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THE OPIOID CRISIS....A BRIEF HISTORY AND CURRENT MANAGEMENT STRATEGIES

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AGENDA

Topics to be covered today

+ Opioid crisis…how did we get here
+ CDC Guidelines
+ STOP Act
+ North Carolina Medical Board CME requirements for prescribers of controlled substances
+ Where do we go from here?

Let’s get started!
+ 1.5 billion worldwide suffer from chronic pain
+ Most common types of pain
  - Low back pain
  - Neck pain
  - Headache
CHRONIC PAIN

+ Chronic pain is the number one cause of long-term disability in the United States

+ 7% of persistent lower back pain develops into chronic pain

+ 77% of people report feeling depressed due to their chronic pain

+ 51% of chronic pain sufferers feel they have little or no control over their pain

+ Most people (63%) see help from their primary doctor
CHRONIC PAIN

+ There are an estimated 100 million chronic pain sufferers in the United States, and the numbers are expected to further increase as Americans age and live longer.

+ 1 in 10 Americans has experienced pain every day for 3 months or more

+ Nearly 2 million Americans ages 12 or older either abused or were dependent on prescription opioids in 2014

+ United States is in the midst of an unprecedented drug abuse epidemic with prescription drug abuse quickly becoming a top public health concern.
Pain is a significant public health problem that costs society at least $560-$635 billion annually, an amount equal to about $2,000.00 for everyone living in the U.S.

The total annual incremental cost of health care due to pain ranges from $560 billion to $635 billion (in 2010 dollars) in the United States.
RISK FACTORS FOR ADDICTION

Diagram showing the relationship between biology/genes, environment, brain mechanisms, and addiction, with specific factors listed for each.
DRUGS CHANGE THE BRAIN’S STRUCTURE

**Drugs Change the Brain’s Structure**

1. **Reward circuit is over stimulated**
   - **1st Impact**: Brain loses ability to gain pleasure from simple activities
   - **2nd Impact**: Brain needs drugs to function normally

2. **Natural chemical message disrupted**
   - **1st Symptom**: Brain develops cravings & obsession
   - **2nd Symptom**: Brain develops tolerance & allergy
DEATHS DUE TO OPIOIDS 1999-2011

Number of deaths due to prescription opioids, cocaine, and heroin from 1999 to 2011. The chart shows an upward trend in deaths due to prescription opioids, with a peak in 2007-2008, and a steady increase in deaths due to cocaine and heroin. The chart notes that the number of times mentioned does not indicate mutually exclusive cases.
2014 Monitoring the Future Study

12th Grader Drug Use in the Past Month
2014 Monitoring the Future Study

- Alcohol
- Illicit Drugs
- Marijuana/Hashish
- Any Prescription Drug
- Narcotics other than Heroin
- Hallucinogens
- MDMA
- Cocaine
- Heroin

% usage in the past month
STATES WITH HIGHEST NUMBERS OF OPIATES

STATES WITH THE HIGHEST NUMBER OF OPIATE PRESCRIPTIONS

- Alabama
- Mississippi
- Louisiana
- Oklahoma
- Arkansas
- Tennessee
- North Carolina
- South Carolina
- Kentucky
- West Virginia
- Ohio
- Indiana
- Michigan
North Carolina statistics
BACKGROUND

North Carolina statistics

- NC has higher than average overdose death rates
- Nearly all of these deaths involve prescription opioid pain relievers (like methadone, and oxycodone, fentanyl, morphine, tramadol, or hydromorphone)
FOUR NC TOWNS IN THE TOP NATIONALLY

Wilmington, Hickory, Jacksonville, Fayetteville in top 4 NATIONALLY
COST OF SUBSTANCE ABUSE

In BILLIONS of dollars

The Cost of Substance Abuse (USD billions)

- Substance Abuse (Health Care)
- Substance Abuse (all costs)
- Federal Mandatory Spending
- Defense Department Budget
- Social Security
- Medicare & Medicaid
SO, HOW DID WE GET HERE???

Let’s take a stroll through the history of opioids….
HISTORY OF OPIOID USE

3400 B.C.- 300 A.D.

+ 3400 B.C.- 300 A.D.--earliest reference to opium growth
+ 460-357 B.C.--Hippocrates, the “father of medicine,” acknowledged opium’s usefulness as a narcotic in treating internal diseases, diseases of women and epidemics.
+ Alexander the Great introduced opium to India near 330 B.C., and the Arabs, Greeks and Romans used it as a sedative
+ 220-264 A.D.-- Chinese surgeon Hua To of the Three Kingdoms used opium preparations and Cannabis indica for his patients to swallow before undergoing major surgery.
1300 - 1799 A.D.

1527, Swiss-German alchemist, Paracelsus, who founded the discipline of toxicology, introduced opium pills containing citrus juice and “quintessence” of gold as an analgesic.

- He called this preparation laudanum, derived from the Latin verb laudare, “to praise.”

Thomas Sydenham, the “father of English medicine,” introduced Syndenham’s Laudanum, containing opium, sherry, and herbs in 1680.
1800’s

+ In 1806 the German chemist Friedrich Wilhelm Adam Sertürner isolated morphine from opium. He named it morphine after the god of dreams, Morpheus.
+ Morphine was commonly used as a pain killer during the Civil War.
+ In 1853, the hypodermic needle was invented, after which morphine began to be used in minor surgical procedures.
+ Heroin was synthesized as a derivative of morphine in 1898. The German chemical company Bayer offered Heroin as a cough suppressant and as a “non-addictive” morphine substitute for medical use.
HISTORY OF OPIOID USE

Early 1900’s

+ Saint James Society in the U.S., began a campaign to supply free samples of heroin through the mail to morphine addicts who were trying to give up their habits
+ In 1909, Congress passed the Opium Exclusion Act
+ In 1914, the Harrison Act passed and Bayer stops mass production of heroin

+ In 1916, German scientists at the University of Frankfurt first synthesized oxycodone with the hope that it would retain the analgesic effects of morphine and heroin with less dependence
HISTORY OF OPIOID USE

1920’s and 1930’s

+ The Heroin Act in 1924, made the importation, manufacture, and possession of heroin illegal in the U.S. Spurred by growing rates of addiction, the Heroin Act made even its medicinal use illegal
+ In 1938, the passage of The Food, Drug and Cosmetic Act gave authority to the U.S. Food and Drug Administration (FDA) to oversee the safety of food, drugs and cosmetics, and drugs at this time needed to be proven safe to be sold
+ In 1942, the Opium Poppy Control Act passed
1950’s, 1960’s, and 1970’s

+ Oxycodone became widely available when it was approved by the FDA in 1950 as Percodan
+ In 1969, the World Health Organization (WHO) abandoned the belief that the medical use of morphine led inevitably to dependence.
+ The Controlled Substances Act was passed in 1970 and began to consolidate all of the regulated prescription narcotic/opioid drugs under existing federal law into five separate schedules.
+ The Drug Enforcement Agency was created by Executive Order in 1973, and President Richard Nixon declared the War on Drugs noting that “America has the largest number of heroin addicts of any nation in the world”
HISTORY OF OPIOID USE

1980’s

+ Vicodin® (hydrocodone and acetaminophen), which was introduced to the U.S. in 1978 by German pharmaceutical company, Knoll, became available as a generic formulation in 1983.

+ President Ronald Reagan and First Lady Nancy Reagan asked Americans to join a national crusade not to tolerate drugs by anyone, anytime and anyplace.

+ Physicians explored the use of prescription narcotics/opioids to treat cases of pain that were not due to terminal illness.
1990’s

+ The undertreatment of pain was the catalyst for clinicians and pain societies to successfully lobby for increased use of opioids for all pain types, including non-cancer pain
+ Marketing efforts to healthcare providers by pharmaceutical companies increased as patient advocates and pain societies asked for more information on pain medications, and the market grew for those medications
HISTORY OF OPIOID USE

2000-2009

+ New standards for pain management incorporating pain as the “fifth vital sign” were issued by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO)
+ In 2002, 6.2 million Americans were abusing prescription drugs, and emergency room visits resulting from the abuse of narcotic pain relievers had increased dramatically
+ In the mid 2000’s a number of pharmaceutical companies began research efforts into formulations of pain medications that would be harder to abuse
HISTORY OF OPIOID USE

2010-Today

+ Forty-eight states have implemented prescription drug monitoring programs
HISTORY OF OPIOID USE

2010-Today

+ In 2013, the Food and Drug Administration issued a Draft Guidance on Abuse-Deterrence for opioid manufacturers
+ In 2016 Centers for Disease Control and Prevention (CDC) released Guidelines for Prescribing Opioids for Chronic Pain
+ In 2017 STOP Act passed and signed into law (NC)
For Prescribing Opioids for Chronic Pain

+ Provide recommendations for the prescribing of opioid pain medication for patients 18 and older in primary care settings.
+ Recommendations focus on the use of opioids in treating chronic pain (pain lasting longer than 3 months or past the time of normal tissue healing)
  ▪ Excludes active cancer treatment, palliative care, and end-of-life care
The Guideline was developed to:

+ Improve communication between clinicians and patients about the benefits and risks of using prescription opioids for chronic pain
+ Provide safer, more effective care for patients with chronic pain
+ Help reduce opioid use disorder and overdose
Recommendations to primary care clinicians to:

+ Help clinicians determine if and when to start prescription opioids for chronic pain
+ Give guidance about medication selection, dose, and duration, and when and how to reassess progress and discontinue medication if needed
+ Help clinicians and patients—together—assess the benefits and risks of prescription opioid use
Recommendations:

+ Opioids are NOT first line therapy
+ Establish goals for pain and function
+ Discuss risks and benefits
+ Use immediate release opioids when starting
+ Use the lowest effective dose
CDC GUIDELINES

Recommendations:

+ Prescribe short durations for acute pain
+ Evaluate benefits and harms frequently
+ Use strategies to mitigate risk
+ Review PDMP data
CDC GUIDELINES

Recommendations:

+ Use urine drug screen testing
+ Avoid concurrent opioid and benzodiazepine prescribing
+ Offer treatment for opioid use disorder
Strengthen Opioid Misuse Prevention Act

+ “Opioid addiction and overdose have ravaged the physical and mental health of thousands of North Carolinians, hurting our people and our economy, and we’re taking action to fight it. With this legislation and the new State Opioid Action Plan, we’re taking important first steps to stem the opioid epidemic.”

- Governor Roy Cooper, June 29, 2017
Provisions

+ Effective July 1, 2017:
  - **Opioid Prescribing Consultations with Supervising Physician**
    - Physician Assistants and Nurse Practitioners prescribing targeted controlled substances are required to personally consult with the supervising physician if (1) the patient is being treated at a facility that primarily engages in the treatment of pain by prescribing narcotic medications or advertises for any type of pain management services, and (2) the therapeutic use of the prescription will, or is expected to, exceed 30 days.
    - Furthermore, when prescribing to the same patient continuously, Physician Assistants and Nurse Practitioners are required to consult with a supervising physician at least once every 90 days to verify that the prescription remains medically appropriate.
Provisions

+ Providing Information on Disposal of Targeted Controlled Substances
  - Hospice and palliative care providers prescribing targeted controlled substances to be administered to a patient in his or her home for the treatment of pain as part of in-home hospice or palliative care shall provide oral and written information upon commencement of treatment to the patient and his or her family regarding the proper disposal of such targeted controlled substances.
Provisions

+ **Distribution of Naloxone**
  - Community distribution of naloxone by organizations that have a standing order to do so. Parties are required to include “basic instruction and information” on how to administer naloxone.
Provisions

+ Effective September 1, 2017:
  - Limitations on Prescriptions for Acute Pain
    - Practitioners cannot prescribe more than a 5 day supply of any Schedule II or Schedule III opioid or narcotic upon the initial consultation and treatment of a patient for acute pain
    - Exception: post-operative acute pain prescription cannot exceed a 7 days supply
Provisions

- Effective January 1, 2020:
  - **Electronic Prescribing**
    - Practitioners must electronically prescribe for all targeted controlled substances
    - Exceptions:
      • administration in a hospital, nursing home, hospice facility, outpatient dialysis facility or residential care facility
      • Practitioners experiencing temporary technological or electrical failure or other extenuating circumstances that prevent the prescription from being transmitted electronically. Practitioners must document the reason for this exception within a patient’s medical record.
Provisions

- Exceptions:
  - Practitioners writing a prescription to be dispensed by a pharmacy located on federal property. Practitioners must document the reason for this exception in the patient’s medical record.
  - Persons licensed to practice veterinary medicine.
Provisions

+ Effective upon completion of NC CSRS technical upgrades* (date TBD):
  - Mandatory Review of NC CSRS
    - Prior to prescribing a Schedule II and Schedule III opioid or narcotic, practitioners are required to review a patient’s 12-month prescription history in the NC CSRS
    - For every subsequent three-month period that the Schedule II or Schedule III opioid or narcotic remains part of the patient’s medical care, practitioners are required to review the patient’s 12-month history in the NC CSRS
    - Reviews should be documented within the patient’s medical record along with any electrical or technological failure that prevents such review. Practitioners are required to review the history and document the review once the electrical or technological failure has resolved
Provisions

+ Certain practitioners may, but are not required to, review the NC CSRS prior to prescribing a targeted controlled substance to a patient in any of the following circumstances:
  - Controlled substances administered in a health care setting, hospital, nursing home, outpatient dialysis facility or residential care facility
  - Controlled substances prescribed for the treatment of cancer or another condition associated with cancer
  - Controlled substances prescribed to patients in hospice care or palliative care
Provisions

+ The STOP Act authorizes NC CSRS to conduct periodic audits to determine prescriber compliance with review requirements. NC CSRS shall report to the North Carolina Medical Board any licensee found to be in violation of the requirement to check NC CSRS; violations may result in regulatory action by the Board.
Continuing Medical Education (CME) Requirements

+ Why is the NCMB implementing a controlled substances CME requirement?
  - NCMB’s primary goal is to ensure that licensees who prescribe controlled substances, particularly opioids, do so in a manner that is safe, appropriate and consistent with current standards of care. Requiring CME in controlled substances prescribing and related topics is one way of supporting this.

+ Who is subject to the requirement?
  - Physicians and physician assistants who prescribe controlled substances
CME requirements (continued)

+ What is the requirement for physicians?
  - The rule requires physicians to complete three hours of eligible CME during each three year cycle. See questions below for further information on content to satisfy the requirement

+ What is the requirement for physician assistants?
  - The rule requires physician assistants to complete two hours of eligible CME during each two year CME cycle

+ When will the requirement be in effect?
  - The new requirement is effective July 1, 2017. Any licensee whose CME cycle renews in 2017 and whose birthday is on or after July 1, 2017 will be required to fulfill the new CME requirement.
CME requirements (continued)

+ Is this a one-time requirement or will licensees be required to earn CME in controlled substances prescribing on an ongoing basis?
  - This is an ONGOING requirement

+ Will any licensees be exempt from the new CME requirement and, if so, who?
  - Yes. Licensees who have not prescribed ANY controlled substances (opioid or non-opioid) since they last renewed and physicians holding a Resident Training License are exempt from the requirement
CME requirements (continued)

+ If you prescribe controlled substances that are NOT opioids, do you still have to comply with the requirements?
  - YES. The requirement applies to physicians and PAs who prescribed ANY controlled substances (including non-opioids) during their most recent CME cycle

+ How will licensees find CME courses that fulfill the requirement?
  - Licensees may select any course that is ACCME Category 1 or similar that covers “controlled substances prescribing practices, recognizing signs of the abuse or misuse of controlled substances, and controlled substance prescribing for chronic pain management”
Free CME

+ The North Carolina Medical Board is partnering with Wake AHEC to develop a free webinar and a live panel presentation that will count towards the CME requirement
  - Already done 4, goal is for 20 more across the state especially in rural areas and hospital settings (Duke, Wake Med)
  - Open to anyone...physicians, mid-levels, dentists, pharmacists...
  - Oriented towards primary care
WHERE DO WE GO FROM HERE???

Just my two cents…from when I was in practice

+ CDC Guidelines are just that…guidelines…do what is best for the patient and document the justification
+ Considering using pain management agreements
+ Start low and go slow
+ Check the PDMP
+ Have your patient secure medications in lock box…not medicine cabinet in the bathroom
+ Consider pill counts
+ Bring bottles to every visit
+ Educate your patients on proper disposal of medications especially opioids
+ Pain management does NOT necessarily equal opioid management
+ Functional improvement is the goal
+ Have those hard conversations with your patients
WHERE DO WE GO FROM HERE???

+ Remember risks versus benefits
+ Risk assessment prior to starting (or continuing) opioids. It is an ongoing assessment
+ Establish expectations in the doctor-patient relationship
+ Goals for treatment
+ Remember the Hippocratic Oath
THANK YOU!

- Thank you for the care that you provide to our members, your patients, on a daily basis
- We appreciate all that you do!

BlueCross BlueShield of North Carolina

WE JUST WANT TO SAY...

THANK YOU!
“ALONE WE CAN DO SO LITTLE; TOGETHER WE CAN DO SO MUCH.”
- Helen Keller
+ https://www.ncmedboard.org/
  ▪ Website, legal dept, communications dept
+ https://paindoctor.com/resources/chronic-pain-statistics/
+ https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm
+ NC DHHS
QUESTIONS? COMMENTS?

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