development of new antibiotics
- Two million infections from antibiotic-resistant bacteria in 2019 – resulting in **23,000 deaths**
  - **Let's talk about my mom's $79K hospital stay**
- Antibiotic resistance leads to longer hospital stays, higher medical costs and increased morbidity and mortality
- Estimates of healthcare and productivity **related costs as high $55 billion / year**

48

Examples of Potential Overuse of Antibiotics in Eyecare

- Use in viral and allergic conjunctivitis
- Use in "poly-pharmacy" treatments
- Use in dry eye treatment
  - About as much evidence supporting use as NOT supporting use – there are opinions

Oral Antibiotics for Meibomian Gland-Related Ocular Surface Disease: A Report by the American Academy of Ophthalmology.*Wladis EJ, Bradley EA, Bilyk JR, Yen MT, Mawn LA. Ophthalmology. 2016 Mar; 123(3):492-6*

49

Common Do's and Don'ts of Medication Prescribing

50

Prescribing "Don'ts"

- Leave Rx pads in open access
- Use pre-printed signatures/DEA numbers on Rx pads
- Abbreviate excessively – best to write things out
  - Forget all the Greek mumbo-jumbo we were taught
- Provide unnecessary refills
- Prescribe to keep your favorite drug rep happy

51

Prescribing "Don'ts"

- Prescribe medications not specifically indicated for the disease
- Provide medication based on patient desire or expectation
- Prescribe "polypharmacy"
- Always consider the "newest" drug in town as first line treatment

52

Prescribing "Do's"

- If treating pain, document pain in the medical record
- Write out quantities – "ten" not "10" (10 easily becomes 100)
- Prescribe within accepted standards and preferred practice patterns
- Watch for side effects and addiction

53

Prescribing "Do's"

- Use the Texas (or other state) PMP program – especially when prescribing opioid narcotics
- Develop high level knowledge of a select set of medications
  - Most options in classes are very similar
- Seek out prevention instead of or in addition to medication treatment
- Seek out non-drug therapy when appropriate

54

Thinking Beyond Drugs

55

Many Patients Desire Conservative or Non-Medication Options

- Patient avoidance may be based on religion, fear of side effects or a general holistic view of medicine
- Be slow to assume the potentially outdated concept that "everyone wants a prescription"
- When appropriate, provide options – medication and non-medication
- Be empathetic, understanding and educational when medication use is imperative

56

Seek Non-Drug Alternatives

- Remember many presentations are totally self-limiting
- Never underestimate the power of human healing
  "Nature performs the cure and the physician takes the fee"
  Benjamin Franklin
- Options can be extensive – nutrition, exercise, supplementation, losing weight, body/mind therapy (Read Marc Micozzi MD and Fred Pescatori MD as examples)
- Lifestyle changes can be the hardest therapy to "sell" as typically requires behavioral changes – ***"can you tell me about that smoking pill?"***

57

Look for Prevention Rather than Symptom Treatment

- Primary care physicians are doctors who work to **prevent**, diagnose and treat… Healthline 2020
- Proper nutrition, weight loss, smoking cessation, body/mind control (yoga, meditation, counseling)
- **Is it time that optometrist seek to become true primary care doctors in a healthcare world that is dominated by the pharmaceutical industry?**

58

Consider "Test of Time" as a Therapeutic Trial

- Again, remember…some presentations are self-limiting (ie. the body fixes the problem)
- Many patients consider a honest explanation just as therapeutic as a drug
- Even when prescribing, initially limit to as few medications as possible

59

Pain Management Plan - Options

ALTERNATIVES
- ✓Tai chi
- ✓Yoga
- ✓Meditation
- ✓Massage / manipulation
- ✓Specific herbs, botanicals
- ✓Neuromodulators

NOT SNAKE OIL!
ALL of these recognized by the American Society of Addictive Medicine as effective alternatives for pain management

60

One other important prescribing decision

Is it legal and/or ethical to provide care, including supply of medication prescriptions to myself, my family or close friends?

61

Let's start with this…

- There is nothing in the Texas Optometry Act or Texas Optometry Board rules that prohibits you treating yourself, your family or your close friends
- Although present in many other states, there is nothing in the laws of Texas that prohibit you treating yourself, your family or your close friends
- There ARE issues and opinions from the American Medical Association and Texas Medical Association that would be wise to consider

62

AMA Ethics Opinion 9.6.6

Regarding prescription decisions in general

- Prescription decisions should be based solely on medical necessity, patient need and a reasonable expectation of the effectiveness of the treatment
- Physicians should not dispense medications in office unless it is totally for the primary benefit of the patient
- In making prescriptive decisions, physicians should avoid any direct or indirect influences that would result in financial gain to the physician

63

AMA Code of Medical Ethics Opinion 8.19

"Physicians generally should not treat themselves or members of their immediate family."

<u>Some exclusions</u>

1) Routine care
2) Minor care
3) Emergency care

64

Other AMA Code of Medical Ethics considerations

When making a decision to treat yourself, friend or family member, consider:

- ? Is the treatment within your level of training and expertise
- ? Have you discussed the primary recommendation that the individual seek care from another physician
- ? Is the proposed treatment the same as you would recommend for any other patient
- ? Have you created a proper medical record for the encounter

65

Texas Medical Association position

There is no prohibition on physicians treating themselves or members of their family

BUT…

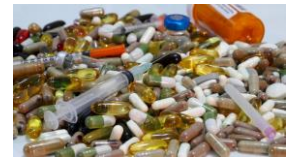
"Physicians are prohibited from prescribing controlled substances for themselves or immediate family member unless it constitutes an immediate need. Even in that case, the prescription dosing is limited to a 72 hour supply."

66

Bottom line…

Self treatment and treatment of immediate family, unless for routine, minor or emergency care, is likely a very bad idea and should be avoided

67



Gotta have ‘em
Gotta use ‘em the right way

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68