

# COMBATting AMERICA'S OPIOID EPIDEMIC WITH MEDICAL TECHNOLOGY

## THE OPIOID CRISIS IS KILLING THOUSANDS OF AMERICANS EACH YEAR

Americans' dependence on opioids has greatly contributed to the current drug abuse epidemic in this country. The human toll of this epidemic has reached alarming proportions with more than 53,000 drug overdoses in 2016,<sup>1</sup> and 33,000 of those deaths were reportedly due to opioids.<sup>2</sup> As a result, the government has declared the opioid crisis a public health emergency.

Opioids are a class of drugs that include synthetic opioids such as fentanyl, and pain relievers prescribed by doctors legally, such as oxycodone (OxyContin®), hydrocodone (Vicodin®), codeine, morphine, and others. Additionally, illegal drugs like heroin are a part of this class of drugs.

In many cases, doctors have prescribed opioids to relieve acute pain related to injuries or surgery. However, a dangerous side effect is that these drugs have a high potential for abuse, and prolonged use can lead to opioid addiction and misuse. According to a 2016 survey data from the Substance Abuse and Mental Health Services Administration, 2.4 million Americans have an opioid-use disorder.<sup>3</sup>

➤ According to the U.S. Centers for Disease Control and Prevention, from 1999-2015, the amount of prescription opioids dispensed in the U.S. nearly quadrupled.<sup>4</sup>

or 2.8 percent of the GDP that year—six times more than any recent estimate.<sup>4</sup> This figure incorporates increased health care costs related to illicit opioids and prescription opioids misuse, lost worker productivity and lost wages due to addiction and incarceration, additional criminal justice costs, and the value of lives lost to opioid overdoses.<sup>4</sup>

➤ More than 650,000 prescriptions for opioids are filled each day in the U.S.<sup>5,6</sup> and many are consumed for non-medical, abuse related purposes.

Further, the opioid epidemic reaches deep in to the health care community, with the Substance Abuse and Mental Health Services Administration estimating that more than 100,000 health care workers struggle with abuse or addiction. Termed “drug diversion,” substance abuse among medical professionals can put patients at risk through job impairment as well as increased risk of infection.<sup>7,8,9,10,11</sup> Improperly disposed, unused opioids are a significant source of drugs for this population.

➤ Tragically, 91 Americans die every day from an opioid overdose,<sup>12</sup> making overdoses the leading cause of death among people under the age of 50.<sup>13</sup>

A recent Council of Economic Advisors report found that the economic cost of the opioid crisis was \$504 billion in 2015,

1. The Altarum Institute, The Potential Societal Benefit of Eliminating Opioid Overdoses, Deaths, And Substance Use Disorders Exceeds \$95 Billion Per Year, November 16, 2017.
2. The Council of Economic Advisors, The Underestimated Cost of the Opioid Crisis, November 19, 2017.
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4. Centers for Disease Control and Prevention, Wide-ranging online data for epidemiologic research (WONDER). Atlanta, GA: CDC, National Center for Health Statistics; 2016. Available at <http://wonder.cdc.gov>.
5. Help, Resources and Information, HHS, viewed January 29, 2018: <https://www.hhs.gov/opioids/>
6. Prescribing Data, Centers for Disease Control and Prevention (CDC), viewed January 29, 2018: <https://www.cdc.gov/drugoverdose/data/prescribing.html>

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11. Baldwin, G. 2015. CDC, Division of Unintentional Injury Prevention, viewed 12 May, 2017, <https://www.fda.gov/downloads/drugs/newsevents/ucm454826.pdf>.
12. Centers for Disease Control and Prevention, Drug overdose deaths in the United States continue to increase in 2015, August 2017.
13. The New York Times, Drug Deaths in America Are Rising Faster Than Ever, By Josh Katz, June 5, 2017.

## MEDICAL TECHNOLOGY HAS THE POTENTIAL TO HELP FIGHT THE OPIOID EPIDEMIC

Today, there are innovative medical technology solutions available that can help play a role in combatting this national crisis. Solutions that have the potential to reduce our country's dependence on opioids include implants and other devices, as well as apps and diagnostic tests that facilitate effective pain management and help curb the misuse, abuse, and overdose of opioids. Additionally, medical technology companies are developing innovations that are minimally-invasive, enabling patients to return to routine activities in a shorter period of time while experiencing less pain and discomfort after surgery.

As the Administration and Congress investigate this critical issue, medical technology solutions should be a part of the national conversation. According to Dr. Scott Gottlieb, Commissioner of the Food and Drug Administration (FDA), the agency has approved more than 200 different medical device alternatives that help treat pain.<sup>14</sup> In addition, a final report issued by the President's Commission on Combating Drug Addiction and the Opioid Crisis encourages research and development of new technologies and devices to assist in the opioid crisis.<sup>15</sup>

## NEW APPROACHES TO ADDICTION: MEDICAL TECHNOLOGIES AND DIAGNOSTICS

### Monitoring Withdrawal & Preventing Overdose

Several technologies and apps have been developed to manage opioid withdrawal symptoms and to help caregivers and first responders administer life-saving drugs quickly and confidently to potential overdose victims. These include:

#### Peripheral Nerve Stimulation (PNS)

- Battery-powered chip, placed behind a patient's ear, that emits electrical pulses to stimulate branches of certain cranial nerves.
- Helps patients block difficult withdrawal symptoms when trying to quit opioids.

#### Auto-Injection System

- Take-home naloxone auto-injection system with voice and visual guidance.
- Naloxone is a medication designed to rapidly reverse opioid overdose.
- Helps caregivers take fast, confident action administering naloxone in an opioid emergency.

- Can temporarily reverse the effects of opioids and help keep a patient breathing until first responders arrive.

#### Naloxone App

- Free mobile app designed to connect any at-risk opioid user to an enrolled naloxone carrier.
- Allows people who are alone to summon a carrier to the geolocation of the victim.
- Paired with a breathing monitor that detects when a victim's breathing rate is in a dangerous range.

#### Battery-Operated Chip

- Emerging intuitive device that uses naloxone to help decrease opioid overdose.
- Sends impulses to specific nerves to block pain.
- Currently in trials – almost 90 percent of patients who use the device make it through the first week of detox and into secondary therapy.

➤ Pain affects more Americans than diabetes, heart disease, and cancer combined.<sup>16</sup> It is cited as the most common reason Americans access the health care system, and is a major contributor to health care costs.<sup>17</sup>

### Treating Acute Pain

Millions suffer from acute pain that usually comes on suddenly and is caused by something specific such as surgery, broken bones, dental work, or childbirth. Acute pain typically does not last longer than six months.<sup>18</sup>

#### Continuous Peripheral Nerve Block (cPNB)

- Small catheter is placed at surgical site during procedure.
- Catheter allows for continuous infusion of fast acting anesthetics using an ambulatory pump, clinically proven to reduce exposure to opioids during and after surgery.
- Can be used in hospitals, home care settings, and alternative care facilities.

#### Cryotherapy (Cold Therapy) Treatment

- Uses the body's natural response to cold to treat peripheral nerves, immediately reducing pain.
- In some cases, delivers cold therapy through a portable, handheld delivery system.
- Reduces opioid use following surgery.

14. U.S. House Committee on Energy and Commerce, Hearing: Federal Efforts to Combat Opioid Crisis: A Status Update on CARA and Other Initiatives, October 25, 2017.

15. The President's Commission on Combating Drug Addiction and the Opioid Crisis, Final Report, November 1, 2017.

16. National Institutes of Health, Pain Management, <https://report.nih.gov/nihfactsheets/ViewFactSheet.aspx?csid=57>

17. Ibid

18. Cleveland Clinic, Acute vs. Chronic Pain. Available at <https://my.clevelandclinic.org/health/articles/acute-vs-chronic-pain>.

## Peripheral Nerve Stimulation (PNS)

- Uses a small, wearable stimulator connected to a thread-like wire lead to deliver tiny electrical pulses to stimulate nerves in a manner that is intended to provide targeted pain relief.
- Delivers pain relief without drugs, implants, anesthesia or incisions.

## Portable Pain Relief Systems

- Part of a multimodal pain management approach after surgery.
- Provides predictable pain relief.
- Stimulation produces endorphin release. Endorphins reduce the perception of pain.
- Reduces postoperative opioid use while achieving pain management.
- Can also be used to treat chronic pain.

## Neuromuscular Electrical Stimulation

- A form of neuromodulation that uses electrical waveform and pulses to stimulate muscles, improve muscle strength, increase range of motion, increase circulation, reduce edema, and reduce weakness or atrophy.

## Managing Chronic Pain

Chronic pain is defined as ongoing pain that lasts longer than one month.<sup>21</sup> A study by the National Institutes of Health found that one in 10 Americans experiences pain every day for three months.<sup>22</sup> Many people accidentally become addicted to opioids while trying to treat their debilitating pain. However, several medical technology alternatives have been proven to reduce or eliminate pain altogether.

### Pain in Numbers

In the United States, 70 million patients are prescribed opioids for postsurgical pain each year. Of those patients, one in 15 will go on to experience long-term use or abuse.<sup>19</sup>

72 percent of patients would choose non-narcotic pain medication for postsurgical pain management.<sup>20</sup>

## Implantable Intraspinal Drug Infusion Pumps

- Neuromodulation treatment that involves administration of medications directly to the body's nervous system.
- Delivers pain medication directly to the fluid surrounding the spinal cord.
- Patients receive about one percent of the drug previously taken orally, greatly reducing the number of opioids needed to treat pain.

## Deep Transcranial Magnetic Stimulation (TMS) therapy

- Performs magnetic stimulation of brain structures and networks related to chronic pain.
- Stimulates superficial cortical regions of the brain.

## Pulsed Electromagnetic Field (PEMF) Therapy

- Uses dual-field electric and magnetic energy to effect a more natural expression of genes and proteins.
- Pain pathways are affected in two ways: Increasing the body's naturally-occurring pain-relief mechanisms, and reduction of inflammation and swelling.
- Treatment is non-invasive and typically sensation-free.
- Patients can be treated in the outpatient setting or at home.

## Radiofrequency Neuroablation

- Uses a minimally invasive procedure to heat up a small area of a nerve or tissue, blocking pain signals traveling from the pain area to the brain.
- Performed as an outpatient procedure and usually does not require general anesthesia.
- Useful for the management of chronic back pain, neck pain, and pain associated with arthritis of the knee and hip.

## Spinal Cord Stimulation (SCS)

- Neuromodulation treatment that involves stimulation of the body's nervous system.
- Uses electrical signals to block pain signals from reaching the brain.
- Can help to manage chronic pain of the neck, back, arms and legs, often after spine surgery, or for other neuropathic conditions.
- Minimally invasive and is trialed for efficacy before a patient receives a permanent implant.

19. Becker's Spine Review: Mary Rechteris Nov 3, 2015: Reducing Opioid Dependence: Available From: <http://www.beckersspine.com/spine/item/27948-reducing-opioid-dependence-the-multimodal-approach-to-pain-management.html>

20. Apfelbaum JL, Chen C, Mehta SS, Gan TJ. Postoperative pain experience: results from a national survey suggest postoperative pain continues to be undermanaged. *Anesth Analg*.

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21. Guidance for Industry Analgesic Indications: Developing Drug and Biological Products: <https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM384691.pdf>.

22. The Good Body, Chronic Pain Statistics: Facts, Figures and Research, 2017.

## ↳ Draining the Health Care System

Cases of chronic pain are the leading cause of long-term disability in the United States. This pain also adversely affects mental and emotional well-being, impacting a person's ability to work, and their quality of life.<sup>23</sup>

Chronic pain alone costs up to \$635 billion each year in medical treatment and lost productivity.<sup>24</sup>

## Monitoring Overdose Risk through Diagnostic Tests

Diagnostic tests are a critical tool to monitor pain medication use and are essential to reducing the number of people addicted to opioids. These tests also help identify high-risk patients who are abusing or diverting prescription drugs, and help doctors determine what medications are appropriate for the individual patient.

### Diagnostic Tests

- Monitor pain medication use, helping ensure the appropriate treatment for patients who can be helped by medications.
- Identify high-risk patients who are abusing or diverting prescription drugs.

### Pain Medication DNA Insight

- Provides genetic testing to help physicians determine appropriate medication.
- Explains how patients metabolize certain drugs, which medications may cause adverse side effects, and which medications may require higher or lower dosages.

### Blood Testing

- Administered to chronic pain patients receiving daily opioids.
- Helps opioid prescribers document and assess patient tolerance, monitor patient safety, and evaluate patient compliance.

## Medication Management Devices and Apps

There are devices and apps that help people manage their daily medications by monitoring the medication dosage and schedule to encourage responsible stewardship. Additionally, medication delivery, dispensing, and disposal technology can help to prevent and detect drug diversion in health care facilities, while also promoting patient safety.

## Medication Management/Dispensing Technology

- Technology that stores and dispenses medications of the correct dose, at the appropriate time.
- Can be used in a hospital setting or at home.
- Technologies can be paired with software that can monitor and track pain levels as well as alert patients if they are late for a dose or don't receive their dose.

## Medication Disposal Technology

- Technology that securely captures partially administered or unused controlled substances and renders them non-retrievable and unusable.
- Used across the care continuum wherever opioids are administered or dispensed by health care professionals, from EMS vehicles to ORs to pharmacies.

## Medicine Management App

- App captures the color and shape of a patient's medications along with dosages and schedules.
- Sends patients push notifications when it's time to take their medications, and notifies a friend or family member if the patient forgets.

## ↳ Less Invasive

Millions of U.S. patients per year undergo surgery resulting in acute post-operative pain. Medical technology enables minimally invasive surgery (inclusive of laparoscopic surgery, video-assisted thoracoscopic surgery, and robotic surgery) which delivers safe and effective treatment while reducing the size of the surgical incision, resulting in less operative trauma versus open surgical approaches.



**AdvaMed.org**

701 Pennsylvania Ave, N.W., Suite 800  
Washington, D.C. 20004

23. American Chronic Pain Association, ACPA Resource Guild to Chronic Pain Medication & Treatment, 2015.

24. American Pain Society, Chronic Pain Costs U.S. Up to \$635 Billion, Study Shows, 2012.