Safe Prescribing Initiative

HANLEY FOUNDATION

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Educate. Change Minds. Save Lives.

Safe Prescribing Toolkit

Know the Risks. Manage the Outcomes.

2023

PARENTS

PATIENTS

PROVIDERS

01.

Introduction

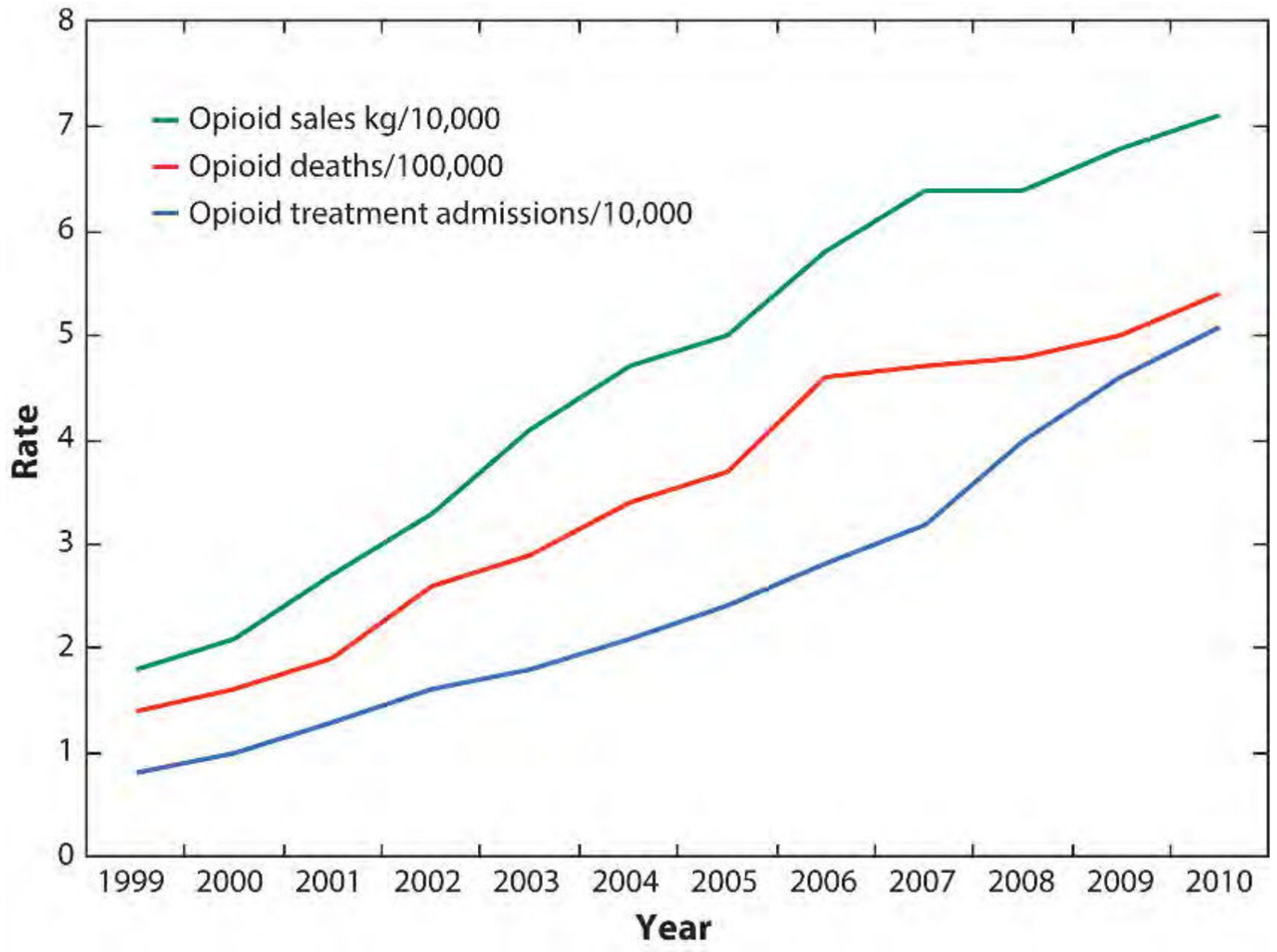
What is an Opioid?

Opioids are a class of drugs that include natural and synthetic analgesics, such as oxycodone and morphine, and the illegal drug heroin. However, despite serious risks and a lack of evidence about their long-term effectiveness, there has been a dramatic increase in the use of prescription opioids for treating less severe chronic pain unrelated to terminal illnesses in recent years.

The Prescription to a Problem

Overdoses from opioids are on the rise and killing Americans of all races and ages. Families and communities across the country are struggling with the health, emotional, and economic effects of addiction to prescription opioids. Research shows that an increased number of opioid overdose deaths is associated with an increase in the number of opioid prescriptions. Therefore, the first step to decreasing the number of opioids caused deaths is to reduce the number of opioid prescriptions.

As a result, the Hanley Foundation has created the Safe Prescribing Initiative, a program aimed at raising awareness of the dangers surrounding prescription opioids and our children and adolescents. The Hanley Foundation has designed the Safe Prescribing Initiative to combat the issue at its root and to stop addiction before it starts.



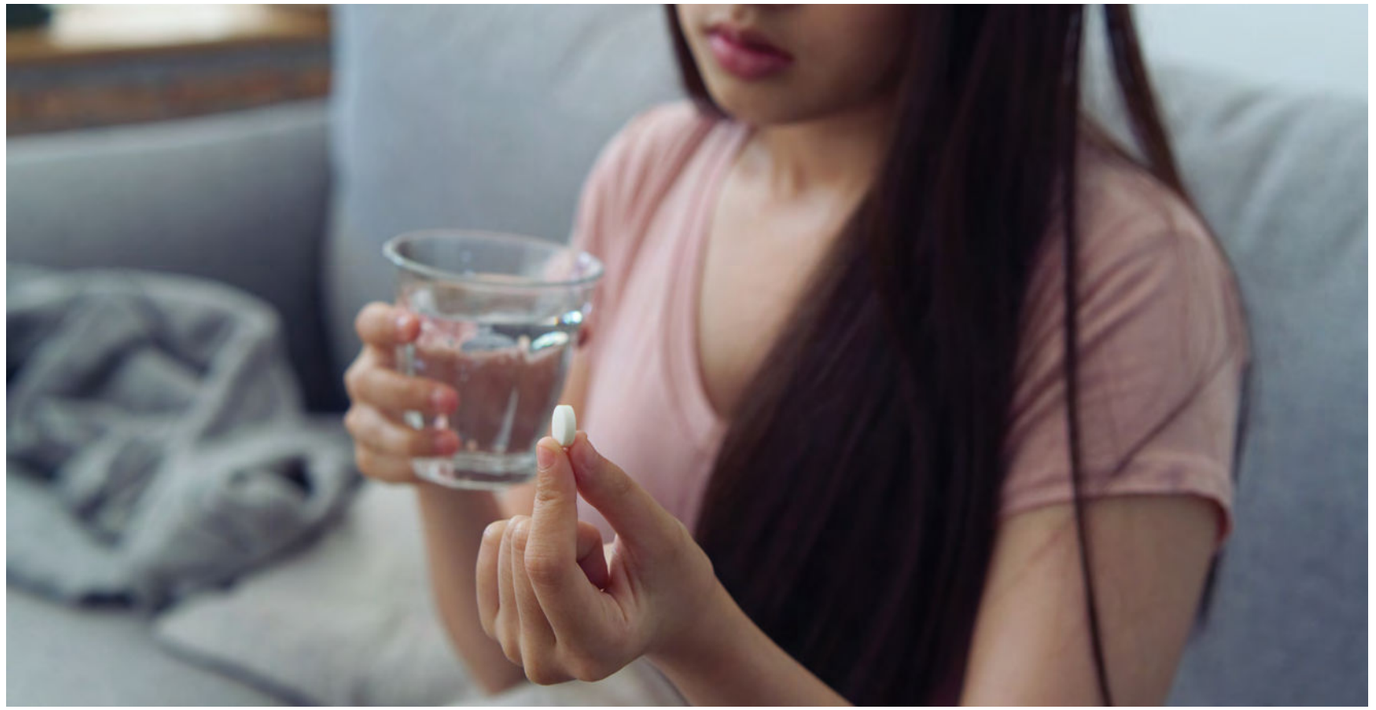
02.

The Safe Prescribing Initiative

Background

The youth, 18 years and younger, is a highly vulnerable group in the present-day opioid epidemic. In addition, adolescents' misuse or abuse of opioids is associated with future opioid use disorder and high-risk behavior. [20, 151, 133] Communities and policy writers must begin vesting a considerate amount of attention and resources in promoting safer prescribing practices among physicians and other prescribers involved in the care of patients 18 years and younger due to the recent increase in opioid-associated deaths in the pediatric population. For instance, a 2013 study found that about 37% of high school seniors misusing prescription opioids were abusing the leftover opioids from their previous prescriptions.

Although research shows that opioid-prescribing practices and perceptions of opioid abuse or misuse differ dramatically among specialized pediatric surgeons, until 2020, there was no evidence-based guideline for prescribing opioids to patients 18 years and younger following surgical procedures. And despite the various label warnings published by government and health agencies, such as the



Food and Administration (FDA) black-box warning, different prescribers continue to send children home with scripts for medications such as tramadol and codeine.[14 JAMA]

The Safe Prescribing Initiative has been designed to target the opioid epidemic in Palm Beach County by raising awareness of the issues associated with our children using prescription opioids. Furthermore, The Safe Prescribing Initiative presents direct and indirect advantages for our community through its integrative, evidence-driven design. For instance, reducing the immediate availability of prescription opioids in adolescents' environments also decreases the risk of misuse of prescription opioids by children and adolescents. And by reducing the risk of misuse or abuse of prescription opioids, we also decrease the risk of addiction, overdose, and death caused by prescription opioids.

Risk & Protective Factors

Evidence has shown that community-focused programs, such as The Safe Prescribing Initiative and policy changes, can help reduce opioid abuse and overdoses. However, such community-focused programs must be carefully designed and tailored to their target audience to make long-lasting changes in the served population. As a result, The Safe Prescribing Initiative has only used evidence-based research to develop its processes and materials.
A key component of successful pilot community programs addressing adolescent addiction is early recognition and integration of population-specific risk factors. After all, one can only adequately implement a solution after correctly identifying the issue.

Research conducted by the 2021 Partnership to End Addiction defined risk factors as "characteristics or circumstances in a child's life that increase the likelihood that they will experience more difficult challenges." Therefore, some children may have characteristics that put them at risk of developing an addiction once exposed to prescription opioids. In contrast, others have lived or are currently living

under circumstances that may lead the child to develop an addiction once exposed to prescription opioids. Such characteristics and circumstances must become part of prescribers' routine as a risk assessment review before prescribing an opioid to any patients, but most importantly to children.

The 2021 Partnership to End Addiction also identified and defined protective factors as "characteristics or circumstances that can serve as buffers against negative outcomes." Once again, indicating that some children have innate traits, and others may live in environments that can serve to

decrease their likelihood of developing an addiction if exposed to a prescription opioid. It is important to note that there are many resources that parents can use to increase or create protective factors for their children while also decreasing or eliminating risk factors that may affect their children. For example, research indicates that interventions must adequately target risk and protective factors at all levels, including individual, family, and community, to maximize the impact of effective substance use prevention initiatives.

After careful review, risk and protective factors were grouped into three environments, school, home, and community. The interactions between the three environments create the blocks for the three main pillars of our children's lives, academic, social, and developmental. Evidence suggests that a minimum benchmark must be met within each pillar for the child to thrive. Therefore, The Safe Prescribing Initiative has been tailored to target the three main aspects of our children's lives: academic, social, and developmental. To effectively reach the three pillars of our children's lives, The Safe Prescribing Initiative has been strategically divided into three major components: education, awareness, and communication.

The education aspect will provide evidence-based materials tailored to the target audience to communicate the risks of using prescription opioids to treat moderate to severe pain. The target audience can be divided into three subgroups: healthcare providers, parents, and patients (children under 18). The awareness component comprises a targeted marketing campaign of billboards, bus banners, and videos to spread awareness of the Safe Prescribing Initiative. Finally, the communication piece will focus heavily on in-office visits to local healthcare providers to discuss alternatives to opioid prescriptions.

All three components of the initiative will be housed on its website, along with on-demand training created for various levels and types of healthcare providers.

Program Framework

Most public health professionals agree that all effective programs consist of a well-designed framework. However, an adequate framework involves more than program goals, stakeholders, and metrics. Instead, an efficient program design consists of practical, feasible, ethical, and accurate procedures.

The Safe Prescribing Initiative has mirrored the Centers for Disease Control and Prevention's (CDC's) Framework for Program Evaluation in Public Health, established in 1997. The Safe Prescribing Initiative has followed the five operating principles for public health programs proposed within the 1997 framework. The operating principles are as follows:

1. To use science as the basis of decision-making and action.
2. To use public health action as a source to expand social equity.
3. To perform effectively as a service agency.
4. To make outcome-focused efforts.
5. To being accountable.

As such, the Safe Prescribing Initiative has developed specific plans through inclusive partnerships with feedback systems that allow learning and ongoing adaptations. For example, we have created two panels, the community, and the professional panels, to integrate evaluation and operations by emphasizing continuous monitoring of the initiative's materials and training that are practical and involve all stakeholders.

Furthermore, the professional panel will serve as a reviewer of evaluations of evidence-based and adapted information used in the initiative's materials. As a result, the professional board will complement program management by reviewing the data used to improve and measure the initiative's effectiveness. Finally, the community panel will function as a pilot for sharing the materials for population testing and refinement.

Using evidence-based sources adapted to our community and reviewed by two external boards with feedback systems for adaptation and data collection allows the Safe Prescribing Initiative to meet all five operating principles. Therefore, the initiative has been created with a science-based framework to expand social equity for all Palm Beach County residents through on-demand access to educational materials and training.

Desired Outcome

Addiction to prescription opioids can happen to anyone at any time, which is why it is so important that we all work together to cease the exposure of our children to potential life-altering opportunities to abuse prescription opioids. Ultimately, the Safe Prescribing Initiative's goal is to keep our children and community safe from addiction by decreasing the number of opioid prescriptions per capita in Palm Beach County.

03.

For the Parents & Patients

PRESCRIPTION OPIOIDS & OUR CHILDREN

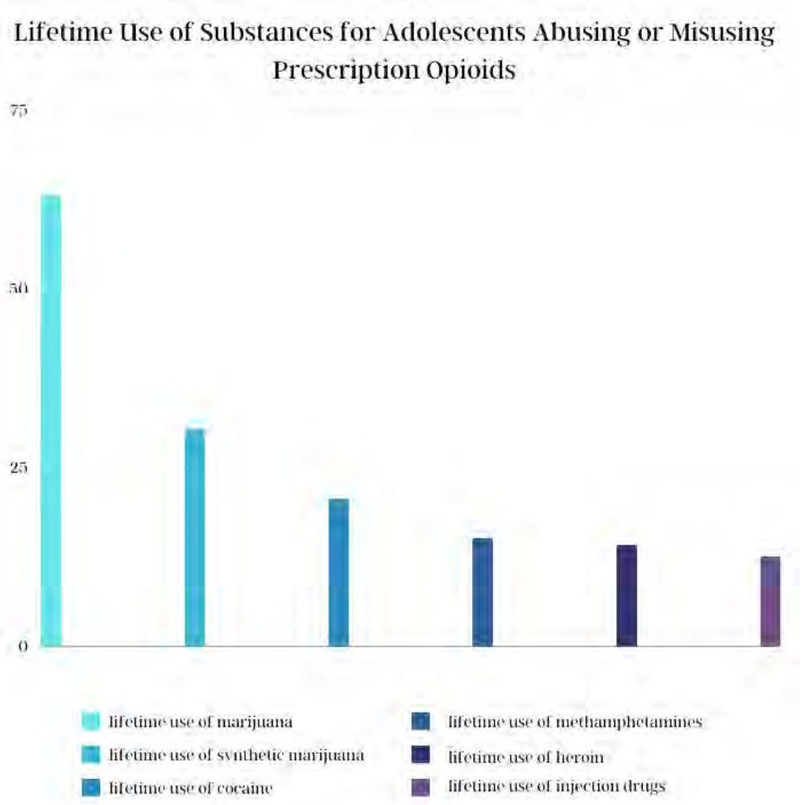
PRESCRIPTION OPIOIDS IN OUR COMMUNITY

A PILL CAN COST A LIFE

KNOW YOUR OPTIONS

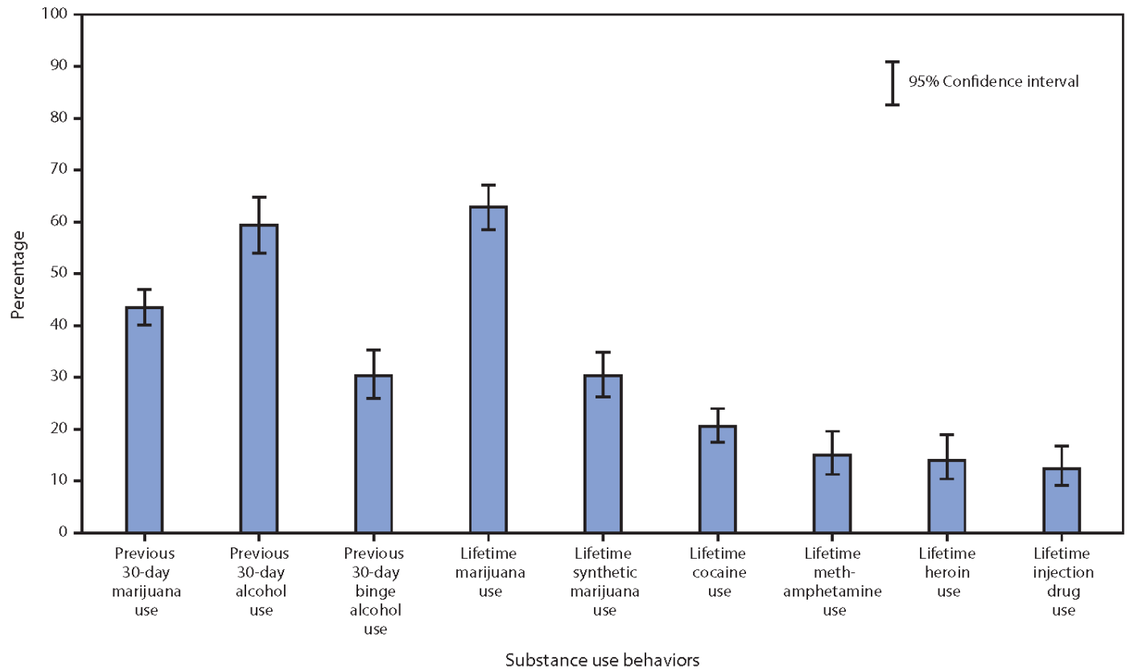
Prescription Opioids & Our Children

Amid the aggressive growth in drug overdose rates across the United States, fatal overdoses among children have received inadequate attention. As a result, pediatric overdose mortality in the United States has more than doubled over two decades, with a slight decline from the peak in 2016. In 2019 a report of high school students in the United States from 2009 to 2019 revealed that 7.2% of high school students in the U.S. reported currently misusing prescription opioids and that the misuse of prescription opioids also led to the concurrent use of other substances. For example, of those high school students misusing prescription opioids, 59.4% reported underage drinking, 30.3% reported binge drinking, and 43.5% reported using marijuana. Furthermore, data shows that adolescents misusing prescription opioids have significantly high lifetime use of intravenous substances such as injection drugs and heroin.



High School Students and Prescription Opioid Abuse

FIGURE. Percentage of co-occurring substance use behaviors among high school students who reported previous 30-day prescription opioid misuse* — Youth Risk Behavior Survey, United States, 2019



* Unweighted N = 661.

Prescription Opioids in Our Community

In 2018, the opioid deaths in Palm Beach County exceeded both the national and the state rate. Moreover, in 2020 the opioid dispensing rate per 100 people in Palm Beach County was 41.7, meaning that in every 100 people, 42 were prescribed an opioid. What is even more alarming than those numbers is that the use of prescription opioids strongly predicts later heroin use.

The most common drugs involved in prescription opioid overdose deaths include:

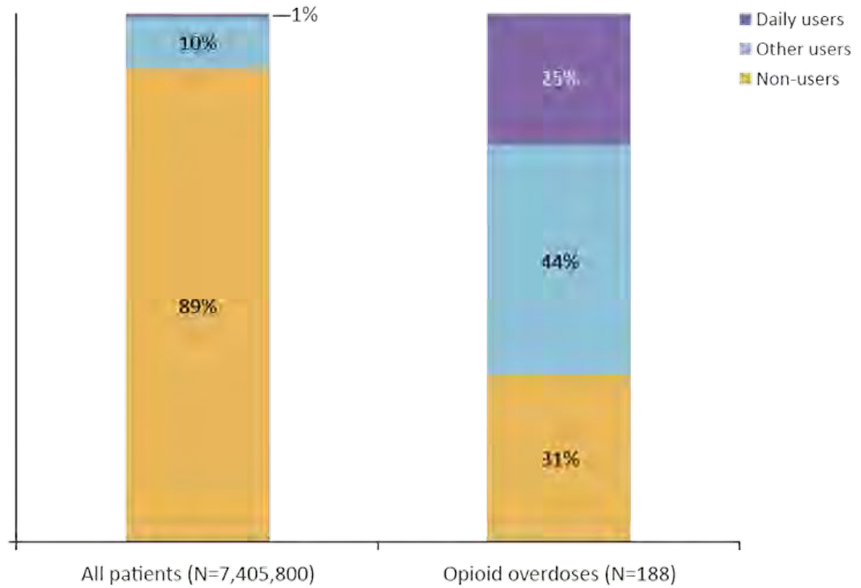
A Pill Can Cost a Life

Opioid-caused overdoses have risen dramatically in the 21st century, which subsequently has played an increasing role in the deaths of children during this century. For instance, pediatric fatal overdoses have considerably increased in the United States over the past several decades, from 16,849 overdose deaths in 1999 to 70,630 in 2019. Furthermore, between 1999 and 2007, opioid-caused deaths of children accounted for 50%. However, from 2010 forward, research shows that prescription opioid-cause deaths in the pediatric population are now between 67% and about 75%. A striking number of patients 18 and younger, children and adolescents, are killed by opioid poisoning in our country each year. In addition, researchers have indicated that the overprescription of opioids, or mismatches between prescribed quantity and patient pain management needs, have led to unused pills, which increases the risks for overdoses among children and adolescents. Therefore, adopting better prescribing practices by prescribers for children is a necessary step to reduce the exposure of children and adolescents to prescription opioids.

In addition to the severe risks of addiction, abuse, and overdose, the use of prescription opioids puts your child at the risk of several side effects, even when taken as directed:

- Tolerance—meaning your child might need to take more of the medication for the same pain relief
- Physical dependence—meaning your child have symptoms of withdrawal when the prescription is suspended
- Increased sensitivity to pain
- Constipation
- Nausea, vomiting, and dry mouth
- Sleepiness and dizziness
- Confusion
- Depression
- Low levels of testosterone, which can result in lower energy, and strength
- Itching and sweating

Risk of Opioid-Related Overdose Increases with Daily Use



Paulozzi et al. Risk of adverse health outcomes with increasing duration and regularity of opioid therapy. J Am Board Fam Med. 2014 May-Jun;27(3):329-38

Know Your Options

In addition, the risks associated with the use of prescription opioids and the development of addiction, another key component of prescription opioid education is knowing that there are alternative medications and procedures to treat chronic and post-surgical pain. Some of these options may work better and have fewer risks, and side effects than prescription opioids, so talk to your child's doctor about ways to manage their pain and care that do not involve prescription opioids.

For example, some of the approved alternatives to prescription opioids, depending on the type of pain you are experiencing, may include one or more of the following:

- Acetaminophen (Tylenol®) or ibuprofen (Advil®)
- Cognitive behavioral therapy – a psychological, goal-directed approach in which patients learn how to modify physical, behavioral, and emotional triggers of pain and stress
- Exercise therapy, including physical therapy
- Medications for depression or seizures
- Interventional therapies (injections)
- Exercise and weight loss
- Other therapies such as acupuncture and massage

To solve this problem, we must work together to increase education about the risks and the evidence-based alternatives to the use of prescription opioids for treating moderate-to-severe pain and chronic pain that is unrelated to end-stage illnesses such as cancer. We must prevent abuse, addiction, and overdose before they start and to do so we must educate all involved in the care of our children.

The health and safety of our children are essential. Know the questions we must ask and how we can work with different treatment providers to set pain management goals and develop a treatment plan to help our children. Follow-up if your pain is not resolving as quickly as expected.

04.

For Healthcare Providers

Introductory Note

Dear prescriber, thank you for taking the time to read this section of the Safe Prescribing Initiative's Toolkit. This section has been created with you and all your colleagues in mind. The primary purpose of this section is to summarize some critical publications related to prescription opioids and patients 18 years and younger. We understand that your time is limited, and therefore we want these facts to be here at your fingertips so that you can guide your patients toward making better decisions concerning using and how to use prescription opioids.

The Risk of Conversion to Long-Term Use

Adolescence is a precarious time in most people's lives, and the ability to make the best judgment calls is anatomically hindered by a not yet fully developed frontal lobe cortex. As such, teenagers are at a critical point of vulnerability to developing substance use disorders. Therefore, it should come as no surprise that data shows that opioid misuse is higher during the teenage years, peaking between ages 18 to 21.[133]

As seen in the table below, 18% of all adolescents on prescription opioids misuse their prescriptions. Moreover, an alarming 14% of adolescents misusing opioids satisfy the Diagnostic and Statistical Manual of Mental Disorders IV (DSM-IV) criteria for opioid dependence or abuse disorders.

Next, the risks of addiction associated with youth and prescription opioids extend far beyond opioid dependence or abuse disorder. For instance, six cross-sectional studies have identified a strong association between opioid misuse and heroin use in youth, and two qualitative studies of intravenous drug users misused opioids in their teen years. [51, 141, 163, 164, 215, 232, 284, 302] Ultimately, a higher likelihood of heroin use is associated with early onset and increased frequency of opioid misuse. [51, 141]

Furthermore, prescribers must understand that prescriptions from healthcare professionals are the number source of opioid diversion for adolescent misuse. As seen below in Table 2, the top two sources of opioids for the adolescent misuse or abuse of opioids were the adolescents' own prescription, and the use of opioids received free from friends or family's remaining pills. Moreover,

Table 1. Estimated Prevalence of Past-Year Opioid Use, Misuse, and Dependence (National Survey on Drug Use and Health 2017)[a]

		% (95% CI)		
Type	Weighted No. (SE)	Population	Any use	Misuse
Any use[b]	4 250 372 (109 465)	17.0 (16.3-17.8)	NA	NA
Misuse[c]	765 645 (42 251)	3.1 (2.8-3.4)	18.0 (16.1-20.0)	NA
Abuse/dependence[d]	106 198 (14 122)	0.4 (0.3-0.6)	2.5 (1.9-3.3)	13.9 (10.3-18.4)

Abbreviation: NA, not applicable.

[a] Population includes individuals aged 12 to 17 years (weighted n = 24 942 794).

[b] Including medical prescription opioid use and nonmedical prescription opioid misuse.

[c] Nonmedical prescription opioid misuse.

[d] Satisfied prescription opioid *Diagnostic and Statistical Manual of Mental Disorders* abuse or dependence criteria.

66.4% of adolescents who received free opioids from friends or family and misused or abused them stated that their friends or family members received their opioids through healthcare professionals.

Research has also shown that a significant number of adolescents prescribed opioids divert them, with as many as 94% of adolescents diverting their opioids when asked. Diversion means that the pills are given away as opposed to sold. Diversion usually occurs between friends and family, and the prevalence of opioid diversion increases with adolescents' age. [30]

It is also vital to note that a study of 70,942 opioid-naive adolescents and young adults discovered that the patients who filled their opioid prescription after a wisdom tooth extraction have about three times higher odds of ongoing opioid use later in life as opposed to those who did not fill their prescriptions. Therefore, it is essential to fully evaluate the writing of even the first opioid prescription and not merely the refills requests.

Table 2. Sources of Misused Prescription Opioid (National Survey on Drug Use and Health 2017)

Source	Weighted No. (SE)	% (95% CI)
Most recent misused prescription opioid[a]		
Got from 1 doctor	161 356 (20 817)	26.0 (20.8-32.0)
Got from more than 1 doctor	14 261 (6999)	2.3 (0.9-6.0)
Stole from doctor, clinic, hospital, or pharmacy	12 118 (5855)	2.0 (0.7-5.1)
Got from friend or relative for free	243 024 (23 051)	39.2 (34.0-44.5)
Bought from friend or relative	74 047 (15 822)	11.9 (7.7-18.1)
Took from friend or relative without asking	45 223 (9223)	7.3 (4.9-10.8)
Bought from drug dealer or other stranger	40 795 (10 716)	6.6 (4.0-10.6)
Got some other way	29 760 (8738)	4.8 (2.6-8.6)
Friend or relative's source of most recent medication[b]		
Got from 1 doctor	134 772 (15 248)	66.4 (57.1-74.6)
Got from more than 1 doctor	1901 (1720)	0.9 (0.2-5.7)
Stole from doctor, clinic, hospital, or pharmacy	2628 (2629)	1.3 (0.2-8.8)
Got from friend or relative for free	17 451 (4338)	8.6 (5.0-14.4)
Bought from friend or relative	9341 (4089)	4.6 (2.0-10.5)
Took from friend or relative without asking	15 431 (6772)	7.6 (3.2-17.0)
Bought from drug dealer or other stranger	10 981 (6168)	5.4 (1.8-15.4)
Got some other way	10 435 (6059)	5.1 (1.7-14.9)

[a] Population was individuals aged 12 to 17 years who misused opioids in the past year (weighted n = 620 584).

[b] Population was individuals aged 12 to 17 years who misused opioids in the past year and reported that they had received their most recent opioid from a friend or relative for free (weighted n = 202 940).

Table 3. Surgical Procedures With Evidence for Opioid-Free Recovery

Procedure	LOE[a]
Opioid-free recovery recommended[b]	
General surgery	
Inguinal hernia repair[129-131]	2,4
Umbilical/epigastric hernia repair[12]	3
Pyloromyotomy[132,133]	3,4
Soft tissue excision	5[d]
Pectus bar removal[134]	5[d]
Central line placement	5[d]
Otolaryngology	
Myringotomy[135,136]	2
Urology	
Circumcision or hypospadias repair[137]	3
Meatotomy	5[d]
Opioid-free recovery possible[c]	
General surgery	
Laparoscopic procedures (eg, appendectomy[138,139])	4
Nuss procedure[140,141]	4
Otolaryngology	
Tonsillectomy/adenoidectomy[142-146]	2,4
Cochlear implant[147]	4
Plastic surgery	
Operative burn debridement[148]	4
Urology	
Orchidopexy[149,150]	3,4
Pyeloplasty[151]	4
Orthopedic surgery	
Anterior cruciate ligament repair[152]	4
Hip or femoral surgery[153]	3

Abbreviation: LOE, level of evidence.

[a] LOEs are based on the Oxford Centre for Evidence-Based Medicine 2011 Levels of Evidence and Grade.[21]

[b] Procedures for which there was either considerable evidence (≥1 studies and level of evidence >4) or unequivocal biologic plausibility based on analogous and less invasive procedures in favor of an opioid-free recovery for most patients under most circumstances.

[c] Procedures for which there was some evidence (≥1 studies) that an opioid-free postoperative analgesia may be possible for some patients under some circumstances.

[d] LOE grading of 5 indicates that the surgical incision is comparable in size and dissection with procedures listed above a procedure marked "d."

Nonopioid Regimens

First and foremost, patients must understand that opioids are a temporary solution to their pain and that these medications will not cure them of the underlying condition causing their pain. Once that initial discussion is completed, the goal of any pain regimen is to balance pain relief and the potential for adverse side effects involved in postoperative recovery or chronic pain management.

Postoperative pain management is possible and recommended for most pediatric patients without opioids. For instance, see Table 3 for a list of opioid-free postoperative procedures. Notably, studies using oral analgesics showed a decrease in opioid use with a reduced pain score in some cases.

Furthermore, studies have shown that the perioperative use of Ketorolac intravenously has proven effective in reducing postoperative pain and the use of opioids, as well as hospitalization cost and length of hospital stay in the pediatric population. [1, 78, 216, 289]

Evidence also suggests that the targeted use of perioperative regional or neuraxial anesthesia techniques is helpful in an opioid-free or sparing regimen for pediatric patients. In addition, a literature review supports the use of regional anesthetics to decrease the use of opioids in numerous pediatric specialties, such as general and plastic surgery, orthopedics, otolaryngology, ophthalmology, and urology. [4, 8, 12, 15, 58, 59, 63, 71, 72, 107, 108, 109, 125, 129, 156, 160, 170, 202, 203, 222, 252, 254, 255, 260, 271, 275, 280, 281]

In addition, recent research indicates that clinically appropriate perioperative enteral nonopioid use, such as the rectal administration of acetaminophen, decreased opioid use without adverse side effects.[2, 230, 249, 304, 314] See Table 4 for details.

Table 4. Surgical Procedures With Evidence Favoring Enteral Analgesic Administration to Decrease Opioid Administration[a]

Surgical specialty	Procedure(s)	LOE[b]
General surgery	Lower abdominal incisions, appendectomy[129,154,155]	2
Ear, nose, and throat	Tonsillectomy/adenoidectomy, myringotomies[142,156-161]	2,4
Plastic surgery	Palatoplasty[162,163]	2,4
Urology	Hypospadias repair[164]	2
Orthopedic surgery	Outpatient procedures (ie, arthroscopy, pinning, etc)[165]	2
Neurosurgery	Craniectomy[166]	4
Ophthalmology	Strabismus repair[167]	2

Abbreviation: LOE, level of evidence.

[a] Includes oral and enteral administration.

[b] Level of evidence based on the Oxford Centre for Evidence-Based Medicine 2011 Levels of Evidence and GRADE.[21]

Patient & Family Education

Research shows that even though pain management is a leading concern for both patients and caregivers, healthcare professionals only spend about six minutes providing pain management education on the day of the surgery.[60, 98, 145, 147, 176, 323] Due to the limited time healthcare professionals have available and the increasing concerns surrounding pain management and prescription opioids, it is critical that patient and caregiver education regarding prescription opioids and pain management alternatives be initiated before the day of surgery.[147, 323]

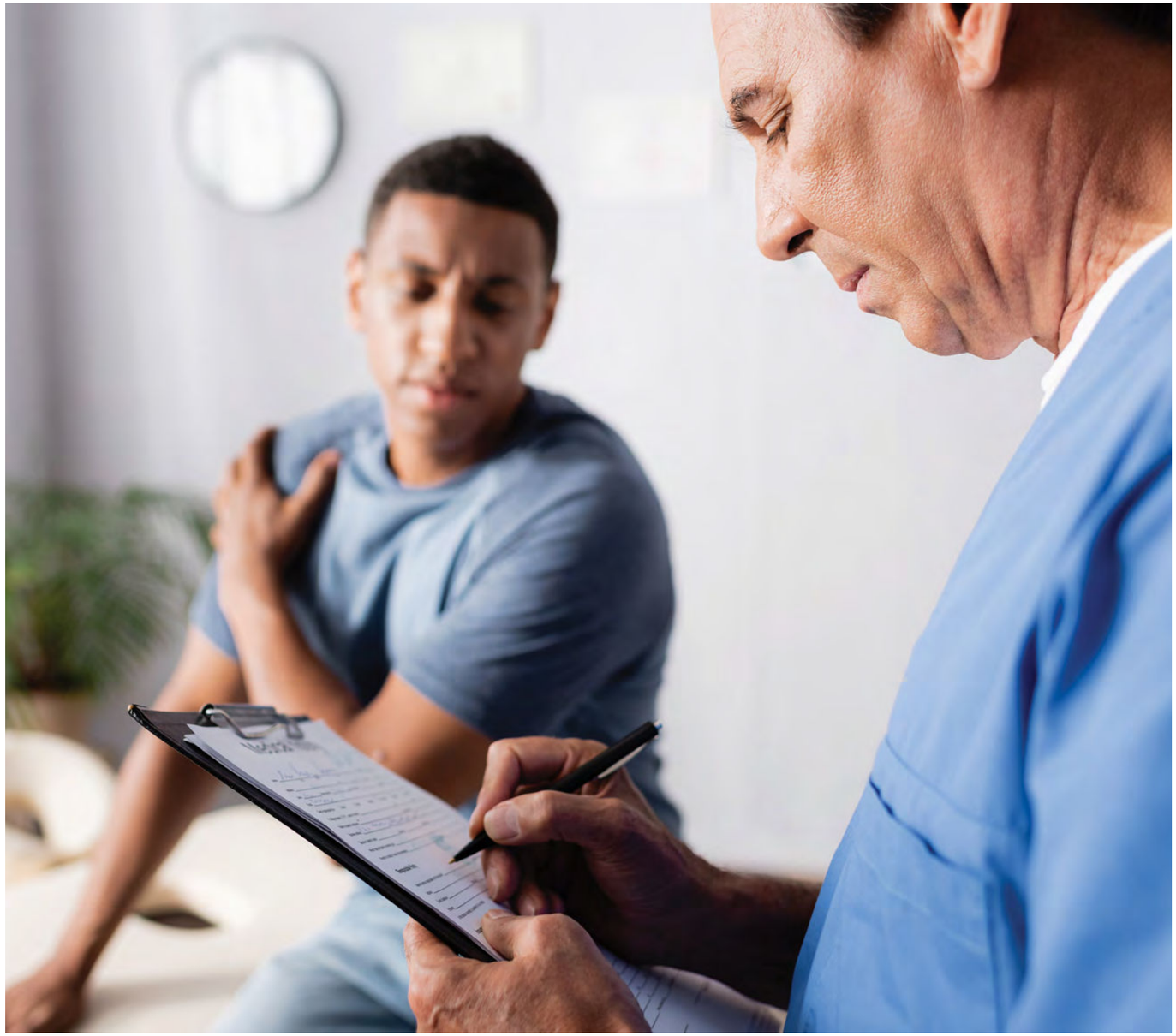
Furthermore, research has also shown that parents want to receive consistent information regarding managing their children's pain.147 Nevertheless, given the sheer volume and lack of a federal guideline on pain assessment and prescription opioid use in pediatrics, reason leads to the conclusion that differences in prescribing opioids within the same medical practice most likely exist.[17, 60, 67, 127, 136, 155, 161, 234, 240, 287, 295, 303, 335] Therefore, to better serve and educate parents and patients, an institutional guideline for education, training, and

informational distribution should be adopted by healthcare professionals managing pediatric pain and surgical procedures.

However, pain management and deciding whether to use prescription opioids should still be adapted to each unique patient's needs. Therefore, the institutional guideline should not determine who gets prescription opioids. Instead, it should outline a list of adopted educational materials and a series of normalized health history questions that every patient must complete before considering opioids. The normalized health history questions will access specific risk factors and based on an average performance score, prescribing professionals would then evaluate the risk-benefit ratio of using an opioid.

The Key Takeaway: How to Make the Best Decision with Your Patient

Notice that the title of this section reads "with" instead of "for" your patient. The word choice was highly intentional because we believe that when deciding whether to use prescription opioids, all potentially affected parties should be a part of the discussion. The responsibility should not only lie on the backs of healthcare professionals, and the patients should understand the risks associated with their choice and how those risks pertain to them individually. However, although every patient is responsible for asking questions and being involved in their healthcare decisions, only you, the prescriber, holds the power to prescribe. Therefore, if a patient has a history of risk factors, please consider alternative options to opioids.



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