Dentistry's Role in Addressing Ohio's Opioid Crisis

Corydon Palmer Dental Society

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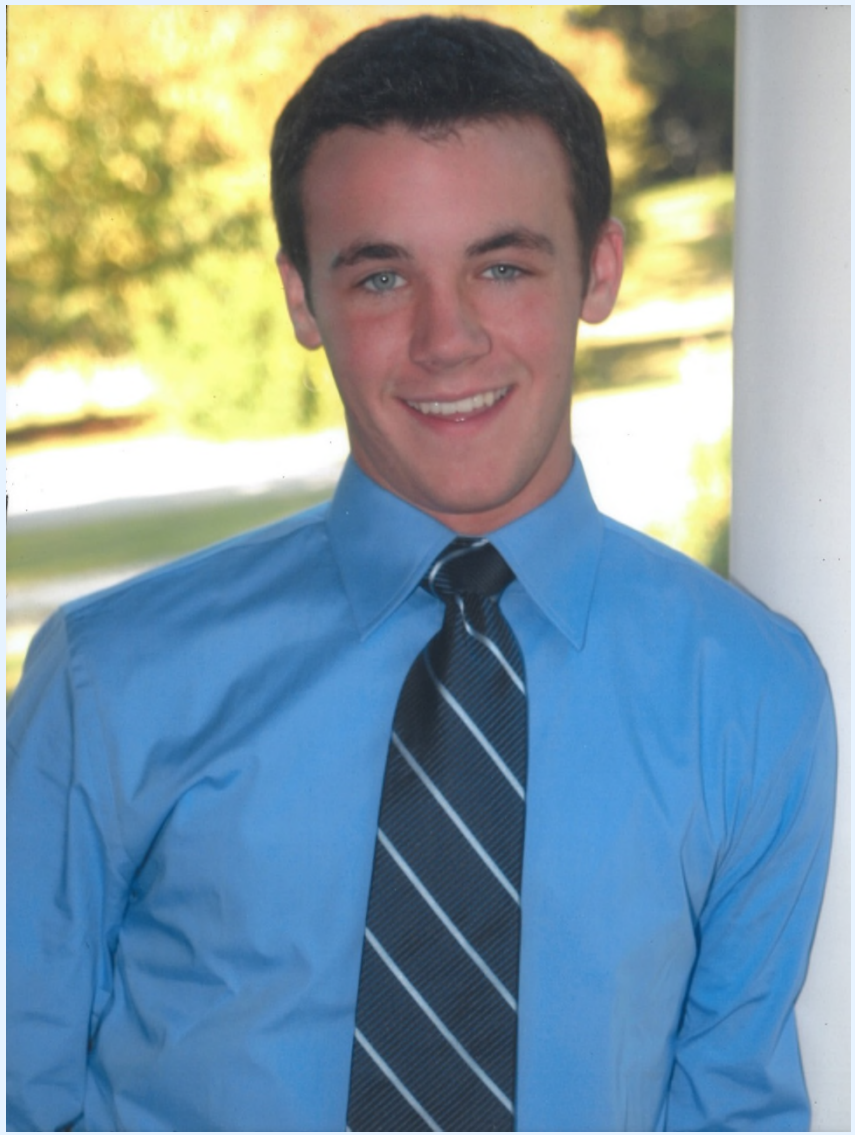

The Adolescent Brain

- Major growth occurs in the PFC between ages 13 - 26
- Adolescents can become addicted 5x faster than adults
- People who start using as teenagers have immature PFC's

Information provided by Brad Lander, PhD, LICDC

Of all the people with addiction, 96.5% started substance use before age 21.

2012 by The National Center on Addiction and Substance Abuse at Columbia University
Information provided by Brad Lander, PhD, LICDC

ADDICTION HAS GENETIC RISK FACTORS

- Genetics account for 40-70% of the risk

Accessed February 08, 2016. http://usatodayhss.com/2015/when-painkilling-becomes-an-addiction-for-young-athletes. Koob, George. "Neurobiology of Addiction." Lecture, Essentials of Addiction Medicine: A Conference on the Treatment of Substance Use Disorders, Anaheim, CA, August 26, 2016. Lecture accessed online January 14, 2017. U.S. Department of Health and Human Services (HHS), Office of the Surgeon General, Facing Addiction in America: The Surgeon General's Report on Alcohol, Drugs, and Health. Washington, DC: HHS, November 2016, 2-22.

OXYCONTIN FDA APPROVED 1995, LAUNCHED 1996

Initial Product Label

- “Latrogenic addiction was ‘very rare’ if opioids were legitimately used in the management of pain.”
- “Oxycodone products are common targets for both drug abusers and drug addicts. Delayed absorption, as provided by OxyContin tablets is believed to reduce the abuse liability of a drug.”
- “OxyContin tablets are to be swallowed whole, and are not to be broken, chewed, or crushed. Swallowing broken, chewed, or crushed OxyContin tablets could lead to the rapid release and absorption of a potentially toxic dose of oxycodone.”
- Sales $45-48,000,000

Mariani, Mike. "How the American Opiate Epidemic Was Started by One Pharmaceutical Company." The Week. March 04, 2015. Accessed February 20, 2016. http://theweek.com/articles/541564/how-american-opiate-epidemic-started-by-pharmaceutical-company.
Zee, Art Van. "The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy." American Journal of Public Health 99, no. 2 (February 2009), 221, 224.
Pokrovnichka, Dr. Anjelina. "History of OxyContin: Labeling and Risk Management Program." Lecture, Anesthetic and Life Support Drugs and Drug Safety and Risk Management Advisory Committees, November 13, 2008.

HOW OXYCONTIN ROSE

Medical Education

- 1996 – 2002, directly or indirectly funded more than 20,000 pain-related educational programs
- Portenoy becomes a speaker for Purdue Pharma
- Promotional materials Brochures, audiotapes, videotapes, websites
- Risk of addiction is “less than 1%”

Whoriskey, Peter. "Rising Painkiller Addiction Shows Damage from Drugmakers' Role in Shaping Medical Opinion." The Washington Post. December 30, 2012. Accessed February 24, 2016. https://www.washingtonpost.com/business/economy/2012/12/30/014205a6-4bc3-11e2-b709-667035ff9029_story.html.
Zee, Art Van. "The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy." American Journal of Public Health 99, no. 2 (February 2009), 223, 225.
Mariani, Mike. "How the American Opiate Epidemic Was Started by One Pharmaceutical Company." The Week. March 04, 2015. Accessed February 20, 2016. http://theweek.com/articles/541564/how-american-opiate-epidemic-started-by-pharmaceutical-company.

CDC Statistics

- Drug overdose is the leading cause of accidental death in the U.S.
  - 52,404 overdoses vs. 30,808 MVA fatalities in 2015
- 2 million addicts in the U.S. abuse prescription pain medications
- 888.7 Opioid RXs/1000 Ohio residents
  - Only Louisiana is higher

IS DRUG ADDICTION A DISEASE OR MORAL FAILING?

DIABETES vs ADDICTION

TYPE II DIABETES

- GENETIC PREDISPOSITION
- ORGAN: PANCREASE
- TOO MUCH: GLUCOSE/ NOT ENOUGH: INSULINE
- RESULT: TISSUE RECEPTOR DOWN REGULATION
- EFFECT: GLYCEMIC INSTABILITY

ADDICTION

- GENETIC PREDISPOSITION
- ORGAN: MID BRAIN
- TOO MUCH: DOPAMINE
- RESULT: RECEPTOR DOWN REGULATION IN BRAIN
- EFFECT: DEPRESSION /CRAVING / ADDICTION

What does it take to change behavior?

“Effective questioning brings insight, which fuels curiosity, which cultivates wisdom.”

Chip Bell Esq.

What is the question we should be asking?

Am I part of the problem or part of the solution?

Prescribing Statistics 2015
Akron Oral Maxillofacial Surgery

- 2268 narcotic prescriptions written
- Of those, 498 were non-oxycodone/hydrocodone
- Default prescription 3rds 2015 (685 cases)
  - Percocet 5/325
  - # 30*
  - sig: 1-2 tabs po Q 4hr prn pain

Prescribing statistics 2015
Akron Oral Maxillofacial Surgery

- Default prescription for tooth extraction
  - Percocet 5/325
  - # 20
  - sig: I-II po Q4hr prn pain

So what…

- 20,550 Percocet/Vicodin tabs for 15-24 year olds in 2015 (Wizzies)
- 21,700 Percocet/Vicodin tabs for other adult extractions, implants, biopsies
- 42,250 CII narcotic tabs total

Let’s extrapolate

- 300 OMFS in Ohio according to AAOMS
- 200 are in practice
- If they prescribe as I did…
- 8,450,00 CII narcotic tabs

Let’s look at the bigger picture

- 7000 dentists in Ohio
- Less the OMFS, Peds and Ortho… 6000
- If the rest prescribe at 10% of my level
  25,350,000 CII tabs

The goal of postoperative medication is to minimize pain and anxiety

Nociception vs. Pain

- Nociception is the indication of a potentially dangerous stimulus.
- Pain is the brains interpretation of that stimulus.

Can we make our postoperative medication routine better?

- Decrease nociception
  - Block with long acting local
  - Decrease inflammation with a NSAID
  - Use acetaminophen to it's fullest potential
- Decrease pain perception
  - Educate the patient and the family
  - Use narcotic as a rescue medication only

How my routine changed in 2016 Wizzies

- Ibuprofen 600mg
- # 20
- Sig: I po QID until gone

- Antibiotic
- #20
- Sig: I po QID until gone

- Percocet/Vicodin
- # 15
- Sig: I PO Q 6hr (only as a rescue med 20 min after 500 mg Tylenol)

How my routine changed in 2016 Extractions

- Ibuprofen 600 mg tabs
- # 20
- Sig: I po QID until gone

- Narcotic only on request
- Percocet/Vicodin
- #10
- Sig: I po Q6hr (rescue medication only after Tylenol)

What I found

- Rarely have requests for refills
- Fewer calls for pain and insomnia
- Nausea calls almost nonexistent
- Parents are THRILLED

“Progress is impossible without change, and those who cannot change their minds cannot change anything.”

George Bernard Shaw

Questions?

Opioid Epidemic

- **Nationwide Opioid Epidemic**
  - Ohio is among states most impacted
    - Number of overdose deaths in Ohio continued to climb in 2016
    - According to the Ohio Department of Health:
      - Total number of overdose deaths in 2016: **4,050** (3,050 in 2015)
      - Deaths from heroin overdoses in 2016: **1,444** (1,424 in 2015)
      - Deaths from fentanyl-related overdoses in 2016: **2,357** (1,156 in 2015)
      - Deaths from carfentanil-related overdoses in 2016: **340**
      - Deaths from prescription opioid overdoses in 2016: **564** (667 in 2015)
        - Declined for the 5th straight year
        - Fewest prescription opioid deaths since 2009
  - Comprehensive approach to fighting drug abuse

Course Overview

- **Topics of Discussion**
  - **Ohio Automated Rx Reporting System (OARRS)**
    - Compliance Overview
  - **Terminal Distributor of Dangerous Drugs License**
    - Compounding
    - Scheduled Controlled Substances
  - **New OSDB Regs on Prescribing Opioids for Acute Pain**
    - Prescribing Limitations
  - **Review: Prescribing Opioids to Minors**
    - Start Talking – Informed Consent
  - **New Requirements for Controlled Substance Prescriptions**
    - CDT Code + Days' Supply

Disclaimer

- This seminar is intended to be informational only and should not be construed as legal advice. Dentists should always seek the advice of their own attorneys regarding specific circumstances.

Automated Rx Reporting System (OARRS)

- **OARRS Overview**
  - Created in 2006 to collect information on all prescriptions for controlled substances
  - State invested $1.5M into upgrading system in 2015
  - Progress
    - OARRS inquiries increased from 778,000 in 2010 to 9.3 million in 2014
    - Number of opioids dispensed declined by 20% between 2012-16
      - 162 Million Doses!
    - Amount of people doctor shopping declined by 78% between 2012-16

Automated Rx Reporting System (OARRS)

- **Registering with OARRS** (OAC 4715-6-01)
  - Who **may** register with OARRS
    - Any prescriber
  - Who **must** register with OARRS
    - Any prescriber who prescribes or personally furnishes opioid analgesics or benzodiazepines
    - Each licensee certifies to the OSDB that they have registered for an OARRS account if necessary upon renewing their license
  - www.ohiopmp.gov

Automated Rx Reporting System (OARRS)

- **When to Access OARRS** (OAC 4715-6-01)
  - **Permissible**
    - Always permissible for patients of record and prospective patients
  - **Clinical Judgment**
    - If a dentist knows or has reason to believe that a patient may be abusing or diverting drugs, the dentist must use sound clinical judgment in determining whether or not a reporting drug should be prescribed or personally furnished
    - To assist in this determination, the dentist must consider whether to access OARRS and document receipt and assessment of the information received if the patient exhibits signs of drug abuse or diversion

Automated Rx Reporting System (OARRS)

- **When to Access OARRS** (OAC 4715-6-01)
  - **Mandatory**
    - Must request patient information from OARRS that covers the previous 12 months before initially prescribing or personally furnishing an opioid analgesic or a benzodiazepine to a patient
    - Must make periodic requests for patient information from OARRS if the course of treatment continues for more than 90 days
    - **Exception**: The drug is prescribed or personally furnished in an amount indicated for a period **not to exceed 7 days** (OAC 4715-6-01(G)(3))

Automated Rx Reporting System (OARRS)

- **When to Access Other State Databases** (OAC 4715-6-01)
  - Dentists practicing in a county adjoining another state are required to check the adjoining state's prescription monitoring program
  - Convenient access to reports from all surrounding states (PA, WV, KY, IN, MI) through OARRS

Automated Rx Reporting System (OARRS)

- **Delegates** (OAC 4715-6-01)
  - Any individual who is either supervised or employed by the dentist can serve as their delegate
  - No limit on number of delegates (each must have separate account)
  - May only run report – not permitted to interpret results
- **OARRS Documentation** (OAC 4715-6-01)
  - A prescriber who is required to review OARRS information must document in the patient's medical record that the report was received and the information was assessed
  - If for some reason the OARRS report is not available, the prescriber should document in the record when the report was requested and its unavailability

Automated Rx Reporting System (OARRS)

- **Dentists are subject to OSDB discipline for failure to comply with these regulations!!!**

Questions?

Terminal Distributor of Dangerous Drugs License

- **TDDD License** (ORC 4729.541)
  - Ohio State Board of Pharmacy
  - Compounded drugs
  - Schedule I, II, III, IV, and V drugs

Terminal Distributor of Dangerous Drugs License

- **Controlled Substances**
  - Schedule I, II, III, IV, and V Controlled Substances
    - "Controlled substance" = https://www.dea.gov/druginfo/ds.shtml
      - https://www.deadiversion.usdoj.gov/schedules/orangebook/c_cs_alpha.pdf
      - Difference Between: Dangerous Drugs – Controlled Substances – Opioids
    - Controlled substances do not include antibiotics, procaine (Novocain®) or vaccines
    - Licensure requirement applies to any location storing controlled substances, including emergency kits, samples or any other stock
    - TDDD license only necessary for physical possession

Terminal Distributor of Dangerous Drugs License

- **Controlled Substances – General Compliance Requirements**
  - Establish proper security protocols (OAC 4729-9-11)
  - Maintain a record of all controlled substances received, administered, dispensed, personally furnished, distributed, sold, destroyed, or used (OAC 4729-9-14)
  - Conduct annual inventory of all controlled substances on hand (OAC 4729-9-14)
  - Labeling requirements for personally furnished dangerous drugs (OAC 4729-5-17)
  - Report theft or loss of dangerous drugs or controlled substances (OAC 4729-9-15)
  - No longer permitted to personally furnish controlled substances in quantities greater than a 72-hour supply (OAC 4729-5-17)

Terminal Distributor of Dangerous Drugs License

- **TDDD Application Process**
  - Visit the Pharmacy Board's website to obtain TDDD license
    - http://www.pharmacy.ohio.gov/Licensing/TDDD.aspx
  - Select "Facility or Practitioner Application"
  - Cost of license = $60 (reduced from $150)
    - Separate from and in addition to DEA license
    - May need multiple TDDD licenses (per location)
    - Complete Fee Reduction Attestation form included in the application to receive a reduced fee
    - Applications must be signed using a wet-ink signature and original copies must be submitted to the Board with correct payment
  - Must be renewed annually by March 31 ($55 late penalty)
    - Expected to become a biannual renewal

Questions?

Prescribing Regulations

- **New Limits on Prescription Opioids** (OAC 4715-6-02)
  - Effective August 31, 2017, dentists shall comply with the following regulations for prescribing opioids for acute pain:
    - Before prescribing an opioid, dentists must first consider non-opioid treatment options
    - If opioids are necessary, dentists are required to prescribe for the minimum quantity and potency needed to treat the expected duration of pain, with a presumption that a 3-day supply or less is frequently sufficient and that limiting the duration of opioid use to the necessary period will decrease the likelihood of subsequent chronic use or dependence
    - Dentist shall advise the patient of the benefits and risks of the opioid, including the potential for addiction (document in patient record)
    - Extended-release or long-acting opioids shall not be prescribed for treatment of acute pain

Prescribing Regulations

- **New Limits on Prescription Opioids** (OAC 4715-6-02)
  - Effective August 31, 2017, Ohio is enforcing the following limitations on the prescribing of opioids for acute pain:
    - **Duration**:
      - No more than **7 days** of opioids can be prescribed for **adults**
      - No more than **5 days** of opioids can be prescribed for **minors**
        - Must obtain written consent from parent or legal guardian!!!
      - **Exception**: Permitted to exceed these limits "for pain that is expected to persist for longer based on the pathology causing the pain" so long as the specific reason for doing so is documented in the patient's medical record
        - **Subject to additional review by OSDB and Pharmacy Board!!!**

Prescribing Regulations

- **New Limits on Prescription Opioids** (OAC 4715-6-02)
  - Effective August 31, 2017, Ohio is enforcing the following limitations on the prescribing of opioids for acute pain:
    - **Dosage**:
      - The total morphine equivalent dose (MED) of a prescription for acute pain **cannot exceed an average of 30 MED per day**.
      - **Exception**: May prescribe 90 MED per day within the initial 72-hour period if:
        1. The patient has a significant prolonged acute pain related to one of the following:
           a) Traumatic orofacial tissue injury with major mandibular/maxillary surgical procedures
           b) Severe cellulitis of facial planes
           c) Severely impacted teeth with fascial space infection necessitating surgical management
        2. Dentist determines it is absolutely necessary to exceed the 30 MED daily limit for the initial 72-hour period following the procedure
        3. Dentist documents the reason for exceeding the 30 MED average in the patient record
      - **Subject to additional review by OSDB and Pharmacy Board!!!**

Prescribing Regulations

- **New Limits on Prescription Opioids** (OAC 4715-6-02)
  - A **morphine equivalent dose (MED)** is the amount of opioid prescription drugs, converted to a common unit (milligrams of morphine), that a patient currently has access to based on the information reported by prescribers and pharmacies to OARRS. Morphine is widely regarded as the "standard" for the treatment of moderate to severe pain and is commonly used as the reference point. As MED increases, the likelihood of an adverse effect increases, therefore identifying at-risk patients is a crucial first step towards improving patient safety. OARRS utilizes conversion factors created by the US Centers for Disease Control and Prevention.

Prescribing Regulations

- **New Limits on Prescription Opioids** (OAC 4715-6-02)
  - Calculation of Daily Morphine Equivalent Dose (MED)
    - Strength per Unit x (Number of Units / Days Supply) x MME Conversion Factor = Daily MED
  - The Pharmacy Board has developed the following tools to assist prescribers in calculating a patient's morphine equivalent dose:
    - MED Conversion Chart
      - www.pharmacy.ohio.gov/MEDtable
    - Online MED Calculator
      - https://www.ohiopmp.gov/MED_Calculator.aspx

Prescribing Regulations

- **New Limits on Prescription Opioids** (OAC 4715-6-02)
  - These new limitations apply to the first opioid prescription for the treatment of an episode of acute pain
    - Permitted to issue another prescription upon subsequent visit
  - These new limits do not apply to inpatient prescriptions
  - These new limits do not apply to opioids prescribed for cancer, palliative care, end-of-life/hospice care or medication-assisted treatment for addiction

Questions?

Prescribing Regulations

- **Prescribing Opioids to Minors** (ORC 3719.061)
  - Prescribers must obtain written documentation of informed consent, in the absence of a medical emergency, prior to issuing a minor (under 18) an initial prescription for any drug classified as an opioid.
    - New OSDB prescribing limits eliminate the "surgery exception" to written consent requirement
  - "Informed Consent" requirement has three components:
    1. Assessing the minor's mental health and substance abuse history
    2. Discussing with the minor and the minor's parent/guardian certain risks and dangers associated with taking opioids
    3. Obtaining the signature of the parent/guardian on the consent form
  - Medical Board developed "Start Talking" Consent Form to assist prescribers
    - http://www.med.ohio.gov/DNN/PDF-Folders/Center-Panel/Start-Talking-Model-Consent-Form.pdf

Prescribing Regulations

- **Prescribing Opioids to Minors** (ORC 3719.061)
  - If the individual who signs the consent form is another adult authorized to consent to the minor's medical treatment, the prescriber is prohibited from prescribing more than a single, 72-hour supply of opioids
  - A signed consent form must be maintained in the minor's medical record and the form must be separate from any other document the prescriber uses to obtain informed consent for other treatment provided to the minor
  - The "Start Talking" consent form is not specifically required by law. Dental offices may develop their own form so long as it contains the required components

Questions?

Prescribing Regulations

- **New Requirements for Controlled Substance Prescriptions** (OAC 4729-5-30)
  - Effective December 29, 2017, prescribers are required to include the full procedure code (Current Dental Terminology – **CDT Code**) on all **opioid** prescriptions.
  - Effective December 29, 2017, prescribers are also required to indicate the **days' supply** on all **controlled substance** prescriptions.
    - "Controlled Substances" include other drugs in addition to opioids
  - Starting June 1, 2018, prescribers will be required to include the full procedure code (Current Dental Terminology – CDT Code) for all other controlled substance prescriptions.

Questions?

Contact the ODA

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