



Improving Pain Treatment Through Education

Opioids, Chronic Pain, and REMS

The PainEDU Webinar Series: January 14, 2015

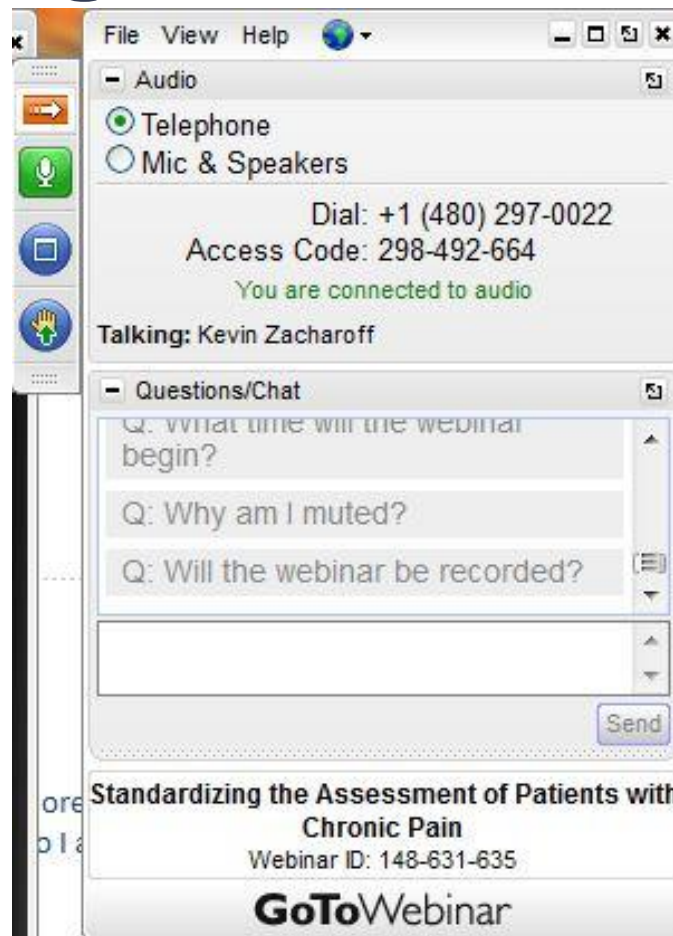
Purpose of the PainEDU Webinar Series

- A new way of communicating with the PainEDU community
- Sharing information and letting you know what we're developing
- Presenting pain-related topics that are engaging and relevant
- A chance for you to ask questions and interact with us

Webinar Logistics

- Telephones **must** be used for audio and should be muted at all times
- You **will not** be able to use your computer's microphone or speakers
- Please **do not** put your phone on hold
- Questions will be answered at the end of the presentation

Webinar Logistics



Availability of Today's Presentation:

- **An email will be sent to all attendees with access to:**
 - An archived recording of the webinar
 - Presentation slides

Faculty: Synne Wing Venuti, MSW



Ms. Venuti is the Product Manager of the Pain Management Programs at Inflexxion which include PainEDU.org, The PainEDU REMS Education Program, painACTION.com, the Inflexxion Health Series publications, and the PainEDU opioid risk assessment tools (SOAPP and COMM). She has over 10 years of experience working on pain management and opioid risk projects.

Faculty: Kevin L. Zacharoff, MD



Dr. Kevin Zacharoff is the Vice President of Medical Affairs at Inflexxion. He is a Board Certified Anesthesiologist with over 20 years of clinical practice experience in Anesthesiology and Pain Medicine. He is an active faculty member and clinical instructor at the State University of New York Stony Brook School of Medicine, and Emeritus Medical Staff Member of St. Catherine of Siena Medical Center, and is a Fellow of the American College of Physician Executives, the American College of International Physicians, and the American Academy of Pediatrics. Dr. Zacharoff's work as an educator has also included speaking and presentations at national pain meetings since 2003, and he has co-authored a number of articles and books on the subject of pain management. His work at Inflexxion includes oversight of the NAVIPPRO intervention and prevention programs, including the nationally-recognized websites, PainEDU.org, a website directed towards healthcare professionals with the mission of improving pain treatment through education, and www.painACTION.com devoted towards educating chronic pain patients.

Introduction

2000

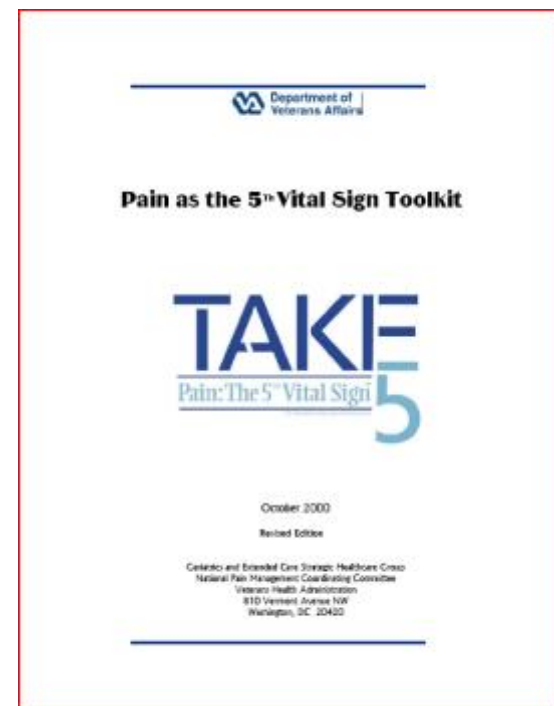
- **A national survey of medical residency programs in 2000¹ found:**
 - Of the programs studied, only 56 percent required substance use disorder training
 - The number of curricular hours in the required programs varied between 3 – 12 hours
- **This was also the beginning of the “*Decade of Pain Control and Research*”**
 - **October 31, 2000** – The 106th U.S. Congress passed H.R. 3244 and President Clinton signed this bill into law²
 - This is only the second Congressionally declared medical decade, the first being the “*Decade of the Brain*” in the 1990s

1. Isaacson JH, Fleming M, Kraus M, Kahn R, Mundt M. A National Survey of Training in Substance Use Disorders in Residency Programs. *J Stud Alcohol*. 61(6):912-915. 2000.

2. Title VI, Sec. 1603, provides for the “Decade of Pain Control and Research”.

An Important Step

- **Pain becomes the 5th Vital Sign^{1,2}**
 - *“Can help nurses and other healthcare providers overcome many of the barriers to successful pain control”²*
 - A successful pain control plan included:
 - Establishing the diagnosis
 - Treating the cause of the pain when possible
 - Optimizing analgesic use
 - Implementing non-pharmacological interventions
 - Maximizing physical and psychological comfort and function
 - Referring the patient for invasive pain management options when indicated



1. Lorenz, K.A. et al. "How Reliable is Pain as the Fifth Vital Sign?" *Journal American Board of Family Medicine* 2009; 22:291-8.
2. Lynch M. Pain as the Fifth Vital Sign. *J Intravenous Nurs.* 2001 Mar-Apr;24(2):85-94.

2011

- **EPIDEMIC: RESPONDING TO AMERICA'S PRESCRIPTION DRUG ABUSE CRISIS**
 - *“A crucial first step in tackling the problem of prescription drug abuse is to raise awareness through the education of parents, youth, patients, and healthcare providers”*
 - *“Although there have been great strides in raising awareness about the dangers of using illegal drugs, many people are still not aware that the misuse or abuse of prescription drugs can be as dangerous as the use of illegal drugs, leading to addiction and even death”*



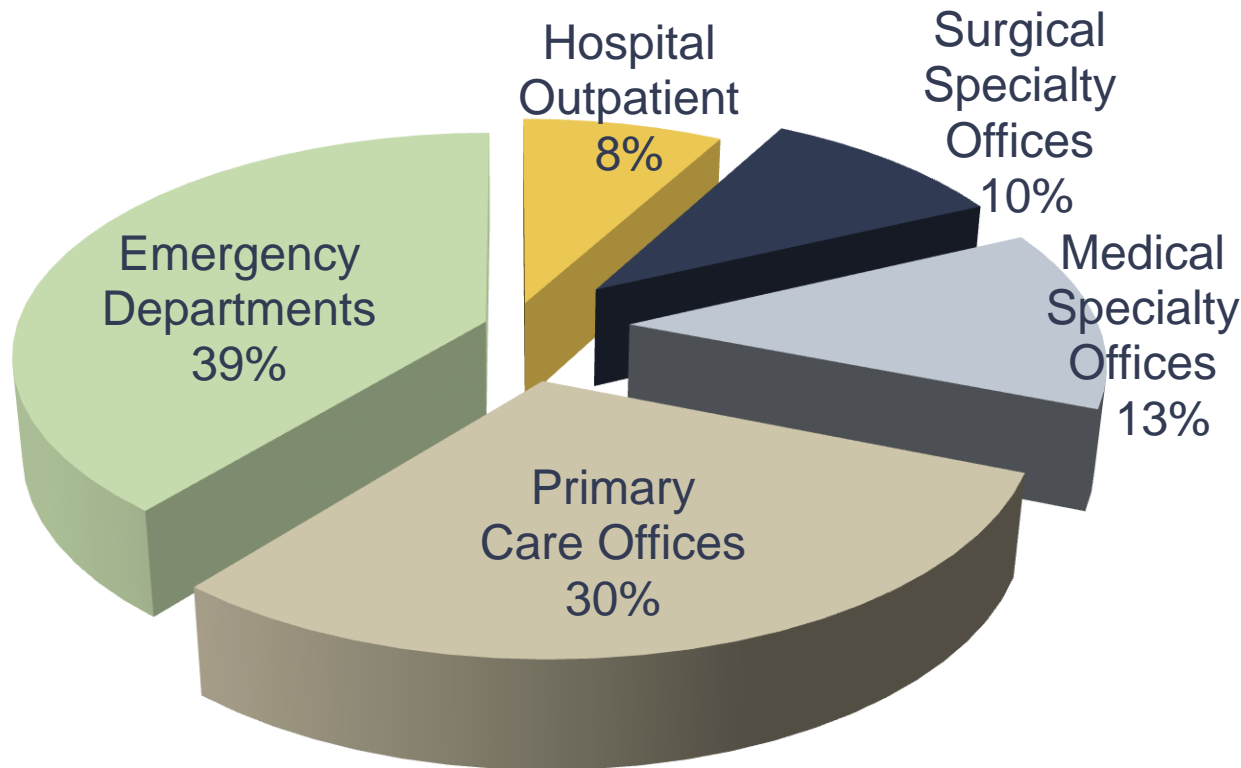
The Landscape

- **Healthcare Providers**
 - Experts
 - Non-experts
- **Where** are the pain patients presenting?
- **Who's** doing the prescribing?
 - The majority of opioids are prescribed by Primary Care Clinicians¹
 - **Family Practitioners (28.8%)**
 - **Internists (14.6%)**
 - **Dentists (8%)** – Largest group of prescribers 10-19 y/o
 - Most prescriptions were for hydrocodone- and oxycodone-containing products (84.9%, 67.5 million) and issued for short treatment courses (19.1% for 2 weeks, 65.4% for 2-3 weeks)



1. Volkow, McLellan, and Cotto . Characteristics of Opioid Prescribing in 2009. JAMA. April 6, 2011—Vol. 305, No. 13.

Distribution of Prescription Opioid Analgesics by Health Care Setting



What *are* REMS?

- ***Risk Evaluation and Mitigation Strategies***
 - On September 27, 2007, the President signed into law the ***Food and Drug Administration Amendments Act*** of 2007 (***FDAAA***)
 - **NEW Authorization for** FDA to require certain drug manufacturers to submit a proposed REMS ***if the FDA determines that a REMS is necessary to ensure that the benefits of a drug outweigh the risks of the drug***
- **REMS ARE ENFORCEABLE**

REMS Goals

- The desired safety-related health outcome or the understanding by patients and/or healthcare providers of the serious risk(s) associated with a certain medication
 - Stated in a way to achieve maximum risk reduction
- Examples:
 - Healthcare providers are aware of **how to assess patients appropriately** to determine the risk/benefit ratio
 - **Patients** taking drug “X” **should be aware** of the serious risks relative to potential benefits

Possible REMS Components

- **Healthcare providers should have:**
 - Particular experience
 - Training
 - In some cases, “certification”
- **For example:**
 - Be able to diagnose the condition for which the medication is indicated
 - Understand/communicate the risks and benefits of the medication
 - Can diagnose and treat potential adverse reactions and negative outcomes

Possible REMS Components

- The drug is dispensed only to patients with evidence or other documentation of safe-use conditions
- For example:
 - Patients have been counseled about risks and benefits and signed acknowledgement about them
 - Patients have been provided a copy of patient educational materials ***and demonstrated that they understand*** the risks and benefits
 - Patients receive the drug only after authorization is obtained ***and verified***

Chronic Pain

- **Pain is one of the most common reasons for seeking medical attention**
 - The population is aging, and the % of people with chronic pain increases in almost a linear fashion
 - New conditions are being identified – e.g., fibromyalgia
 - Poorly controlled acute pain may be more likely to develop into chronic pain
- **Economic consequences**
 - Productivity
 - Absenteeism
 - Billions in healthcare \$\$

Opioids and Chronic Pain

- Opioids have demonstrated to be effective in treating chronic pain in a variety of clinical conditions
- Alternatives to opioids may also carry risk
 - NSAIDS
 - COX-2s
 - Surgery
- Can be safely and effectively if used appropriately...
 - By prescribers
 - By patients

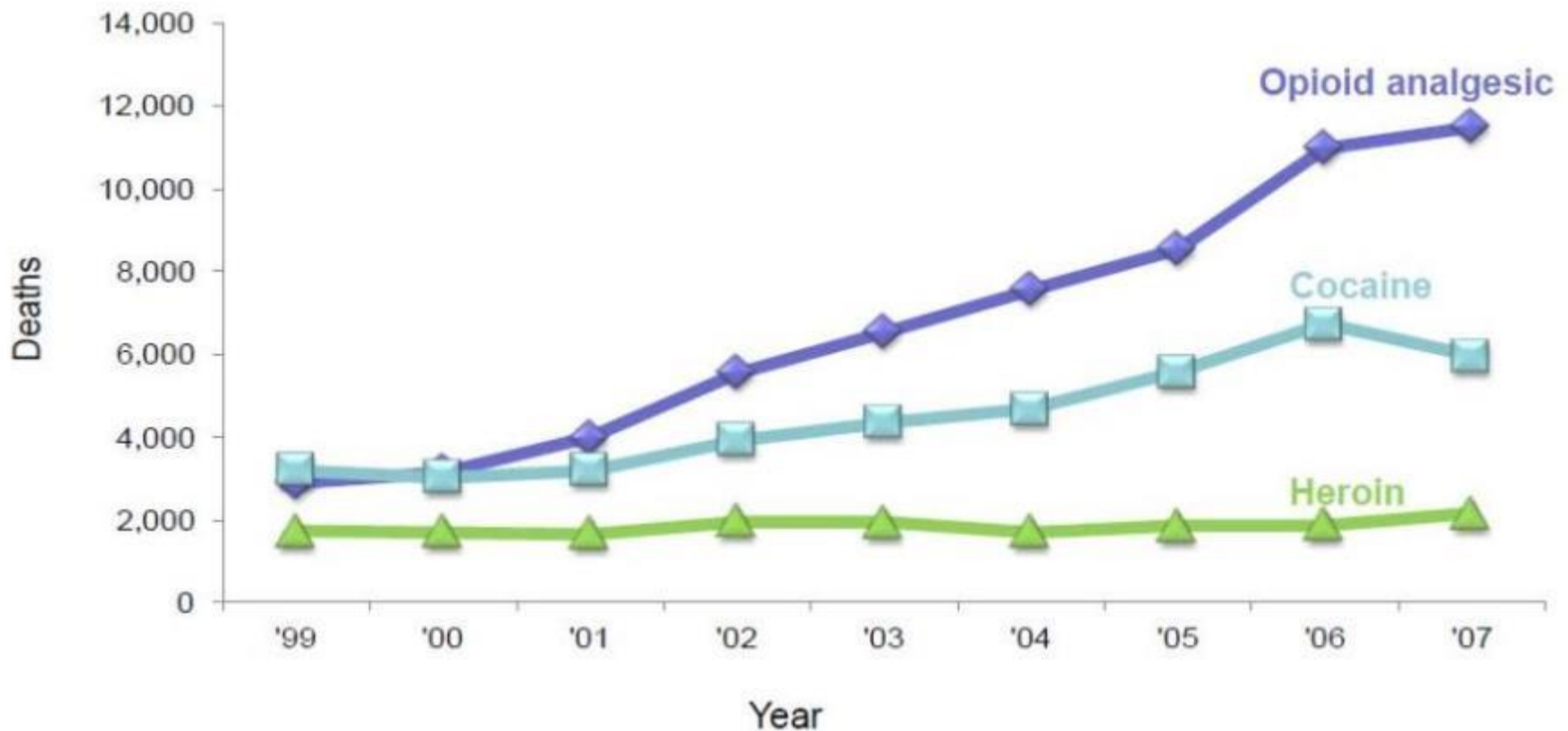
Challenges to Healthcare Providers

- **Challenges Include:**
 - **Policies** – Assess and treat
 - **Guidelines** – APS/AAPM, Joint Commission, AAHPM, ACS
 - **Expectations** – Treat or be sued, bill of rights
 - **Ever-shorter office visits** – 7 minutes or less?
 - **Complicated patients** – Hx of addiction or abuse
 - **Little training** in pain management and aberrant drug-related behavior – Educational deficits are huge
 - **Regulatory scrutiny** – FDA, DEA, FDAAA, etc.

Opioid Risk

- ***“New” Definition vs. “Old” Definition***
 - Adverse effects
 - Aberrant drug-related behaviors
 - Abuse
 - Misuse
 - Diversion
 - **Addiction**
 - ***Unintended Deaths***

Unintentional Overdose Deaths Involving Opioid Analgesics, Cocaine, and Heroin



Source: CDC Public Health Grand Rounds 2.18.2011 Data from the National Vital Statistics System.
<http://wonder.cdc.gov>, multiple cause dataset

PainEDU REMS Education Program



Dependent on Prescription Drugs, Even Before Birth
By ABBY GOODNOUGH and KATIE ZEZIMA New York Times Published: April 9, 2011

Montefiore
THE UNIVERSITY HOSPITAL

EINSTEIN
Albert Einstein College of Medicine
OF YENNEBA UNIVERSITY

AN INFLEXION SOLUTION

“*The Letter*” about REMS

- Written to all manufacturers of extended-release/long-acting opioids from the FDA
 - This letter is to inform you (*insert manufacturer’s name*) that the Agency has determined certain opioid products, including *DRUG NAME*, will be required to have Risk Evaluation and Mitigation Strategies (REMS), to ensure that the benefits of the drugs continue to outweigh the risks of:
 - **Use of certain opioid products in non-opioid-tolerant individuals**
 - **Abuse**
 - **Overdose, both accidental and intentional**
 - The REMS will include elements to assure safe use to ensure that prescribers, dispensers, and patients are aware of and understand the risks and appropriate use of these products

Stakeholders

- **The Federation of State Medical Boards**
- **Government agencies**
- **Prescribers**
- **Patient and consumer advocates**
- **Pharmacists/dispensers**
- **Pain and addiction treatment communities**
- **Professional societies**
- **State Licensing Boards**

2015

- **Prescriber Education (*Voluntary*)**
 - Information about appropriate patient selection, dosing, and patient monitoring
 - Training for patient counseling on the safe use, storage, and disposal of opioids
 - Demonstration by sponsors of prescriber training, and that the knowledge of appropriate use was improved, via surveys of the prescribing community
 - No formal prescriber enrollment or real time verification of the training at the pharmacy level

The “Blueprint”

- **Outlines that prescribers should:**
 - Understand how to assess patients for treatment with ER/LA opioids
 - Be familiar with how to initiate therapy, modify dose, and discontinue use of ER/LA opioids
 - Be knowledgeable about how to manage ongoing therapy with ER/LA opioids
 - Know how to counsel patients and caregivers about the safe use of ER/LA opioids, including proper storage and disposal
 - Be familiar with general and product specific drug information concerning ER/LA opioids

Patient Assessment

- **Consideration of risks involved with ER/LA opioids and balance these against potential benefits**
 - Risks of concern include:
 - Overdose due to the high dosage of opioid available as an ER/LA formulation
 - Intentional abuse by patient or household contacts
 - Addiction
 - Interactions with other medications and substances
 - Inadvertent exposure to household contacts (e.g., children)

Initiating Therapy, Modifying Dosing, and Discontinuing Use of ER/LA Opioids

- Awareness of federal and state regulations
- Consideration that dose selection is critical
- Knowledge about conversion from IR to ER/LA, and from one ER/LA to another
- Issues surrounding cross-tolerance
- Equianalgesic dosing concepts and monitoring
- Necessity for tapering when decision is exit strategy

Managing Ongoing ER/LA Therapy

- **Clear establishment of goals of treatment**
 - Regular re-evaluation for pain, function, and QOL
- **Use Patient-Provider Agreements (PPA)**
 - Not mandated
- **Assurance that patients are adherent to treatment plan**
- **Monitor patients for aberrant behaviors**
 - Awareness
 - Interview
 - PDMPs
 - Screening for substance abuse/behaviors (e.g., SOAPP, ORT)
 - Understand the role of drug-screening (e.g., UDT)
 - Medication reconciliation at each visit

Counseling of Patients and Caregivers

- **Product-specific information**
 - Directions for safe and appropriate use
 - Adverse effects
- **Explicit warning against modification of formulation (e.g., crushing, chewing)**
- **Caution about use of other CNS depressants concomitantly**
- **Signs/Symptoms of withdrawal**
- **Warning about sharing**
- **Safe storage/Disposal**

General Information about ER/LA Opioids

- **General characteristics**
- **Toxicity**
- **Drug interactions**
- **Examples:**
 - Respiratory depression
 - Constipation
 - Drug-drug interactions
- **Tolerance**
- **Specifics about formulation (e.g. oral, transdermal)**

Specific Information About ER/LA Opioids

- Knowledge related to the molecule
- Dose form/strength
- Dosing interval
- “Key” instructions to convey to patients
- Major drug interactions
- Use in opioid-tolerant patients
- Drug-specific adverse events
- Morphine equivalency

- **The PainEDU REMS Education Program:**
 - Is a direct response to the FDA Risk Evaluation and Mitigation Strategy (REMS) and is sponsored and certified by Albert Einstein College of Medicine and Montefiore Medical Center, under the direction of Naum Shaparin, MD. and Kevin L. Zacharoff, MD
 - Consists of 3 one-hour CME activities, totaling 3.0 AMA PRA Category 1 Credits, and focuses on the safe and effective management of pain with ER/LA opioid analgesics in accordance with the FDA Blueprint
 - Is directed towards prescribers of ER/LA opioid analgesics, but is also relevant for other healthcare professionals

- **Topics covered:**
 - Fundamentals of Safe and Effective use of ER/LA Opioid Analgesics in the Management of Chronic Pain
 - Safe and Effective Management of ER/LA Opioid Analgesic Therapy
 - General Concepts and Information About ER/LA Opioid Analgesics



In Summary

Questions and Answers

Post-Webinar Activities

- Visit the PainEDU REMS Education Program Website:
<https://rems.painedu.org>
- Contact us:
 - Phone: 617-614-0375
 - Email: **rems@painedu.org**



Improving Pain Treatment Through Education

Thank You

**The next PainEDU webinar will take place
in the spring so stay tuned!**