InforMed
Continuing Medical Education
By Colibri Healthcare

State Specific Continuing Medical Education

2023 Georgia Medical Licensure Program

- **2 Hours**
  Professional Boundaries ***(NEW)****
- **3 Hours**
  Controlled Substances

ACCME ACCREDITED

*New CME Requirement:

2 Hours on Professional Boundaries and Sexual Misconduct required for 2023 renewals.

CME FOR: *AMA PRA CATEGORY 1 CREDITS™* MIPS MOC STATE LICENSURE

GA.CME.EDU

ONLINE

2023 GEORGIA

01 **GUIDANCE ON PROFESSIONAL BOUNDARIES AND SEXUAL MISCONDUCT**
COURSE ONE | 2 CREDITS*

19 **EFFECTIVE MANAGEMENT OF ACUTE AND CHRONIC PAIN WITH OPIOID ANALGESICS**
COURSE TWO I 3 CREDITS+

48 **LEARNER RECORDS: ANSWER SHEET & EVALUATION**
REQUIRED TO RECEIVE CREDIT

*Completion of this course satisfies the Georgia Composite Medical Board mandatory requirement for two (2) *AMA PRA Category 1 Credits*™ or equivalent on professional boundaries and sexual misconduct.

+Completion of this course satisfies the Georgia Composite Medical Board mandatory requirement for three (3) *AMA PRA Category 1 Credits*™ or equivalent on controlled substance prescribing practices, abuse/misuse, and pain management for Initial Licensees (First Time Renewals). This is a one-time requirement.

CME that counts for MOC

Participants can earn MOC points equivalent to the amount of CME credits claimed for designated activities (see page iii for further details). InforMed currently reports to the following specialty boards: the American Board of Internal Medicine (ABIM), the American Board of Anesthesiology (ABA), the American Board of Pediatrics (ABP), the American Board of Ophthalmology (ABO), the American Board of Otolaryngology–Head and Neck Surgery (ABOHNS), and the American Board of Pathology (ABPath). To be awarded MOC points, you must obtain a passing score, complete the corresponding activity evaluation, and provide required information necessary for reporting.

$55.00

PROGRAM PRICE (5 CREDITS)

DATA REPORTING: Federal, State, and Regulatory Agencies require disclosure of data reporting to all course participants. InforMed abides by each entity's requirements for data reporting to attest compliance on your behalf. Reported data is governed by each entity's confidentiality policy. To report compliance on your behalf, it's mandatory that you must achieve a passing score and accurately fill out the learner information, activity and program evaluation, and the 90-day follow up survey. Failure to accurately provide this information may result in your data being non-reportable and subject to actions by these entities.

InforMed has joined the Elite Learning family

Two of the nation's top healthcare education providers have joined forces with one goal in mind: to offer physicians a state-of-the-art learning experience that fulfills your state requirements and empowers you with the knowledge you need to provide the best patient care.

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- **ACCOUNTS:** You'll also have access to a personalized learner account. In your account you can add, organize, and track your ongoing and completed courses. For instructions on how to set up your account, email us at office@elitelearning.com.
- **BOOK CODES:** You may notice a book code on the back cover of the latest InforMed program you've received in the mail. When entered on our new site, this code will take you directly to the corresponding self-assessment. See more information below.

How to complete

Please read these instructions before proceeding.

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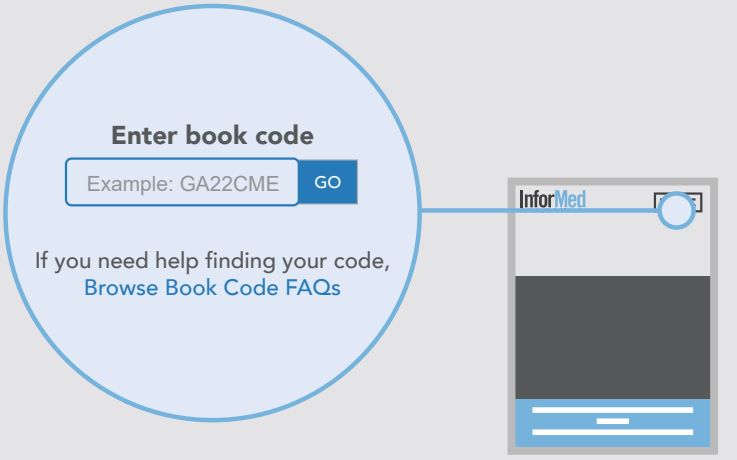
- If you already have an account created, sign in to your account with your username and password. If you do not have an account already created, you will need to create one now.
- Follow the online instructions to complete your self-assessment. Complete the purchase process to receive course credit and your certificate of completion. Please remember to complete the online evaluation.
- To complete individual courses, or to find additional elective hours, please visit **GA.CME.EDU**.



By mail

- Fill out the answer sheet and evaluation found in the back of this booklet. Please include a check or credit card information and e-mail address. Mail to **InforMed, PO Box 2595, Ormond Beach, FL 32175-2595**.
- Completions will be processed within 2 business days from the date it is received and certificates will be e-mailed to the address provided.
- Submissions without a valid e-mail will be mailed to the address provided.

By fax

- Fill out the answer sheet and evaluation found in the back of this booklet. Please include credit card information and e-mail address. Fax to **1-800-647-1356**.
- All completions will be processed within 2 business days of receipt and certificates will be e-mailed to the address provided.
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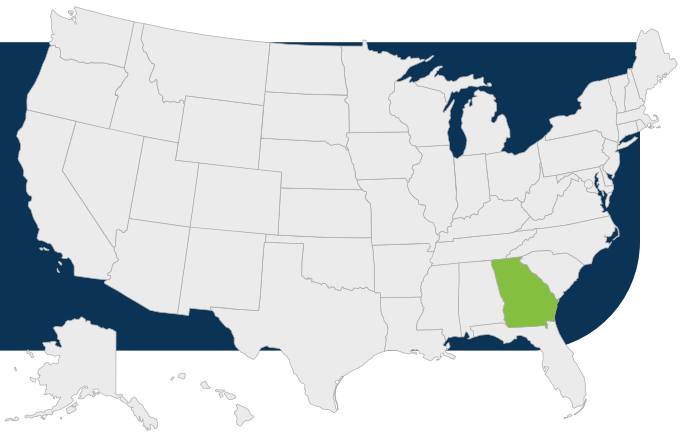
INFORMED TRACKS
WHAT YOU NEED, WHEN YOU NEED IT



Georgia Professional License Requirements

MANDATORY CONTINUING MEDICAL EDUCATION FOR LICENSE RENEWAL

Physicians (MD/DO) must complete forty (40) credit hours of continuing medical education during their two year licensure period. All of these credits must be *AMA PRA Category 1 Credits*™ or equivalent. Currently, for all licensed physicians their license will expire at midnight on the last day of the licensee's birth month in even or odd years.

Physician assistants (PAs) must complete forty (40) *AMA PRA Category 1 Credits*™ or equivalent hours biennially. At least ten (10) hours shall be directly related to the specialty of the Board approved primary supervising physician. Physician assistants who are authorized to issue prescription drug orders shall complete a minimum of three (3) hours in practice specific pharmaceuticals in which the physician assistant has prescription order privileges. Currently, for all licensed physician assistants their license will expire on the last day of the licensee's birth month in even or odd years.

PROFESSIONAL BOUNDARIES AND SEXUAL MISCONDUCT ***(NEW)***

Beginning January 1, 2022 all physicians (MD/DO) shall complete a minimum of two (2) hours on professional boundaries and physician sexual misconduct. Completion of this requirement may count as two hours toward the CME requirement for license renewal. This is a one-time requirement.

CONTROLLED SUBSTANCES

Initial physician licensees who maintain an active DEA certificate and prescribe controlled substances who are renewing for the first time (except those holding a residency training permit), shall complete a minimum of three (3) *AMA PRA Category 1 Credits*™ or equivalent designed specifically to address controlled substance prescribing practices. This is a one-time requirement. The certification of such completion must occur at the first renewal following licensure. Completion of this requirement may count as three (3) hours toward the overall CME requirement for license renewal.

We are a nationally accredited CME provider.
For all board-related inquiries please contact:

Georgia Composite Medical Board
2 Peachtree Street, NW
6th Floor
Atlanta, GA 30303
P: (404) 656-3913
F: (404)-656-9723

COMPLETION DEADLINE:
Prior to your next license renewal

LICENSE TYPES:
MD/DO
PA

MOC/MIPS CREDIT INFORMATION

In addition to awarding *AMA PRA Category 1 Credits™*, the successful completion of enclosed activities may award the following MOC points and credit types. To be awarded MOC points, you must obtain a passing score and complete the corresponding activity evaluation.

Table 1. MOC Recognition Statements		
Successful completion of certain enclosed CME activities, which includes participation in the evaluation component, enables the participant to earn up to the amounts and credit types shown in Table 2 below. It is the CME activity provider's responsibility to submit participant completion information to ACCME for the purpose of granting MOC credit.		
Board Programs		
MOCA®	**ABA**	American Board of Anesthesiology's redesigned Maintenance of Certification in Anesthesiology™ (MOCA®) program, known as MOCA 2.0®
ABIM CME MOC ACCREDITED	**ABIM**	American Board of Internal Medicine's Maintenance of Certification (MOC) program
	ABO	American Board of Ophthalmology's Maintenance of Certification (MOC) program
ABOHNS	**ABOHNS**	American Board of Otolaryngology – Head and Neck Surgery's Continuing Certification program (formerly known as MOC)
CME for ABPath CC	**ABPath**	American Board of Pathology's Continuing Certification Program
PART 2 MOC THE AMERICAN BOARD of PEDIATRICS	**ABP**	American Board of Pediatrics' Maintenance of Certification (MOC) program.

Table 2. Credits and Type Awarded							
Activity Title	***AMA PRA Category 1 Credits™***	**ABA**	**ABIM**	**ABO**	**ABOHNS**	**ABPath**	**ABP**
Guidance on Professional Boundaries and Sexual Misconduct	*2 AMA PRA Category 1 Credits™*	2 Credits LL	2 Credits MK	2 Credits LL & SA	2 Credits SA	2 Credits LL	2 Credits LL+SA
Effective Management of Acute and Chronic Pain with Opioid Analgesics	*3 AMA PRA Category 1 Credits™*	3 Credits LL	3 Credits MK	3 Credits LL & SA	3 Credits SA	3 Credits LL	3 Credits LL+SA
Legend: LL = Lifelong Learning, MK = Medical Knowledge, SA = Self-Assessment, LL+SA = Lifelong Learning & Self-Assessment, PS = Patient Safety							

Table 3. CME for MIPS Statement
Completion of each accredited CME activity meets the expectations of an Accredited Safety or Quality Improvement Program (IA PSPA_28) for the Merit-based Incentive Payment Program (MIPS). Participation in this Clinical Practice Improvement Activity (CPIA) is optional for eligible providers.

GUIDANCE ON PROFESSIONAL BOUNDARIES AND SEXUAL MISCONDUCT

COURSE DATES:	MAXIMUM CREDITS:	FORMAT:
Release Date: 1/2022 Exp. Date:12/2024	*2 AMA PRA Category 1 Credit*™	Enduring Material (Self Study)

TARGET AUDIENCE

This course is designed for all physicians and other health care providers.

HOW TO RECEIVE CREDIT:

- Read the course materials.
- Complete the self-assessment questions at the end. A score of 70% is required.
- Return your customer information/ answer sheet, evaluation, and payment to InforMed by mail, phone, fax or complete online at program website.

COURSE OBJECTIVE

The purpose of this course is to provide important information to help understand and maintain professional boundaries and appropriate relations with patients, including strategies for initiating and conducting sensitive examinations and the communication that is required as a component of such examinations.

LEARNING OBJECTIVES

Completion of this course will better enable the course participant to:

1. Understand requirements for qualified chaperones, intimate exam recommendations, and respectful communication with patients.
2. Describe types of sexual misconduct and how to maintain appropriate boundaries with patients.
3. Understand professional boundaries in practice, including recognizing prevalence and underreporting of sexual misconduct.
4. Identify the ethical and legal imperatives as well as appropriate channels to report sexual misconduct and understand what is meant by trauma-informed care.

ACCREDITATION STATEMENT

InforMed is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians.

DESIGNATION STATEMENT

InforMed designates this enduring material for a maximum of 2 *AMA PRA Category 1 Credits*™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

FACULTY

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Michael Brooks
CME Director
InforMed

DISCLOSURE OF INTEREST

In accordance with the ACCME Standards for Integrity and Independence in Accredited Continuing Education, InforMed implemented mechanisms, prior to the planning and implementation of this CME activity, to identify and resolve conflicts of interest for all individuals in a position to control content of this CME activity.

COURSE SATISFIES

SPECIAL DESIGNATION

This course satisfies two (2) hours on professional boundaries and sexual misconduct.

The Georgia Composite Medical Board now requires all physicians (MD/DO) to complete a minimum of two (2) hours on professional boundaries and physician sexual misconduct. This is a one-time requirement.

FACULTY/PLANNING COMMITTEE DISCLOSURE

The following faculty and/or planning committee members have indicated they have no relevant financial relationship(s) to disclose with ineligible companies whose primary business is producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients:

- Sarab Sodhi, MD, MAUB
- Beth Dove
- Michael Brooks

STAFF AND CONTENT REVIEWERS

InforMed staff, input committee and all content validation reviewers involved with this activity have reported no relevant financial relationships with ineligible companies whose primary business is producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients.

DISCLAIMER

Introduction

Into whatsoever houses I enter, I will enter to help the sick, and I will abstain from all intentional wrong-doing and harm, especially from abusing the bodies of man or woman, bond or free.

~Hippocratic Oath (translated from 1923 Loeb edition)

Trust is implicit and imperative in the physician-patient relationship. From the Hippocratic Oath to the American Medical Association's (AMA) Code of Medical Ethics, members of the medical profession are charged to give medical care that is competent, compassionate, and respects human dignity and rights. AMA Core values include the ethical responsibility to place patient welfare above the physician's self-interest.[3] When care is disrupted by sexual misconduct on the part of the physician, repercussions are severe and ongoing.

The trauma experienced when physicians cross a line endures, harming patients' mental, psychological, emotional, and physical health.[1] Repercussions extend to families, communities, and the wider public.[1] Targeted patients are known to refrain from seeking necessary medical care down the line with associated implications for morbidity and mortality. Thus, sexual violations committed by a minority of practicing physicians undermine the integrity of the entire medical field.[1]

Efforts are underway to examine the extent of physician misconduct and to scrutinize current practices of state medical boards and professional regulatory authorities. A workgroup formed by the Federation of State Medical Boards (FSMB) reviewed available data on sexual misconduct regarding incidence and severity of behaviors, disciplinary actions, and barriers to reporting.[1] Additionally, the workgroup scrutinized and examined how professional culture influences willingness to report physician impropriety. According to the workgroup report published in May 2020, physician sexual misconduct is underreported by patients and medical professionals in the workplace, and shared efforts are necessary to enact widespread cultural and systemic changes.[1]

Calls for more accountability come from many quarters. The #MeToo and Time's Up movements – and the accompanying societal attention -- have grown into advocacy and victim support networks that reach into every strata and corner of society, including the physician's exam room. Media accounts highlight not only egregious misconduct but the organizational complacency that failed to halt it. Examples published on MedPage Today include:[4]

- 17 women who sued Columbia University and its affiliated hospitals claiming the institutions concealed known sexual assaults during office visits by Robert Hadden, MD, a former obstetrician-gynecologist at New York-Presbyterian
- Dozens of men who filed suits against Ohio State University alleging that former wrestling team doctor Richard Strauss, MD, sexually abused them under the guise of medical examinations
- More than 200 women who alleged that George Tyndall, MD, the longtime campus gynecologist at the University of Southern California, assaulted them during their appointments, prompting a grand jury investigation
- More than 150 women, many minors at the time, who testified to being sexually abused by former USA Gymnastics team doctor Larry Nassar, DO, at Michigan State University

As important and timely as this topic is, it is rarely and inadequately covered in medical training. Historically, psychiatry is the field with the most attention paid to professional boundaries regarding patients, but the need is pressing for more formal education that occurs earlier within the framework of broader clinical practice.[1,2] For example, a 2007 search of the University of Vermont College of Medicine's curriculum revealed a dearth of teaching on the concept of professional boundaries.[2] Furthermore, although maintaining professional boundaries begins with respectful communication, which is particularly important when conducting sensitive exams, clinical communications skills receive limited curricular time in U.S. medical schools and even less so for practicing physicians.[5] In recognition of these deficiencies the FSMB workgroup called for education beginning in medical school and residency and continuing throughout the life of a physician's (or other healthcare professional's) career.[1]

At minimum, physicians and medical students should:[1,6]

- Know what constitutes appropriate physician-patient boundaries
- Identify and avoid common and potential consequences to both the patient and the physician when professional boundaries are not maintained
- Know what defines physician sexual misconduct
- Learn the prevalence of physician sexual misconduct and be encouraged to remain vigilant and report it
- Be educated regarding the degree of harm patients experience as a result of sexual trauma

Physicians require skills in self-monitoring and self-reflection as well in enacting and enforcing practice policies to ensure sexual misconduct is prevented, detected sooner, stopped from recurring, and reported to the appropriate regulatory and legal authorities without fear of repercussions from colleagues or superiors. Training or review is also necessary on how to initiate and conduct sensitive examinations with patients and the communication that is required as a component of such examinations. This CME activity presents important information to help physicians understand and maintain professional boundaries and appropriate relations with patients. These skills are aimed at improving outcomes for patients, facilitating ongoing practice-based learning, and providing a framework for risk management.

Prevalence of Physician Sexual Misconduct

It is known that sexual harassment is common in academic medicine and in healthcare work environments.[7] However, the prevalence of sexual misconduct or assault experienced by patients from the physicians entrusted to care for them has not been well studied.[6,8] Prevalence data are based on disciplinary actions by state medical boards or federal agencies or on self-reported anonymous surveys (Table 1).[9] Anonymous surveys indicate the problem is more widespread than would be inferred from disciplinary actions alone.

Sexual misconduct is among the most common reasons healthcare professionals are disciplined by medical boards.[6,10] Data from past decades show that 761 physicians were disciplined for sex-related offenses from 1981 through 1996.[11] In 1994, the year with the most reports, 5.2% of all orders were sex related, and 0.02% of 621,129 practicing physicians in the country were disciplined for sex-related offenses.[11] Although few physicians were disciplined, reports of offenses were increasing and incidents were relatively severe, involving patients 75% of the time and including sexual intercourse, rape, sexual molestation, and sexual favors for drugs.[11] Most alarming, "a substantial proportion" of offenders were allowed to continue or return to practice. Because offenders often repeat their misconduct, many patients can be affected over years or even decades.

More recent reports in media outlets have led to increased public awareness of the scope of the problem. In 2016, the Atlanta Journal-Constitution published a six-part series on doctors and sex abuse.[12] Reporters examined more than 100,000 disciplinary documents from across the country, eventually identifying more than 3,100 doctors accused of sexual infractions who were publically disciplined since January 1, 1999. Of those sanctioned, more than 2,400 of the violations clearly involved patients. The investigation found that about 70% more physicians were accused of sexual misconduct than were classified as such in the public version of the National Practitioner Data Bank (NPDB), which tracks complaints against physicians.[6,12] Furthermore, the reporters identified an additional 450 physicians from allegations during 2016 and 2017.[13]

When self-report by physicians is anonymous, the rates of reported violations are higher than those pulled from disciplinary actions. While a literature review published in 2009 reported a rate of approximately 1.6% of U.S. physicians disciplined for sexual boundary violations with patients, when the same report combined self-report survey samples, closer to 6.8% (257 of 3758) of respondents admitted to such boundary violations.[9]

Table 1. Prevalence of Sexual Boundary Violations by U.S. Physicians (adapted from Sansone and Sansone)[1]				
Study Authors	**Characteristics**	**Prevalence**		
		Number	%	% Male
From Disciplinary Actions				
Post[2]	New York State	68/40,000	0.20%	--
Enbom and Thomas[3]	Oregon State Medical Board	77/4931	1.60%	97.4
Dehlendorf and Wolf[4]	Federal agencies/state medical boards	761/?*	0.02%	--
Morrison and Wickersham[5]	Medical Board of California	37/104,000	0.04%	97.3
From Anonymous Self-Report Surveys				
Kardener et al[6]	California medical society (males only)	33/460	7.20%	100.00
Gartrell et al[7]	AMA Members	176/1891	9.30%	93.2
Bayer et al[8]	AMA Members	26/787	3.30%	96.3

AMA=American Medical Association

*Total number not reported

1. Sansone RA, Sansone LA. Crossing the line: sexual boundary violations by physicians. Psychiatry (Edgmont (Pa : Township)). 2009;6(6):45-48.
2. Post J. Medical discipline and licensing in the State of New York: a critical review. Bull N Y Acad Med. 1991;67(1):66-98.
3. Enbom JA, Thomas CD. Evaluation of sexual misconduct complaints: the Oregon Board of Medical Examiners, 1991 to 1995. Am J Obstet Gynecol. 1997;176(6):1340-1346; discussion 1346-1348.
4. Dehlendorf CE, Wolfe SM. Physicians disciplined for sex-related offenses. JAMA. 1998;279(23):1883-1888.
5. Morrison J, Wickersham P. Physicians disciplined by a state medical board. JAMA. 1998;279(23):1889-1893.
6. Kardener SH, Fuller M, Mensh IN. A survey of physicians' attitudes and practices regarding erotic and nonerotic contact with patients. Am J Psychiatry. 1973;130(10):1077-1081.
7. Gartrell NK, Milliken N, Goodson WH, 3rd, Thiemann S, Lo B. Physician-patient sexual contact. Prevalence and problems. The Western journal of medicine. 1992;157(2):139-143.
8. Bayer T, Coverdale J, Chiang E. A national survey of physicians' behaviors regarding sexual contact with patients. South Med J. 1996;89(10):977-982.

Therefore, although an estimated 5-10% of physicians have had sexual contact with patients, the true extent of violations is probably underreported.[13,14]

Underreporting and Consequences of Physician Misconduct

Most patients who are sexually violated by medical practitioners do not report it, estimated as 1 in 10, which is significantly lower than the overall U.S. rate of 36% of female rape or sexual assault.[6] The underreporting of sexual misconduct exist within a culture in which all types of physician misconduct toward patients often goes unreported: 18% of U.S. adults have experienced some type of unprofessional conduct from a physician, but only 33% reported the behavior or filed a complaint, according to survey results released by FSMB with data from 2,018 respondents.[15] Women were twice as likely as men to experience unprofessional conduct from physicians (24% vs 12%) but were less likely to report it (41% vs 30%).

Patients do not report their experiences of sexual misconduct for a variety of reasons that include:[1,6]

- Distrust in institutions (e.g., state medical boards, hospitals, other healthcare organizations)
- Fear of abandonment or retaliation by the physician
- Stigma, shame, embarrassment, and unwillingness to relive trauma
- Lack of knowledge in how to file complaints
- Uncertainty over whether a traumatic event was truly unprofessional and unethical (e.g., not realizing that an ungloved vaginal examination was medically unnecessary)
- Complicity in the violation (e.g., to obtain drugs)
- Being unaware of the violation (e.g., under sedation)

Patients frequently lack faith that boards and organizations charged with taking action will actually do so in cases of sexual misconduct. If they do wish to report the misconduct, they often feel intimidated or confused by the reporting process. Shame and guilt may arise as they wonder if they "did something" to invite the misconduct. The nature of an intimate examination may cause them to question their own version of events and wonder whether what happened was truly a violation. Even if they should overcome these barriers and come forward, many believe authorities ultimately would take a physician's word over theirs.

Unfortunately, these fears may not be unfounded. According to the Atlanta-Journal Constitution, physicians who behave inappropriately with patients have numerous advantages that protect them from consequences:[6,16]

- Colleagues and nurses do not fulfill their duty to report offenses
- Hospitals and healthcare organizations minimize accusations
- Organizations quietly discharge physician-offenders or push them to resign without reporting them to law enforcement or state agencies
- State medical boards give physician-offenders second chances
- Prosecutors dismiss or reduce charges with the goal of keeping physicians practicing and off sex offender registries
- Communities support physician-offenders

When it comes to disciplinary actions, sex-related offenses tend to be treated more stringently than non-sexual violations with 72% involving revocation, surrender, or suspension of a medical license in one study.[11] However, as of March 1997, approximately 40% of physicians disciplined for sex-related offenses between 1981 and 1994 were still licensed to practice.[11]

For patients, the lasting effects of sexual trauma are devastating and can be life-altering. As with survivors of sexual violence in the general population, experiences of physician misconduct can produce depression, anger, drug and alcohol abuse, trust issues, and post-traumatic stress disorder (PTSD) symptoms.[6,17] They may also feel shame and guilt about the encounter. Any combination of these reactions can have the effect that the patient avoids gynecological exams or even the entire medical profession altogether with serious health consequences.[14] Thus, physician misconduct disrupts continuity of care, which is a patient right.[18]

Physician Characteristics Involved in Misconduct

Sexual misconduct happens in all types of practice settings in all states.[1] Some reports indicate that greater numbers of reported allegations involve the fields of family medicine, psychiatry, internal medicine, and obstetrics and gynecology.[9,13] Sexual misconduct by physicians during labor and delivery has been reported in a large survey of U.S. and Canadian obstetric support personnel, who reported hearing use of sexually degrading language with laboring women or witnessing the performance of genital examinations or procedures without patient consent.[19] An investigation conducted by The Atlanta Journal-Constitution also found acts of physician sexual abuse in anesthesiology, ophthalmology, pediatrics, and radiology.[12] Encouragingly, there is some indication that education and awareness, the identification of high-risk practitioners, and the appropriate use of deterrence in the form of disciplinary action by state boards are useful in lowering the number of complaints.[13,20]

A question is whether there are some commonalities of sexual misconduct in physician characteristics. Of 101 cases of sexual violations in medicine analyzed for physician and patient characteristics, practice settings, kinds of violations, and consequences to the perpetrator, the five most common characteristics of offenders were:[6]

- Male physicians (100%)
- Older than age 39 (92%)
- Not board certified (70%)
- Practiced in nonacademic settings (94%)
- Always examined patients alone (85%)

Primary forms of sexual violations were as follows:[6]

- 33% inappropriate touching
- 31% non-penile anal or vaginal penetration without consent
- 16% rape
- 14% child molestation
- 7% consensual sex

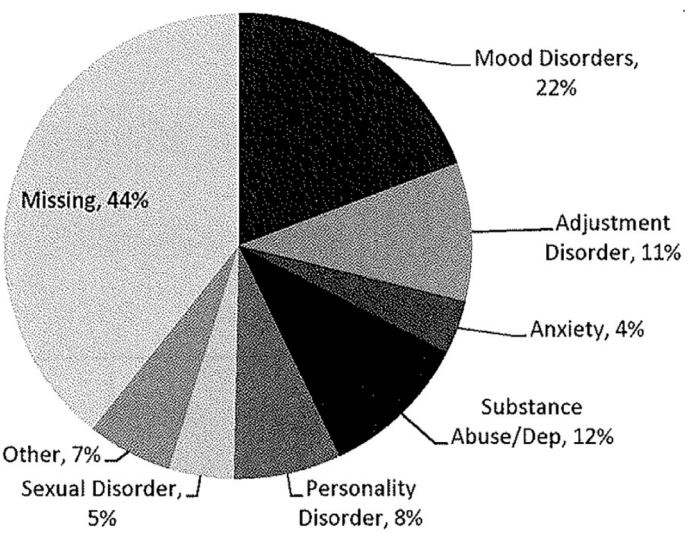
Physicians who molested children were more likely to commit sexual offenses such as exhibitionism or voyeurism with other patients than were physicians who engaged in other forms of sexual abuse.[6] Physicians who committed child molestation, nonconsensual, non-penile anal or vaginal penetration , and rape were much more likely to engage in inappropriate comments and touching with other patients than physicians who engaged in consensual sex. Personality disorders were suspected most frequently in cases of rape, and board certification was more common in cases of consensual sex with patients.[6]

In another study, a chart review of 120 physicians monitored for boundary violations by a single Physician Health Program (PHP) in Colorado found that, compared to the general PHP population, more individuals with violations were men between 40 and 49 years of age, had been mandated for evaluation, and reported an abusive history.[21] Diagnoses varied, but mood disorders, adjustment disorder, and substance-use disorders were common (Figure 1).[21]

Although certain physician characteristics (older, male, non-board-certified, in private practice) were associated with more deviations, these characteristics are also frequently shared by the vast majority of physicians who never commit any type of offense. Therefore, characteristics alone cannot and should not be used to infer that a physician is likely (or unlikely) to be an offender. Physician sexual misconduct is usually male to female but can happen to anyone of any age, racial or ethnic background, gender identity, or sexual orientation. Furthermore, reports of sexual boundary violations of patients by females do occur.[22]

In most cases, misconduct happens more than once and when a physician is alone with a patient without a chaperone present.[6] However, some instances of misconduct take place with others present: 19% of cases of nonconsensual, non-penile anal or vaginal penetration occurred with a chaperone, parent, nurse, or other individual in the room with the patient and physician.[6]

Figure 1. Diagnoses Among Physicians with Boundary Violations[21]



Ambulatory or office-based settings are at risk for boundary-violating behavior, perhaps because there is less scrutiny and oversight, and the physician is more often a sole authority.[23] Cases also have been publicized of physicians violating unconscious or otherwise compromised patients.[14] In any practice setting, including hospitals and emergency rooms, patients with special vulnerabilities for abuse include anesthetized patients, patients who do not speak English or whose immigration status make them less likely to report misconduct, minors, and patients with limited mental capacity.

Definitions and Kinds of Misconduct

Preventing sexual misconduct begins with preventing sexual harassment. The AMA Code of Medical Ethics Opinion 9.1.3 defines sexual harassment as "unwelcome sexual advances, requests for sexual favors, and other verbal or physical conduct of a sexual nature."[24] Sexual harassment of colleagues by physicians is an unethical abuse of power that interferes with work performance and appropriate professional advancement. The hostile environment created by harassment sets a culture in which professional boundary violations with patients become conceivable.

A professional boundary is a term that encompasses respect for the personal bodily and psychological integrity and separateness of the patient.[25] A boundary crossing is a benign modification of the therapeutic relationship on behalf of the patient, such as accepting a hug or a gift of modest value from an appreciative patient.[25] Boundary crossings may differ across specialties and context, lack the motive of exploitation, and can usually be discussed and altered. In contrast, sexually-motivated contact with a patient is an absolute (i.e. black-and-white) boundary violation. One example of a boundary violation would be including a patient's confidential clinical information in a published report without consent. Sexual misconduct with a patient is an extreme and egregious boundary violation.

Physician sexual misconduct is defined by the FSMB as behavior that exploits the physician-patient relationship in a sexual way.[1] The behavior may be verbal or physical, occur in person or virtually, and may include expression of thoughts and feelings or gestures that are of a sexual nature or that a patient (or patient surrogate) may reasonably construe as sexual.[1] The FSMB further divides sexual misconduct into two categories: sexual impropriety and sexual violations. (Examples may include but are not limited those shown in Table 2).[1,13]

Sexual misconduct behaviors exist along a continuum of escalating severity. Behaviors that constitute sexual impropriety might include inappropriate gestures or expressions that are seductive, sexually suggestive, disrespectful of patient privacy, or sexually demeaning to a patient.[1] Inappropriate language or gestures have the effect of embarrassing, shaming, and humiliating the patient. Such sexual impropriety can take place in person, but may also occur online, by mail, by phone call, and by text.[1]

Table 2. Examples of Physician Sexual Misconduct[1,2]	
Sexual Impropriety	**Sexual Violations**
Neglecting to employ disrobing or draping practices respecting patient privacy or Deliberately watching patient dress or undress	Sexual intercourse, genital-to-genital contact
Performing intimate examination or consultation without clinical justification or appropriate consent	Oral-to-genital contact
Subjecting patient to intimate examination in presence of medical students or other parties without patient's informed consent or informed consent withdrawn	Oral-to-anal contact, genital-to-anal contact
Examining or touching genital mucosal areas without the use of gloves (or with gloves without clinical justification)	Kissing in a romantic or sexual manner
Making inappropriate gestures or comments about or to the patient, including but not limited to: • sexual comments about patient's body or underclothing • sexualized or sexually demeaning comments to patient • criticizing patient's sexual orientation • non-clinically-relevant comments during examination about potential sexual performance	Touching breasts, genitals, or any sexualized body part for any purpose other than appropriate examination or treatment or when the patient has refused/withdrawn consent
Using patient–physician relationship to solicit date/romantic relationship	Encouraging the patient to masturbate in the presence of physician*
Initiating conversation regarding physician's sexual problems, preferences, or fantasies	Masturbating by physician while patient is present
Requesting details of sexual history, likes, or dislikes not indicated for type of examination or consultation	Offering practice-related services, such as drugs, in exchange for sexual favors
*The American College of Obstetricians and Gynecologists recognizes the value of physician-guided sexual health counseling in the proper clinical context by an appropriately trained provider. 1. Sexual Misconduct: ACOG Committee Opinion, Number 796. Obstet Gynecol. 2020;135(1):e43-e50. 2. Federation of State Medical Boards (FSMB). Report and Recommendations of the FSMB Workgroup on Physician Sexual Misconduct. 2020; http://www.fsmb.org/siteassets/advocacy/policies/report-of-workgroup-on-sexual-misconduct-adopted-version.pdf. Accessed November 10, 2021.	

Severity further increases with physical contact that is explicitly sexual or reasonably interpreted as such. An example of a sexual violation might include performing an intimate exam without medical necessity or without obtaining informed consent. It might also involve any type of sexually-motivated physical contact with the patient. Sexual assault is any nonconsensual sexual act proscribed by federal, tribal, or state law.[13] Assault occurs through physical force, threats of force, coercion, manipulation, imposition of power, or circumstances where a person lacks the capacity to provide consent due to age or other circumstances.[1]
Actions that constitute sexual assault range from sexual coercion to unwanted kissing, touching, or fondling to rape.[13]

Grooming behaviors may not be misconduct but serve as precursors to more severe violations and include such actions as adjusting appointment timing to facilitate time alone with a particular patient, contacting the patient outside of clinic hours, or divulging personal information to a patient as a means to gain trust or to gauge whether an abuse opportunity exists.[1] Grooming behaviors should be taken seriously because severity of sexual misconduct tends to escalate: in one study of sexual violations by physicians, inappropriate comments or touching preceded 94% of cases of nonconsensual, non-penile anal or vaginal penetration and 88% of cases of rape.[6]

It is important to understand that consent or seeming consent on the part of the patient does not alter the finding of a violation of the physician-patient relationship.[6] A sexual relationship concurrent with a treatment relationship is sexual misconduct.[25] Physical sexual contact between a physician and patient is a violation, whether or not the contact was initiated by the patient.[1] Data indicate that such encounters occur most frequently with patients whose mental health status make them vulnerable and are marked by considerable disparities in power, status, and emotional vulnerability.[17] Consider that the patient sees a physician because of a medical problem, and there may be implicit or explicit suggestion that continued care is contingent on willingness to accept sexual contact. Furthermore, treating as a patient a person with whom a physician has a current romantic or sexual relationship may violate the ethical proscription against treating family members. Physicians, therefore, must respect the inherent power differential and understand that sexual relationships with patients that are consensual or believed to be consensual breach one's professional commitment to provide respectful, competent medical care.

Relationships with Former Patients, Others in the Clinical Context

The imperative to treat patients professionally does not stop when they leave a practice. It is also unethical to misuse the trust, knowledge, or influence from a professional relationship to pursue a sexual or romantic relationship with a former patient.[13] From a risk management standpoint, at minimum, if a sexual relationship is to be initiated with a patient or employee, the person must be referred elsewhere for medical care or dismissed as an employee.[26] Regardless, consent by the patient to sexual contact is not considered valid if it occurs shortly after termination of the clinical context[1] and, in some circumstances, such relationships are never permitted.

Some professional groups and disciplinary or licensing boards designate time limits for commencing a sexual relationship with a former patient following termination of a physician-patient relationship, but consensus is not complete. The American Psychiatric Association prohibits sexual activity with former patients,[27] and such relationships are viewed with grave concern by other professional associations because of the potential for undue influence and abuse of power. The American Association of Orthopaedic Surgeons (AAOS) acknowledges the variety of opinions and notes that ethical propriety depends on the nature and context of the former relationship.[14] Other professionals believe relationships with former patients are always unethical.[14]

Importantly, some states prohibit dating a former patient no matter how much time has elapsed.[26] Questions that may come up are whether the termination of treatment was formally documented, whether the patient's care was transferred to another provider, how long the treating relationship lasted, the time lapse since the physician-patient relationship ended, how much personal private information the patient confided, the nature of the patient's health problem, and the degree of patient emotional dependence and vulnerability.[1] It is unacceptable and still considered sexual misconduct if one terminates a physician-patient relationship so that sexual contact can occur.[1]

Furthermore, it would be grossly unethical to use private information obtained during treatment to coerce a former patient into a sexual relationship under threat of disclosing the information.

A physician also often interacts with third parties (e.g., spouses or partners, parents, guardians, and proxies), offering them information, advice, and emotional support. Factors to consider in judging the appropriateness of engaging in sexual or romantic relationships with third parties include the following:[28]

- Nature of the patient's medical problem
- Length of the professional relationship
- Degree of the third party's emotional dependence on the physician
- Importance of the clinical encounter to the third party and the patient

The AMA Code of Medical Ethics suggests that third-party relationships are more troubling when the person is deeply involved in the clinical encounter and in medical decision making for the patient.[28] Physicians should refrain from pursuing such relationships with key third parties if based on the use or exploitation of trust, knowledge, influence, or emotions derived from a professional relationship.

BEFORE MOVING ONTO THE NEXT SECTION, PLEASE COMPLETE CASE STUDY 1.

Maintaining Professional Boundaries

Each state's Medical Practice Act defines unprofessional conduct within that state. Many states have commonalities in examples of unprofessional conduct, which often include:[29]

- Alcohol and substance abuse
- Sexual misconduct
- Neglect of a patient
- Failing to meet the accepted standard of care in a state
- Prescribing drugs in excess or without legitimate reason
- Dishonesty during the license application process
- Conviction of a felony
- Fraud
- Inadequate record keeping
- Failing to meet continuing medical education requirements

Establishing professional boundaries to prevent sexual misconduct begins with recognizing and preventing workplace sexual harassment, which may range from inappropriate to unlawful. Any sexual harassment permitted within a professional culture risks dire consequences to patients and fosters an unwillingness by bystanders to report misconduct.[1,24] In the case of consensual relationships involving professional colleagues, no supervisory role is appropriate and should be eliminated if both parties wish to pursue a relationship. Firm and enforceable policies around sexual harassment set the tone and culture for professional practices that will extend to respecting and safeguarding patients.

The responsibility to set and maintain professional boundaries in interactions with patients lies with the physician.[13,14,30] Because of lack of education or awareness, practicing physicians may encounter situations in which they have unknowingly violated their state Medical Practice Acts through boundary violations.[1] Dubois and colleagues notes that 40% of boundary violations in their study involved inappropriate touching or consensual sex, suggesting an opportunity to remediate ignorance in regard to medical professionalism by developing better insight into one's behavior and its impact on others.[1,6] One way to do this is ask oneself the motivation for any action that would be considered clinically unorthodox and to know that it is misconduct if it is sexually motivated.

Boundary Crossings

Some actions with patients may be benign (or thought to be benign) but lie outside of usual clinical practice. Boundary crossings consist of actions that deviate from a physician's standard practice and represent forays into a "gray zone."[2] The concept of the "slippery slope" from the field of psychiatry says boundary crossings may progress to boundary violations down the line. Whether a boundary crossing is harmful, neutral, or beneficial can only be assessed within the clinical context. Therefore, it is important to consider the relevance to the patient and the motivation by the physician for any deviation from usual practice.

Case Study 1

Instructions: Please read through the case study below and consider the questions that follow.

A 22-year-old college student sought care from her family physician of four years for a suspected urinary tract infection. A diagnosis was made via urinalysis, and antibiotics were prescribed. During the clinic visit, the student mentioned a possible wish for birth control, and the physician suggested she make an appointment for a full gynecological exam. He mentioned that he could check "her equipment" for any problems she might have achieving orgasms and that he could help her performance live up to her "porn star" looks. He was otherwise kind, professional, and attentive to her other clinical concerns, including checking an ankle she had recently strained, suggesting that she continue to elevate it nightly for a week or two and use ibuprofen as needed. The student attended college out-of-state from her hometown and so sought medical care for the first time on her own with this physician. She first saw him at age 18 for treatment of dehydration following a severe case of seasonal flu. At that time, she had found him to be professional and competent. She now felt confused by his statements regarding her purported intimate concerns, which he, not she, had raised.

1. **Does the behavior on the part of the physician constitute grooming?** _____

2. **What issues are raised in regard to professional boundaries (e.g., sexual impropriety vs. violation)?** _____

Discussion: The physician's comments go beyond grooming behaviors, which might include maneuvering to see a patient after normal clinic hours meant to "test the waters" to see whether a patient will object and/or whether an opportunity for misconduct exists. The inappropriate comments were meant to create an environment of intimacy and were a form a sexual impropriety that may also be a precursor to other, more severe forms of sexual misconduct.

The nine boundary domains identified by Guthail and Gabbard along with some examples of issues or motivations to consider concerning these domains are:[31]

1. Role (e.g., is that part of what a doctor does? Are you also a friend, spiritual mentor, other?)
2. Time (e.g., standard vs. special hours, alone in building at end of day)
3. Place and Space (e.g., deviating from usual settings)
4. Money (e.g., reduced fees for which gratitude or other "currency" is expected)
5. Gifts and Services (e.g., set policy regarding max dollar value, perceived obligation)
6. Clothing (e.g., self-expression vs. cultural/community norms, institutional expectations)
7. Language (e.g., first names, colloquialisms, humor)
8. Self-Disclosure (e.g., rapport, reassure patient, burden patient, patient curiosity)
9. Physical Contact (e.g., handshake standard pre-pandemic, touch on shoulder, hugs)

Regardless of intent, physicians should avoid any clinical or nonclinical contact with a patient that could be construed as sexual or romantic.[13] Examples might include any evaluation of a patient outside the usual clinic setting that could be seen as blurring the boundaries between professional and nonprofessional interactions (exceptions might include an emergency or medically-indicated home visit). During clinic visits, expressions of humor should steer clear of sexual innuendo and provocation. Interactions by telephone, e-mail, text, or social media all should reflect the same high standard of professional boundaries.

Physicians should be aware that physical contact that may be intended as a comforting gesture (e.g., placing a hand upon a patient's knee) may be experienced differently by the patient. The American College of Obstetricians and Gynecologists (ACOG) Committee on Ethics issued the opinion that under some circumstances, limited physical contact between a physician and a patient, including a brief hug or holding a patient's hand, may provide valuable therapeutic support with clear indication that the patient is open to such contact and its duration is appropriately limited.[13] The patient's age, gender identity, nationality, community norms, and many other factors influence how physical gestures are received. A handshake has been considered standard and expected when good hand-washing practices are observed;[2] however, Covid-19 protocols have shifted practices in this regard. When in doubt, ask the patient. If the patient offers an appreciative hug, it is best to consider one's own comfort level with the gesture and to respond accordingly. This might entail tactfully deflecting physical gestures that lie outside the clinical context. If a patient initiates inappropriate contact, physicians should separate themselves from the patient, reinforce professional boundaries, and, if feeling unsafe, exit the room and request any needed assistance.[32]

Awareness is key to preventing the progression to boundary violations. Physicians are asked to reassess their motivations and to ask the primary question of whether an action that is not within the one's usual practice is beneficial to the patient and relevant to the patient's medical care.[2] Physicians are also asked to reflect upon personal vulnerabilities that might motivate instances of self-disclosure, non-clinically-indicated touch, or other crossings of professional boundaries. Questions for self-reflection might include what circumstances might be affecting one's decision making, including whether one is bored, sick, lonely, recently divorced, or experiencing other life stresses.

A "Slippery Slope" Scenario[2]

- » Patient starts addressing you by your first name
- » You start scheduling that patient on Fridays, at the end of the day
- » You share a recent personal crisis with the patient
- » The patient gives a hug at the end of that appointment
- » Weeks later, you accept the patient's invitation for coffee
- » The relationship moves on to dating and physical intimacy

Duty to Report

State medical boards depend on individuals and entities to submit information pertinent to patient safety to fulfill their mission to regulate medicine in the best interests of patients. Physicians and medical students are ethically and often legally required to report suspected instances of sexual misconduct and patient harm.[1,25,30] Failure to report may be considered professional misconduct and is subject to disciplinary action by medical boards.[14] The FSMB further suggests that when self-regulation fails, state medical boards should be empowered to levy fines against institutions who fail to report egregious conduct, perhaps publicizing the reasons, increasing reputational risk and thus incentive for institutions to report.[1]

Many professional organizations (AMA, AAOS, ACOG) as well as state licensing and disciplinary agencies require reporting of sexual misconduct as an ethical standard.[14] The AMA states that responsibility to the patient is paramount and includes the imperative to report physicians engaged in unethical behavior.[33] An FSMB position statement on the duty to report highlights the professional obligation to "do no harm" and the "ethical principle of beneficence."[34] These obligations encompass preventing direct harm (or circumstances with high risk of harm) to patients and also by removing conditions that would lead to harm. Thus, the duty to report is considered fundamental to fulfilling the principle of beneficence by removing potentially harmful conditions.

The AMA website lists reporting incompetent or unethical behaviors by colleagues among the top 10 ethical issues students should learn in medical school.[35] This requirement goes to the heart of medicine's long tradition of self-regulation, which calls on physicians to safeguard patients' welfare. Professional codes of ethics and other statements from medical associations are expressions of self-regulation but lack strong enforceability, being limited to such actions as censure or loss of membership.[23,36]

In most jurisdictions, there is also a legal obligation to report physician misconduct.[14] Most states make it a condition of licensure for physicians to formally report to the board of licensure any reasonable basis to believe another licensee has violated any of the board's regulations.[25] In addition, most states protect from lawsuits those who report in good faith.[25]

State Medical Practice Acts and other relevant legislation outline responsibilities in regard to patient welfare.[34] For a good example of the duties incumbent upon physicians, organizations, hospital leaders, medical officers, and medical staff in reporting professional misconduct or incompetence to state medical boards see the document, "Essentials of a State Medical and Osteopathic Practice Act:" https://www.fsmb.org/siteassets/advocacy/policies/essentials-of-a-state-medical-and-osteopathic-practice-act.pdf. Similar language is included in most state law. However, states vary in how legislation describes the mandatory duty to report with language that may require actual or first-hand knowledge, reasonable cause, or reasonable probability (as distinguished from mere probability) that an action constitutes misconduct.[1] The FSMB suggests the "theme of reasonability" as a guide to reporting colleague actions. Therefore, if "it is reasonable" to believe misconduct occurred, physicians must report the actions to the state medical board and (with some exceptions) to law enforcement.[1] State medical boards also may take disciplinary action against licensed physicians who fail to report misconduct.[1]

The Challenge to Report

Unfortunately, much misconduct observed among medical colleagues and in learning environments goes unreported, despite the ethical and legal imperatives. A survey of 3504 physicians found that while 96% of respondents agreed that physicians should report impaired or incompetent colleagues to authorities, 45% of respondents had encountered such colleagues and not reported the information.[37] Other data indicate that the patient is nearly always the one to report misconduct, rarely another member of the medical team.[6]

Physicians and other healthcare colleagues fail to report misbehavior in the workplace and educational environment for several reasons that include:[1,25]

- Moral distress and discomfort with reporting colleagues
- Power dynamics that put reporting physicians at risk for professional consequences

- Institutions that neglect prioritizing reporting and transparency
- Fear of damaging colleagues
- Fear of retaliation
- Confusion about what happened
- Uncertainty about what to report and to whom
- Concerns over loss of friendships
- Concerns over having one's motives questioned
- Misunderstood requirements of confidentiality
- Reduced motivation stemming from conflicting and unpredictable responses by institutions (e.g., hospitals, professional societies, licensing boards)

These barriers cause fear and discomfort in physicians who observe professional misconduct, leading to avoidance, denial, and a wish to rationalize away the behavior. But there is no duty of confidentiality when a colleague has violated or is danger of violating the rights of a patient. Confidentiality is a duty in such a situation only if the offender is one's patient or another person receiving a formal consultation.

Concerns may also arise that patients may be harmed more by a physician workforce shortage, but such excuses for leniency are not acceptable. The report from the FSMB workgroup puts it this way: "In cases involving sexual misconduct, it is simply not true that unsafe or high-risk care is better than no care at all. A single instance, let alone many instances, can cause an extremely high degree of damage to individuals and the communities in which they reside."[1]

Physicians who are not appropriately reported are not stopped. They may move to other states or practices and continue to reoffend.[38] Failure to report results in avoidable additional harms to patients as nearly all professional breaches are repeated, suggesting that many incidents of sexual misconduct go undetected for years.[6] In short, nothing supersedes the ethical and legal duty to report an unfit colleague.

How to Report Misconduct

Early reporting of sexual misconduct can facilitate prevention and remediation of any harms and is one of the few ways less egregious conduct (such as grooming behaviors) can be addressed before it can lead to more egregious violations.[1] In addition to state medical boards, other entities may need to be notified, including law enforcement, hospital or medical staff administration, and medical school or residency program directors and supervisors.[1] When colleagues have substance-use disorders or other problems that interfere with safe practices, physicians' assistance organizations can offer opportunity for rehabilitation. Sexual assaults, as defined earlier, should be reported to law enforcement immediately, except in cases where reporting would contravene the wishes of an adult complainant and such non-reporting is permitted by state law. [1,13]

Steps to take when one becomes aware of or strongly suspects conduct that threatens patient welfare include the following:[33]

- Report the conduct to appropriate clinical authorities (i.e., peer review body if in a hospital) in the first instance misconduct is observed or suspected so that patient welfare can be assessed and any needed remedial action taken
- Report directly to the state licensing board when there is an immediate threat to the health and safety of patients or a violation of state licensing provisions
- Report to a higher authority if the conduct continues unchanged despite initial reporting
- Protect the privacy of any involved patients to the greatest extent possible, consistent with due process
- Report to the appropriate authorities (e.g., sexual assaults to law enforcement)
- Physician-supervisors who receive reports of alleged incompetent or unethical conduct should:
    - evaluate the information critically and objectively
    - hold the matter in confidence until resolved
    - ensure that identified deficiencies are remedied or reported to other appropriate authorities for action
    - Notify the reporting physician when appropriate action has been taken, except in cases of anonymous reporting.

If one is uncertain after observing something troubling in this domain, it is recommended to consult with an experienced clinician and not to avoid the issue through rationalization.[25] As Glass wrote in the AMA Journal of Ethics, "Ask yourself not just, 'What should I do?' but, when the rubber meets the road, 'Who do I hold myself to be?'"[25]

BEFORE MOVING ONTO THE NEXT SECTION, PLEASE COMPLETE CASE STUDY 2 ON THE NEXT PAGE.

State Medical Board Investigations

The mission of state medical boards is to protect the public. To accomplish this, boards have investigative power and ability to impose punitive measures. Sexual misconduct is grounds for disciplinary action. Sexual misconduct that falls under the category of sexual violation or assault also may meet the criteria for criminal prosecution.[13]

When a party makes a complaint, it sets an investigative process in motion that may encompass interviews, audits of patient charts, and/or visits by undercover agents to pose as patients.[23] Medical boards will also review any previous complaints to identify a pattern of behavior. Even before an investigation is complete, a board may issue an emergency suspension against a physician's license to practice medicine if the physician is judged to pose a risk of imminent harm to patients, whether this determination is made by a pattern of complaints or a single egregious incident.[1,29] Statutes of limitations may not apply in cases of rape, sexual assault, and other forms of sexual misconduct, as a trend toward removing these time thresholds is growing within state legislatures.[1] This is being done in recognition that a person who experiences trauma may need time to process the event or to be willing to relive it as part of a complaint process.

If the investigation shows a high probability sexual misconduct took place, the board may order a comprehensive evaluation of the physician with the goal of understanding the behavior.[1] The evaluation may require input from multiple disciplines and include conclusions about fitness to practice. Information sought includes any illness, impairment, or underlying conditions that may have predisposed the physician to engage in sexual misconduct or that might put patients at risk and whether any maladaptive behavior is a longstanding pattern.

If the board finds enough evidence, the next step is usually to initiate formal charges and schedule an administrative hearing. In most jurisdictions, this step is information that is available to the public.[1] In subsequent hearings and other legal encounters, a physician may offer factual and mitigating defenses. Some states require hearings to be public, although others do have statutory authority to close a hearing during testimony that could reveal the patient-complainant's identity.[1] Overall, a priority of the board is to guard against public disclosure that might discourage a patient from coming forward with a legitimate complaint against a physician. Expert witnesses may testify to provide insight into factors that led to the alleged sexual misconduct, the level of harm sustained by the patient, and the physician's risk for recidivism and potential to be rehabilitated. The witnesses may testify as to professional standards expected of a treating physician, the mental health diagnosis, treatment, and relevant status of the accused physician, including level of insight and change.[1]

The FSMB calls for fairness in the treatment of complainants and physicians alike.[1] Questioning of complainants and physicians is meant to collect information, not to serve as an aggressive cross-examination.[1] Patient-complainants must be granted fair treatment throughout the regulatory process and be afforded opportunities to report injustices committed against them. Similarly, physicians who are accused of sexual misconduct must be granted due process as cases are investigated and adjudicated. If discipline is required, it should be proportional to the offense. The principle of proportionality in the discipline of physicians highlights the significant shame that is visited upon a disciplined physician and also guides severity of discipline with egregious forms of sexual impropriety.[1]

Case Study 2

Instructions: Please read through the case study below and consider the questions that follow.

Two male physician-colleagues in a group practice are having lunch together when one begins to describe an unusual pattern of meeting with a patient, a 34-year-old woman. The patient has severe ongoing headaches that have been recalcitrant to treatment, and she makes frequent clinic appointments. The physician who sees her describes her as attractive, resembling, he says, his ex-wife. She does not get along with others in the clinic office, however, and has had verbal altercations with the office staff. He believes he can help her and has offered to meet with her at a coffee shop across the street from the clinic for her regular follow-up, so as not to subject her to upsetting encounters, which cause her pain levels to spike. Not long after this lunch, the physician who served as the confidante notices that the ongoing coffee shop encounters are now scheduled at the end of the work day and last longer than a typical clinic appointment. At the two men's next lunch together, the treating physician shares beach photos of the patient, which he says she texted to him. He mentions that he and she are making plans for a play date, as they are both divorced and have young children. He reports that her headaches appear to be improving, and he is hopeful that his combination of prescribed medication and cognitive behavioral therapy is helping her.

1. **Is there a legal duty to report the treating physician's behavior, and what considerations inform this decision?**_____

2. **Is there an ethical duty involved for the colleague who witnessed this behavior, and how are decisions reached regarding what to do?**_____

Discussion: A "slippery slope" scenario is when the fraying of treatment boundaries is apparent but the behavior by physician has not crossed any legal lines. Because colleagues work together, they may be first to recognize behavior that can serve as a warning that a colleague's judgment may be off in regard to a particular patient. It is better to address the behavior early before it becomes even more concerning. The ethical duty to report impaired or unprofessional colleagues is bound up in the duty to patients with safety being the crucial issue. Because the patient is not in imminent danger, a possible first step might be to voice concerns about the non-clinical encounters directly to the treating physician. For example, "It is obvious that you care about this patient, but it sounds like her treatment is evolving in a way that she could misunderstand and could end up as a problem for you."[25] This would give the treating physician an opportunity for self-reflection and correction and also enable the confidante to gauge whether other problems, such as mental-health or substance-use disorders might be causing impairment of judgment. Reporting might next involve a supervisor if the behavior subsequently is unmodified or worsens.

Reducing Implicit Bias

Medical boards are encouraged to seek training in implicit bias related to gender, gender identity, race, and ethnicity to ensure fair processes in investigations. Areas investigators are asked to be mindful of any personal bias that might affect their judgments, including status as having experienced sexual assault or having been accused of sexual misconduct.[1] The FSMB suggests that public members on state medical boards serve to reduce bias while amplifying the patient perspective.

Some of the factors medical boards consider in determining the appropriate disciplinary response include:[1]

- Patient harm
- Severity of behavior and context
- Culpability of physician-licensee
- Existence of a physician-patient or therapeutic relationship along with its scope and depth
- Inappropriate termination of physician-patient relationship
- Age and competence of patient
- Vulnerability of patient
- Number of times behavior occurred
- Number of patients involved
- Period of time relationship existed
- Prior professional misconduct, including disciplinary and malpractice history
- Results of evaluation and assessment and recommendations by evaluating or treating professionals and/or state PHP
- Risk of reoffending

Range and Variation in Possible Disciplinary Actions

If a physician is found culpable, the medical board report will detail particulars of the misconduct and cite which sections of the state Medical Practice Act have been violated. The board will then match the infraction with a broad range of possible sanctions that might include one or more of the actions shown in Table 3.[29]

A license to practice medicine is likely to be lost in cases of forced sexual contact.[14] If mitigating factors exist, a license revocation may be stayed in favor of practice limitations or conditions of probation.[1] A physician may be allowed to continue to practice with gender- or age-based restrictions in place, although the FSMB cautions boards only to take this action with a high degree of confidence the physician is not at risk of reoffending.[1] Practice monitors may be required to protect patients and must be properly trained and lack existing relationships with the monitored physician.[29] In addition, the physician may undergo a special evaluation and be required to attend courses on ethics and boundary violations. Physicians found guilty of sexual misconduct may also face other professional liability claims and criminal charges, when the circumstances warrant them.

The FSMB workgroup report states that private letters of warning are inappropriate in cases involving sexual misconduct.[1] When behavior is concerning (e.g., grooming) but does not rise to the level deserving disciplinary action, boards may issue a non-disciplinary letter of education that remains on the physician's record to facilitate revisiting cases to identify patterns that might pose future risk to patients.[1]

Medical boards may choose not to inform law enforcement of violations under certain conditions that include request by the complainant or less egregious misconduct (e.g., inappropriate language).[1] It is important to know that some states and some circumstances require mandatory reporting to law enforcement. There is increased discussion toward requiring state medical boards to report credible allegations of sexual misconduct to law enforcement authorities, particularly if the patient is vulnerable by definition.[6] Only 11 states require medical boards to report sexual violations to police or prosecutors when the victim is an adult.[6,12] Any abuse of a child, minor, or dependent adult must be reported to law enforcement, regardless of complainant wishes.[1] Each person has a responsibility to ensure the safety of children in healthcare settings and to scrupulously follow legal and ethical reporting procedures.[39]

Table 3. Possible Disciplinary Actions by State Medical Boards[1]	
Administrative action	**Non-punitive action**
Fine	Monetary penalty against physician
Continuing medical education required (CME)	Physician required to complete CME
Conditions required	Physician must fulfill certain conditions to avoid further sanction
License denied	Physician's application/renewal denied
License restricted	Physician may practice medicine within limitations (e.g., loss of prescribing privileges)
License revoked	Physician can no longer practice medicine within state or territory
License surrendered	Physician voluntarily surrenders medical license, sometimes during disciplinary investigation
License suspended	Physician may not practice medicine for specified period, perhaps due to investigation or until board requirements fulfilled
Probation	Physician's license monitored by state board for specified period
Reprimand	Physician issued warning or letter of concern

1. Federation of State Medical Boards (FSMB). About Physician Discipline: How State Medical Boards Regulate Physicians after Licensing. https://www.fsmb.org/u.s.-medical-regulatory-trends-and-actions/guide-to-medical-regulation-in-the-united-states/about-physician-discipline/ Accessed December 13, 2021.

Some states detail what behaviors are considered sexual misconduct while others give only brief definitions.[14] Furthermore, variation in state responses to physician misconduct has had the effect of sending many physicians with severe disciplinary actions back to practice.[38]

Recommendations to help heighten boards' consistency and prevent egregious misconduct include the following:[38]

- Permanently revoke or suspend medical licenses for first-time egregious offenses (e.g., rape)
- Permanently revoke or suspend medical licenses for repeated lesser offenses following remediation efforts
- Routinely ask victims of sexual abuse whether they want to pursue criminal charges and respect patient wishes (knowing requirements of mandatory reporting)
- Be cognizant that boards have the authority to remove physicians from medical practice more swiftly than the criminal justice system.

To prevent the physicians from changing jurisdictions undetected, medical boards voluntarily share licensee data with the FSMB's Physician Data Center. This information can allow the FSMB Disciplinary Alert Service to alert state boards within 24 hours when one of their physician-licensees receives disciplinary action in another state or territory.[29]

Public disclosure of information regarding the outcome of investigative findings and any disciplinary actions is important to guard patient welfare but also restricted by state statute in many jurisdictions. With the public welfare in mind, the FSMB workgroup favors making information available via state medical board websites, the FSMB Physician Data Center, and the NPDB.[1] Certain states, including California and Washington, require patient notification at the point of making an appointment when a physician's license has any restrictions related to sexual misconduct.[1] Other states may follow suit.

Remediation and Education

Remedial educational programs can be one component of disciplinary orders. Current risk stratification for choosing remediation involves considering severity of actions along with mitigating and aggravating factors, such as:[1]

- Physician character
- Physician insight and remorse
- Physician understanding of how actions violated ethics and legislative strictures
- Consequences to patient and public of allowing remediation/practice re-entry

Remediation efforts should be aimed at stopping offenders both initially and before they can reoffend, and in setting and enforcing professional guidelines for basic and intimate patient examinations that include recommended chaperones and other best practices. Partners in remediation are to be given access to investigative information so as to tailor remedial education to the context in which the sexual misconduct took place. To successfully complete remediation, participants must articulate why their actions were wrong, how they arrived at the point of committing the actions, and how they intend to guard against committing such actions in the future. Following remediation efforts, the physician is monitored during practice to ensure avoidance of circumstances similar to those of the sexual misconduct.

The ProBE Program (an acronym for "Professional Problem-Based Ethics) is one source of professional ethical remediation for physicians with disciplinary orders.[36] Between 1992 and 2013, 11.4 percent of ProBE participants were referred for sexual misconduct.[36] The program uses small-group settings to help participants discover and articulate how their misconduct violated ethical and professional responsibilities and recommit to professional ideals. The program parameters do not include predatory or addictive sexual behavior but rather sexual boundary violations with patients in which physicians "exercised poor judgment in a personal relationship that created a professional vulnerability."

Remediation emphasizes the role of judgment and self-regulation. This and similar programs of remediation are in line with FSMB recommendations when there are "some less egregious forms of sexual impropriety with mitigating circumstances."[1]

Successful remediation includes the following components:[1]

- Have clearly outlined goals
- Outline expectations for acceptable physician performance
- Be completed in person (online or distance learning is insufficient)
- Be related to the offense (which is fully disclosed)
- Be targeted to individual vulnerabilities and risks for committing sexual misconduct
- Have tailored remedial education particular to the context of misconduct
- Have a longitudinal mechanism for maintaining the physician's engagement
- Ensure longitudinal mechanism demonstrates the physician's commitment to accountability and the board's monitoring reach

When a license has been revoked, the potential goal of remediation is to reinstate the license, but medical boards are to remain mindful that remediation and reinstatement should be abandoned if the physician demonstrates any risk of reoffending.[1] Petitions to remove license restrictions should be considered in coordination with any treating professionals and the state PHP or other approved evaluation team.[1] The PHP model provides therapeutic alternatives to discipline for physicians with substance-use and mental health disorders; however, in cases that involve sexual misconduct, PHPs offer support to state medical boards but cannot serve as an alternative to discipline.[30] If asked, PHPs may coordinate comprehensive, multidisciplinary assessments or forensic evaluations to identify any treatable condition that may have contributed to poor judgment or assist with determining fitness for duty, sometimes with restrictions.[30]

Although remediation may be appropriate for some misconduct, evidence regarding its effectiveness is limited and recidivism is hard to study. More research is needed in many areas, including group learning experiences, instruction in victim empathy, the effect of adding other interventions to remediation, and how to identify those at an elevated risk of reoffending.[1]

Another factor that hampers study is indistinct coding when behavior is reported, and the specific label "sexual misconduct" is recommended over vaguer terms such as "disruptive physician behavior," "boundary violation,"[1] or "other."[38] Furthermore, the category "not applicable" in reports to the NPDB has been called "unhelpful, overused, and unnecessary," perhaps even enabling the non-reporting of serious offenses.[12]

Monitoring Physician Behavior

Monitoring capabilities and resources to track a physician's behavior going forward vary among states. A practice monitor (distinct from a chaperone) who is required to be present at all patient encounters or those restricted by gender and age, is one method that might be mandated by a state medical board.[1] Patients must be informed that the practice monitor is mandated as part of a practice restriction. If the patient is uncomfortable with the presence of the practice monitor, they must seek care from a different physician. Patient supporters such as family members or friends also may be present but do not replace a mandated practice monitor.

Criteria for practice monitors recommended by the FSMB workgroup include the following:[1]

- Formal training in role, including safe and appropriate ways to intervene
- A clinical background
- Not an employee or colleague of monitored physician
- If unknown contact is not available, existing professional relationship is disclosed (helpful if licensed in another health discipline)
- No disciplinary history
- Submits regular reports to state medical board

Guidelines for a Professional Practice

A healthcare practice requires strong policies and supporting interventions to end misconduct by physicians. Leadership within the organization is imperative. All parties within the system should understand the organization's guidance on professional behaviors and the duty to report unprofessional conduct. All members of the team should see role models for this behavior in daily practice.

Studies show that physicians can make positive changes given the right feedback and that serious practice violations may be prevented when there is a systematic approach to observation.[38] Peer review can be provided through medical society-sponsored registries of risky, invasive procedures.[38] Solo medical practitioners can receive peer review from afar through use of electronic medical records.[38]

Physicians and other colleagues in the workplace, including those in training, should be able to report sexual misconduct "without fear or loss of favor."[33] The persons reporting must be protected from retaliation (including through whistleblower legislation)[40] and any implication that progress through medical school and training or in promotions or other career advancement might be impeded.[1] Providing channels to remain anonymous while making complaints and during the hearing processes encourages a culture that reports adverse events without fear of retaliation or jeopardy to inter-professional relations.[34] When anonymous complaints are impossible or infeasible, complainants' identities should remain confidential and physicians with a complaint against them should not contact complainants.[34]

Physicians should promote and adhere to strict sexual harassment policies in medical workplaces.[24] The National Academies of Sciences reports that organizational culture that enables and appears to accept harassment leads to behaviors that are typically repeated and harmful to medical students and trainees.[7] A culture that permits harassment extends perceived license to engage in such behaviors, putting patients at risk for dire consequences.[1]

Grievance committees should represent diverse colleagues to ensure balanced discussion and decisions in regard to gender identity, age, ethnicity, sexual orientation, profession, and employment status.[24] Committees should make themselves available to those they are charged to serve and be able to enforce the policies they enact.

A summary of recommendations to create professional practices with ethical boundaries in place include the following:[8,38]

- Educate physicians at every training stage about the enormity of sexual misconduct, how to avoid it, and how to seek help if they are struggling with boundary challenges
- Educate the public how to prevent, recognize, and report physician sexual misconduct
- Encourage and empower patients who observe wrongdoing to report it and establish standardized processes for doing so
- Mandate reporting of observed misconduct by medical colleagues, medical students, residents, nurses, and others in the workplace and establish standardized processes for doing so
- Institute necessary measures to prevent reprisal against individuals who report misconduct
- Investigate credible complaints in a timely manner, balancing concerns for privacy with need for transparency
- Recognize that sexual harassment is strictly prohibited
- Never tolerate behavior that threatens patients or creates a hostile workplace
- Conduct physician evaluations with objective data comparing them to peers or 360° (multisource) evaluations from diverse stakeholders (e.g., colleagues, patients, caregivers, family members, supervisors, peers, allied health co-workers, trainees)
- Provide chaperones by default when an intimate examination is medically indicated
- Institute a systematic approach to peer review and oversight of group practices
- Warn all members of the healthcare team not to submit false or malicious reports or expect disciplinary action in response to any frivolous claim.[1]

A change in culture is achieved by making failure to report a professional liability in itself, one that is well understood to be unacceptable and liable for sanction.[1] Any false or frivolous reporting, whether driven by competition, personal animosity, or some other reason, should be met with stern disciplinary action.[1] The goal is to make the duty to report a core component of the medical profession rather than a burden that falls on the shoulders of a few.

Guidelines for Basic and Intimate Examinations

Good professional conduct starts with respectful, clear communication. Communication should occur throughout any examination that takes place without general anesthesia and should convey:[39]

- The medical necessity
- What the exam/procedure will involve
- Any discomfort the patient might experience
- Expected benefits
- Potential risks
- Any findings

For intimate examinations, it is especially important to communicate clearly to explain the parameters of interaction for physician and patient and minimize potential misunderstandings of the physician's actions.[39] Misunderstandings arise when sexual misconduct has occurred but the patient does not recognize it as such, as well when a patient perceives an interaction as sexual or romantic when the physician had no such intent.[13] Interactions that require sensitive physical examinations and disclosure of private information must be respected as times of intense vulnerability for patients.

Respecting a patient's dignity during intimate physical examinations requires providing a comfortable and considerate atmosphere. Some best practices include the following:[13,41]

- Provide appropriate gowns
- Provide private facilities for undressing
- Use draping sensitively
- Clearly and appropriately explain components of the physical exam
- Perform only with the patient's consent
- Perform with minimum amount of physical contact to inform diagnosis and treatment
- Offer the patient the opportunity to ask questions or raise concerns about any element of the exam

- Have a chaperone present for all breast, genital, and rectal exams
  - irrespective of gender of the examining physician
  - in inpatient and outpatient settings
  - during labor and delivery
  - during diagnostic studies (e.g., transvaginal ultrasonography and urodynamic testing)
- Report observed or suspected sexual misconduct to appropriate authorities
  - Supervisors
  - Department chairs or other institutional authorities
  - Peer review organizations
  - Professional licensing boards
  - Law enforcement, in cases of sexual or physical assault
- Create and follow clear guidelines for staff to report without fear of retaliation
- Educate students and trainees regarding the inherent power imbalance in the patient-physician relationship, procedures for reporting suspected misconduct, risk factors for sexual misconduct, and need to avoid sexually offensive or denigrating language

More on Use of Chaperones

Chaperones in the exam room reassure the patient of the professional nature of the exam and intent of the physician, witness all events that take place, and deter potential inappropriate behavior.[13] Guidelines from an ACOG committee now recommend routine use of chaperones for all intimate examinations, which is a change from the organization's previous "opt-in" approach when mandated by policy or requested by the patient.[13] Exceptions would be in an emergency when a failure to perform the exam would result in significant and imminent harm to the patient or when a patient declines the use of a chaperone.[13] A patient who declines having a chaperone present should be counseled as to the reason a chaperone is integral to providing good medical care and be informed that the policy is to protect both patient and physician. The physician should listen to any concerns of the patient and, if possible, take steps to address the concerns. If the patient still refuses the chaperone, the physician is to respect and document the decision.[13] A physician may elect to defer breast, genital, or rectal exams if they are to be performed unchaperoned. Therefore, patients may opt out of a chaperoned exam, but physicians are not compelled to examine without the protection of chaperone except in cases of medical emergencies. All information regarding chaperones, should be documented in the medical record.

The AMA position regarding chaperones is that physicians should ensure:[41]

- Patient are free to request a chaperone during any physical exam, and that this policy is communicated to patients
- A patient's request for a chaperone is honored
- A chaperone is an authorized member of the health care team
- Chaperones are held to clear expectations of upholding professional standards of privacy and confidentiality of health information
- There is general use of chaperones even when a patient's trusted companion is present
- Opportunities occur for private conversation with the patient without the chaperone present
- Inquiries or history taking of a sensitive nature is minimized during a chaperoned examination

Chaperones should be trained in best clinical practices and empowered to report misconduct through an independent process.[13] Use of trainees, such as medical students or residents, as chaperones is discouraged unless they are similarly trained in best practices and empowered to report any concerns independent of the physician.[13] Family members may be present if requested by patients but are not to be used as chaperones.[13] Staffing should be adequate to protect patient privacy and permit routine use of chaperones. Any failure by a physician to adhere to policy concerning chaperones should be reported to the appropriate manager (e.g., medical director, chief, or chair). Organizations should have channels for anonymous reporting either by phone or by online template.

Unfortunately, sexual misconduct can and does occur with a chaperone (or others) present. It is telling that disgraced gymnastics doctor Nassar engaged in sexual misconduct with patients with parents present in the room.[38] Chaperones sometimes look away or engage in doing paperwork out of a mistaken idea that they are respecting patient privacy or implying trust in the process. It is essential that the chaperone be properly trained to observe while maintaining patient privacy, to remain engaged, to recognize inappropriate behavior, and to know how to speak up if sexual misconduct is seen.[6]

BEFORE MOVING ONTO THE NEXT SECTION, PLEASE COMPLETE CASE STUDY 3 ON THE NEXT PAGE.

Respectful Communication/Social Media Use

Generational values evolve in terms of what is considered respectful communication. In the past, such values might have manifested in speaking of "romantic relationships" with patients or as fear of putting physicians "out of work" by reporting misconduct. The FSMB report on sexual misconduct states that so-called "romantic" behavior between a physician and a patient would at least constitute grooming and is never appropriate despite any appearance of consent on the part of the patient.[1]

There are other examples of generational change. Previous calls to separate personal and professional identities online have been lately criticized as unnecessary or impossible.[42] Some modern physicians are not sticklers for being addressed as "Doctor" rather than by their first names. Guidelines can be expected to change further along with technology and the larger culture. Yet however culture changes, principles of medical professionalism are still rooted in respectful recognition of boundaries.[43] The goal is to earn and retain the public's trust.

Some best practices in every circumstance include to:[43]

- Guard against excessive self-disclosure
- Maintain integrity, compassion, and respect for others
- Respect patient privacy and autonomy
- Maintain accountability to patients, society, and the profession
- Be sensitive to diverse populations
- Commit to ethical principles regarding care, confidentiality, informed consent, and business practices

Lines may become blurred when there is limited access to medical care, including in rural areas where physicians are well-known members of the community. Even so, well-established professional boundaries can help protect physician practices and preserve quality patient care. Suggestions for properly establishing the physician-patient relationship and precluding even the appearance of impropriety include:[44]

- Discouraging informal inquiries by insisting patients be seen in-office whenever possible
- Engaging in ongoing evaluation of objectivity in treating friends or family members
- Realizing when objectivity is compromised regarding any patient and referring immediately to another physician
- Redirecting patients who call outside of office hours to the on-call physician or to wait until morning, excepting emergencies
- Always charging for services
- Examining members of the opposite gender only with a staff person of same gender as the patient in the room
- Politely but firmly deflecting any behavior (e.g., hug or kiss on the cheek from a close friend) that may be regarded by staff or others as inappropriate conduct with a patient
- Referring intimate partners to another physician
- Refraining from intimate partnerships with staff members and patients

Communication skills include using social media professionally. Social media is now part of medical education, patient engagement, and quality improvement initiatives[43] and also provides professional opportunities, camaraderie with others in the medical field, and opportunities to disseminate beneficial public health messages. With these privileges come responsibilities and new challenges to the patient-physician relationship. Social media posts are public and can have immense longevity and reach as a result of being shared by others.[43]

Case Study 3

Instructions: Please read through the case study below and consider the questions that follow.

A woman presented to a male family medicine physician for treatment of a spinal injury suffered in the workplace. A female chaperone was invited into the room by the physician and was present throughout the examination. The physician began by assessing the patient's pain level and history of injuries. The physician then handed the chaperone a closed laptop and asked her to record the information from the physical exam and history in the patient medical record. He then turned to the fully clothed patient and began an examination of her spine from top to bottom. He asked her to reach down and touch her toes and when she did so, he put his hand in her underwear and inserted an ungloved finger into her anus. He did not explain why this was a necessary medical procedure, nor did he obtain informed consent prior to performing this action. When she turned her head to assess the physician's intent, she found him smiling at her with his finger still inserted. Quickly, he told her she could straighten up then turned to the sink and washed his hands, explaining that he did not believe she had a fracture in her spine. The chaperone who had had difficulty accessing the patient record was now entering information into the laptop as previously instructed. The patient objected verbally to what had just occurred. The chaperone had not observed the behavior.

1. **What actions might the chaperone take?** _____

2. **What training is necessary for chaperones to perform their duties, and what is a physician's responsibility?** _____

Discussion: The chaperone is there to act as a witness and should stand in a location where the examination can be observed. A chaperone has the right to stop a sensitive procedure or examination if they suspect the physician's behavior is inappropriate. In this case, the chaperone did not witness the behavior directly or stop the exam. But the patient complaint of unacceptable behavior means the chaperone should immediately report this incident to the appropriate manager, who should ask the patient if she would like to file a complaint and/or criminal charges. It is a physician's responsibility to know what constitutes appropriate training of a chaperone and to ensure that the presence of a chaperone provides protection to the patient through observation and reporting. More uniform expectations and clear education in regard to chaperones adopted throughout the medical profession can help ensure that they provide more than the illusion of safety and that harmful (or criminal) behaviors do not go unnoticed.

Considerations all physicians should weigh when online include the following:[45]

- Maintain patient privacy and confidentiality, refraining from posting identifiable patient information
- Follow ethics guidance regarding confidentiality, privacy, and informed consent when posting for educational purposes or to exchange information professionally with other physicians
- Use privacy settings to safeguard personal information and content while realizing privacy settings are not absolute and content on the internet is likely permanent
- Routinely monitor own internet presence to ensure that personal and professional information and (to the extent possible) content posted about oneself by others is accurate and appropriate
- Maintain same appropriate boundaries of the patient-physician relationship as in any other context if interacting with patients
- Consider separating personal and professional content online
- Bring unprofessional content posted by any colleague to the attention of the individual; if behavior significantly violates professional norms and the individual does not take appropriate action to resolve the situation, report the matter to appropriate authorities
- Recognize that actions online and content posted may harm reputations, have consequences for medical careers (particularly for physicians-in-training and medical students), and can undermine public trust in the medical profession

Trauma-Informed Care

Individual trauma results from an event, series of events, or set of circumstances experienced as physically or emotionally harmful or life threatening and that has lasting adverse effects on the individual's functioning and mental, physical, social, emotional, or spiritual well-being.[1,46]

Trauma-informed programs, organizations, or systems:[1,46]

- Realize the widespread impact of trauma
- Understand potential paths for recovery
- Recognize signs and symptoms of trauma in clients, families, staff, and others
- Respond by fully integrating knowledge about trauma into policies, procedures, and practices
- Seeks to actively resist re-traumatization

Physicians should also be familiar with how trauma can affect investigations. With a patient-complainant who has experienced trauma, the emotions may not appear to match circumstances of the complaint, the report of the event may not be linear, and seemingly salient details may be unreported or unknown to the complainant.[1]

The Ohio Alliance to End Sexual Violence maintains an online resource (https://oaesv.org/what-we-do/resources-for-providers/advocates/) for providers and advocates to facilitate the survivor's recovery process, from immediately following the crime to decades later. The page contains information on underserved victims of sexual assault, including the elderly, culturally-specific communities and limited English-proficient speakers, people who are deaf or hard of hearing, American Indian and Alaskan Native women, children and youth, individuals who identify as LGBTQ, immigrant women, male survivors, and people who live in rural populations and communities of color.

Other resources for physicians are shown in Table 4.[1] This is not a comprehensive list but gives some guidance on preventing sexual misconduct and maintaining professional boundaries, providing trauma-informed care, and understanding and addressing implicit bias.

Resources and Education for Patients

It is essential that patients know how to file complaints about their physicians to state medical boards. But roughly half of Americans do not know that medical boards are responsible for licensing and regulating physician practice in the United States.[15] Only 3 in 10 Americans say they know how to find out if their physician's medical license has received a disciplinary action.[15] Some mistakenly believe the best resource to contact is the physician's office or hospital, the AMA, or a lawyer.

It must be reemphasized that responsibility of ensuring competent, professional care lies with physicians.[30] However, patients are empowered by information, and it is appropriate to provide them with written education (for example, ACOG's "Your First Gynecologic Visit").[38]

Table 4. Resources for Physicians[1]	
On Sexual Misconduct and Maintaining Professional Boundaries:	
Source	**Title with links**
American Medical Association: Code of Medical Ethics	Sexual and Romantic Boundary Violations Duties to Report Unprofessional Conduct: Physician Wellness and Professional Conduct Political Matters, Contributions, Gifts, and Social Media
American Academy of Orthopaedic Surgeons	Sexual Misconduct in the Physician-Patient Relationship
Federation of State Medical Boards	Directory of Physician Assessment and Remedial Education Programs
North Carolina Medical Board	Guidelines for Avoiding Misunderstandings During Patient Encounters and Physical Examinations
University of Vermont	Mandatory Reporters and CSAs (Sample Reporting Guidelines)
Vanderbilt University Medical Center Online	CME Course: Hazardous Affairs — Maintaining Professional Boundaries
Vanderbilt University Medical Center	Boundary Violations Index (questionnaire) The Sexual Boundary Violation Index: A Validation Study
On Trauma-Centered Care:	
Source	**Title**
Substance Abuse and Mental Health Services Administration	Concept of Trauma and Guidance for a Trauma-Informed Approach
National Institute for the Clinical Application of Behavioral Medicine	How Trauma Impacts Four Different Types of Memory
Frontiers in Psychiatry	Memory Distortion for Traumatic Events: the Role of Mental Imagery
Government of Canada, Department of Justice	The Impact of Trauma on Adult Sexual Assault Victims
National Institutes of Health Public Access	Trauma-Informed Medical Care: A CME Communication Training for Primary Care Providers
Western Massachusetts Training Consortium	Trauma Survivors in Medical and Dental Settings
American Academy of Pediatrics	Adverse Childhood Experiences and the Lifelong Consequences of Trauma
American Academy of Pediatrics	Protecting Physician Wellness: Working With Children Affected by Traumatic Events
Public Health Agency of Canada	Handbook on Sensitive Practice for Health Care Practitioners
Psychiatric Times	CME: Treating Complex Trauma Survivors
NHS Lanarkshire (Scotland)	Trauma and the Brain (Video)
London Trauma Specialists	Brain Model of PTSD - Psychoeducation Video
On Implicit Bias:	
Association of American Medical Colleges	Unconscious Bias Resources for Health Professionals
Association for the Study of Medical Education	Non-conscious bias in medical decision making: what can be done to reduce it?
American Public Health Association	Patient Race/Ethnicity and Quality of Patient–Physician Communication During Medical Visits
Institute for Healthcare Improvement	Achieving Health Equity: A Guide for Health Care Organizations
BMC Medical Education	Training to reduce LGBTQ-related bias among medical, nursing, and dental students and providers: a systematic review
American Psychological Association	CE: How does implicit bias by physicians affect patients' health care?
Joint Commission	Implicit bias in health care
Oregon Medical Board	Cultural Competency — A Practical Guide for Medical Professionals
StratisHealth	Implicit Bias in Health Care (Quiz)

1. Federation of State Medical Boards (FSMB). Report and Recommendations of the FSMB Workgroup on Physician Sexual Misconduct. 2020; http://www.fsmb.org/siteassets advocacy/policies/report-of-workgroup-on-sexual-misconduct-adopted-version.pdf. Accessed November 10, 2021.

Educational resources help patients learn what to expect during intimate examinations and procedures (e.g., use of chaperones) and to know what is and is not normal practice.[39]

Patients should be encouraged to do the following:[6]

- Report sexual assaults to police
- Ask physicians for an explanation if unsure of the medical necessity to undress or another portion of an intimate exam
- Never allow children to be examined alone
- Request the presence of a nurse or other chaperone if a minor requires a conversation or exam without parent present
- Trust their instincts if something does not look or feel right to them

Informed consent is key to shared decision making. Patients should be informed at minimum of the reason for the treatment, a discussion and comparison of treatment options, and risks involved with treatments or procedures.[1] The informed consent process should also encompass the patient's values and preferences and a documented record of this shared decision.[1]

With exceptions for urgent, emergency, or same-day care, one should obtain patient consent well in advance with the understanding that patients are disadvantaged by the requirement to give quick decisions at the point of care.[1] If anesthesia (or the possibility of anesthesia) is involved, informed consent should include information about the effects, including the possibility of amnesia, with a view to preventing particular dangers of sexual misconduct in these patients.[1] If any photograph or video is to be taken, the patient must give consent that is then documented in the medical record.[13]

All informed consent materials should be written in common language that is easily accessible to the lay public. If consent cannot be obtained (due to anesthesia or any other reason), only medically-necessary intimate examinations should be performed and never for purely educational reasons.[1] Patients capable of making decisions have the right to refuse any examination or procedure.[13]

How State Medical Boards/ Professional Associations Can Facilitate Patient Reporting of Sexual Misconduct[1]

- » Provide multiple channels (e.g., writing, phone, email, online form)
- » Clearly post process of state medical board websites
- » Ensure translation of complaint materials for complainants who do not speak English
- » Educate as to types of physician behaviors to expect
- » Educate as to types of physician behaviors that warrant complaint
- » Educate on what to do if made uncomfortable by physician's actions
- » Educate on what actions would warrant direct report to law enforcement
- » Ensure public anonymity of complainant (anonymity to board may not be possible)

Conclusions

The overwhelming majority of physicians who provide compassionate, competent care within professional boundaries risk compromise to the reputation of their profession from the "bad apples" within their ranks. Sexual misconduct by a physician is an abuse of power and is grounds for investigation, sanction, and, when warranted, criminal prosecution. Because offenders often repeat their misconduct, many patients can be affected over years or even decades.

Sexual misconduct by physicians is properly and effectively addressed through standards and expectations of professionalism, preventive education, meaningful disciplinary action, law enforcement when required, traditional self-regulation, and the modern concept of shared regulation.[1]

Best practices during intimate examinations include routine use of chaperones, obtaining patient consent, using the minimum amount of physical contact to inform diagnosis and treatment, and maintaining open, informative, and respectful communication. All physicians have a duty to report observed or credible suspicion of sexual misconduct by colleagues and superiors. Effectively addressing physician sexual misconduct will require widespread cultural and systemic changes and medical education across the practice continuum.[1]

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GUIDANCE ON PROFESSIONAL BOUNDARIES AND SEXUAL MISCONDUCT

Self-Assessment

Choose the best possible answer for each question and mark your answers on the self-assessment answer sheet at the end of this book. There is a required score of 70% or better to receive a certificate of completion.

1. **Percentage of people believed to report sexual misconduct by medical practitioners:**
   A. Approximately 50%.
   B. Approximately 15%.
   C. Approximately 10%.
   D. Approximately 5%.

2. **Ways to increase reporting of incidents of physician sexual misconduct in the workplace include:**
   A. Ensuring reports can be filed anonymously and free from fear of retaliation.
   B. Expecting some frivolous claims of misconduct as a "cost of doing business".
   C. Protecting the anonymity of the institution involved from media representatives.
   D. Requiring at least two reports of misconduct by colleagues of the physician.

3. **During intimate examinations, the physician is advised to:**
   A. Communicate with patients by clearly explaining each part of the exam.
   B. Minimize privacy concerns by seeing the patient alone.
   C. Instruct chaperones to document each physician action in the medical record.
   D. Put the patient at ease by using distraction methods common to trauma-informed care.

4. **To run a professional practice with appropriate patient boundaries, a physician-leader:**
   A. Requires medical staff to report sexual misconduct to an immediate supervisor ahead of any outside agency.
   B. Assumes patients with symptoms of post-traumatic stress disorder have experienced sexual trauma.
   C. Strictly prohibits sexual harassment in the workplace.
   D. Trains all medical staff to act as chaperones during intimate exams.

5. **A trained chaperone is not necessary during a patient exam when:**
   A. The physician and patient are the same gender.
   B. The physician-patient relationship is established.
   C. The patient has signed a release.
   D. The patient refuses a chaperone.

6. **Which of the following is an example of a physician sexual impropriety that does not rise to the level of a sexual violation, according to criteria of the Federation of State Medical Boards (FSMB)?**
   A. Inserting a gloved finger into the anus during an intimate examination.
   B. Asking a patient to meet for coffee outside of clinic hours to discuss medical care.
   C. Commenting on the attractiveness of a patient's breasts.
   D. Kissing the patient on the mouth.

7. **Which of the following is an example of a sexual violation that rises beyond the level of sexual impropriety?**
   A. Rubbing an erect penis against the patient's leg.
   B. Inviting a medical student to watch an intimate examination without the patient's consent.
   C. Stopping the patient from leaving by placing both hands on the patient's shoulders.
   D. Reciprocating a hug initiated by the patient.

8. **Which of the following statements is true of the lasting effects of trauma?**
   A. Adults inevitably reenact the types of trauma learned in the childhood home.
   B. A person who experienced trauma may exhibit emotions that do not appear to match the trauma.
   C. Children rarely show effects of trauma until years after the traumatizing event.
   D. A person who has experienced trauma can usually recall the exact time of a traumatizing event.

9. **Accepting a brief hug from a patient who is expressing appreciation for medical care is:**
   A. A cause for remediation.
   B. An action for which a written report to a superior is advised.
   C. An action that, if observed, might bring a warning letter from a state medical board.
   D. An example of a boundary crossing that may offer therapeutic value in some circumstances.

10. **Which of the following constitutes a reason a medical board might take disciplinary action?**
    A. Failure to report observed sexual misconduct by a colleague.
    B. Pattern of asking patients to coffee outside of clinic hours.
    C. Rural physician who examines family friends, including for intimate exams as medically indicated.
    D. A comment to a patient that could be judged as excessive self-disclosure.

EFFECTIVE MANAGEMENT OF ACUTE AND CHRONIC PAIN WITH OPIOID ANALGESICS

COURSE DATES:	MAXIMUM CREDITS:	FORMAT:
Release Date:10/2021 Exp. Date: 9/2024	3 *AMA PRA Category 1 Credits™*	Enduring Material (Self Study)

TARGET AUDIENCE

This course is designed for all physicians and other health care professionals involved in the management of patients with pain.

HOW TO RECEIVE CREDIT:

- Read the course materials.
- Complete the self-assessment questions at the end. A score of 70% is required.
- Return your customer information/ answer sheet, evaluation, and payment to InforMed by mail, phone, fax or complete online at program website.

COURSE OBJECTIVE

This CME learning activity is designed to increase physician knowledge and skills about guideline-recommended principles of pain management, the range of opioid and non-opioid analgesic treatment options, and specific strategies for minimizing opioid analgesic prescription, diversion, and abuse.

LEARNING OBJECTIVES

Completion of this course will better enable the course participant to:

1. Identify the range of therapeutic options for managing acute and chronic pain, including non-pharmacologic approaches and pharmacologic therapies.
2. Explain how to integrate opioid analgesics into a function-based pain treatment plan individualized to the needs of the patient, including counseling patients and caregivers about the safe use of opioid analgesics.
3. Discuss recommendations and rationale for incorporating emergency opioid antagonists into prescribing practice for training patients and family members on the use of naloxone.
4. Identify medications currently approved for the treatment of opioid use disorder and the ways these medications differ in terms of mechanisms of action, regulatory requirements, and modes of administration.

ACCREDITATION STATEMENT

InforMed is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians.

DESIGNATION STATEMENT

InforMed designates this enduring material for a maximum of 3 *AMA PRA Category 1 Credits™*. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

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DISCLOSURE OF INTEREST

In accordance with the ACCME Standards for Commercial Support of CME, InforMed implemented mechanisms, prior to the planning and implementation of this CME activity, to identify and resolve conflicts of interest for all individuals in a position to control content of this CME activity.

COURSE SATISFIES

SPECIAL DESIGNATION

This course satisfies three (3) *AMA PRA Category 1 Credits*™ on controlled substance prescribing practices, abuse/misuse, and pain management.

The Georgia Composite Medical Board requires all Physicians (MD/DO) and Physician Assistants (PA) to complete forty (40) *AMA PRA Category 1 Credits*™ or equivalent hours during their two-year licensure period as a condition of license renewal. Additionally, this course satisfies the three (3) hour one-time requirement on controlled substances for Initial Licensees (First Time Renewals).

FACULTY/PLANNING COMMITTEE DISCLOSURE

The following faculty and/or planning committee members have indicated they have no relationship(s) with industry to disclose relative to the content of this CME activity:

- Annette Skopura, PHD
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The following faculty and/or planning committee members have indicated they have relationship(s) with industry to disclose:

- Paul J. Christo, MD, MBA has received honoraria from GlaxoSmithKline and Eli Lilly.

STAFF AND CONTENT REVIEWERS

InforMed staff, input committee and all content validation reviewers involved with this activity have reported no relevant financial relationships with commercial interests.

DISCLAIMER

The challenge of pain management

Physicians caring for patients in pain face an unusually daunting set of challenges. As with many other chronic conditions, clinicians must carefully balance expected benefits of treatment with the potential for harm from such treatments. Treating pain, however, involves an additional level of complexity because one of the most commonly-used classes of pain medications—opioids—are at the center of national efforts to stem the epidemic of opioid-related abuse, addiction, and overdose.[1]

The United States has seen three successive waves of opioid overdose deaths related to both legal and illegal opioids (Figure 1).[2] The first began in the 1990s and was associated with steadily rising rates of prescription opioids. In 2010, deaths from heroin increased sharply, and by 2011 opioid overdose deaths reached "epidemic" levels as described by the Centers for Disease Control and Prevention (CDC).[3] The third wave began in 2013 with a sharp rise in overdose deaths attributed to synthetic opioids, particularly those involving illicitly-manufactured fentanyl.

In late 2020, the CDC announced that 81,230 drug overdose deaths occurred in the 12 months ending in May, 2020, which was the highest level of overdose deaths ever reported.[4] The surge was primarily driven by a 34% increase in overdose deaths related to synthetic opioids, primarily fentanyl.[4] Overdose rates appear to have accelerated during the COVID-19 pandemic.[5] Between 1999 and 2019, the CDC estimates that nearly 500,000 people in the United States died from such overdoses.[6]

Coupled with rising rates of overdose death are equally dramatic increases in the number of people misusing or abusing opioids. As many as 1 in 4 patients on long-term opioid therapy in a primary care setting are estimated to be struggling with opioid use disorder (OUD), also called opioid addiction.[7-9] In 2016 approximately 11.5 million Americans reported misusing prescription opioids in the previous year.[10] According to the federal Substance Abuse and Mental Health Services Administration (SAMSHA), approximately 80% of heroin users started on their path to addiction after using oral opioid analgesics (either prescribed to them or illicitly).[11]

Although the rates of opioid prescriptions have leveled off or declined slightly in recent years, the average days of supply per opioid prescription has continued to rise [10]

It is against this background that providers must make daily decisions about how best to treat their patients in pain. Unfortunately, many providers are unfamiliar with the growing evidence base suggesting that opioids are actually not very effective for relieving chronic non-cancer pain in the long-term and, in fact, may be associated with harms such as increased pain, reduced functioning, and physical opioid dependence.[12,13] Providers may also not be aware of the expanding range of both non-opioid medications and non-pharmacological therapies shown to be effective in reducing many common chronic pain conditions.

This CME learning activity discusses the management of chronic and acute pain in a variety of patient populations and is structured to conform to the latest Food and Drug Administration (FDA) Blueprint for Health Care Providers Involved in the Treatment and Monitoring of Patients with Pain (2018). It reviews evidence for non-opioid therapies, including non-drug and non-opioid drug options, as well as current evidence regarding opioid efficacy, harms, and overdose prevention with naloxone, and how to slowly and safely taper opioid doses.

Key opioid-related terms

Opioid: any psychoactive chemical resembling morphine, including opiates, and binding to opioid receptors in the brain. This term describes opioid and opiates.

Opiate: "natural" opioids derived from the opium poppy (e.g., opium, morphine, heroin).

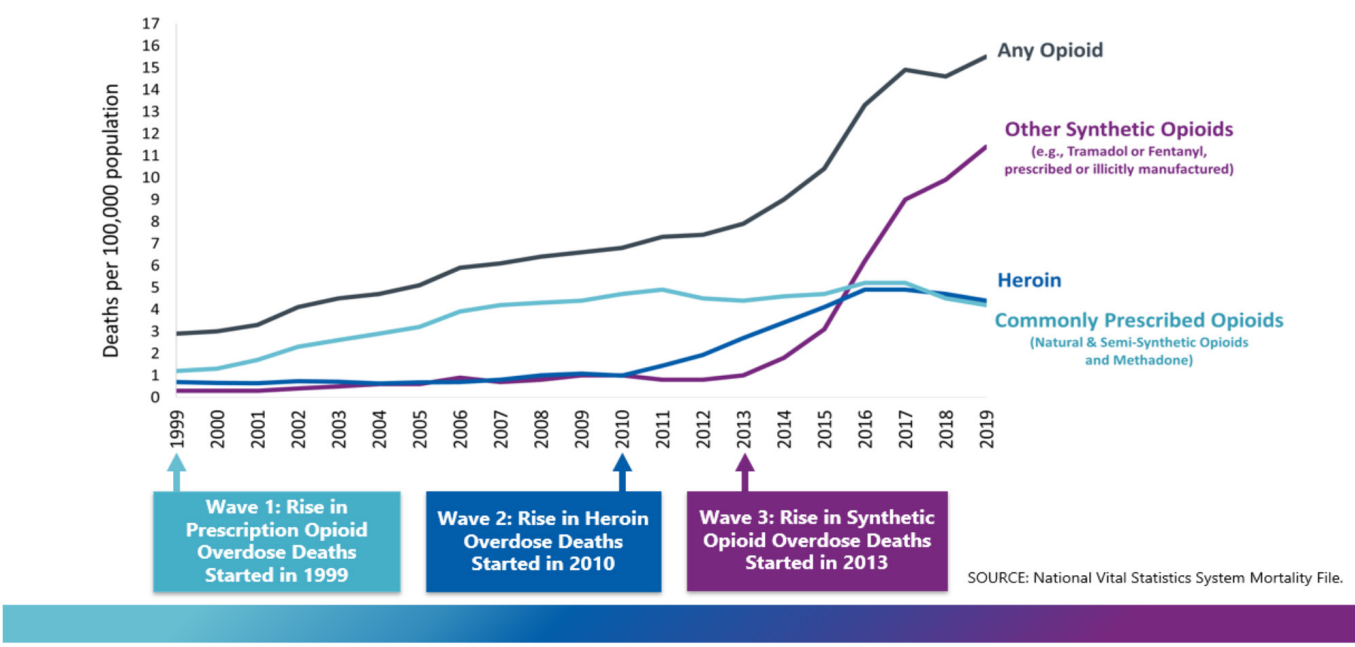
Semi-synthetic opioids: analgesics containing both natural and manufactured compounds (e.g., oxycodone, hydrocodone, hydromorphone, oxymorphone).

Synthetic opioids: fully-human-made compounds (e.g., methadone, tramadol, and fentanyl).

Types of Pain

Differentiating between nociceptive and neuropathic pain is critical because the two respond differently to pain treatments. Neuropathic pain, for example, may respond poorly to both opioid analgesics and non-steroidal anti-inflammatory (NSAID) agents.[14] Other classes of medications, such as anti-epileptics, antidepressants, or local anesthetics, may provide more effective relief for neuropathic pain.[15]

Figure 1. Opioid-related overdose deaths by type in the United States[6]



Another important dimension of pain is its effects beyond strictly physiological functioning. Pain is currently viewed as a multi-dimensional, multi-level process similar in many ways to other disease processes which may start with a specific injury but which can lead to a cascade of events that can include physical deconditioning, psychological and emotional burdens, and dysfunctional behavior patterns that affect not just the sufferer, but their entire social milieu (illustrated in Figure 2).[16]

Although pain is expected after injury or surgery, the patient pain experience can vary markedly. The intensity of pain can be influenced by psychological distress (e.g., depression or anxiety), heightened illness concern, or ineffective coping strategies regarding the ability to control pain and function despite it.[17] It may also be shaped by personality, culture, attitudes, and beliefs.

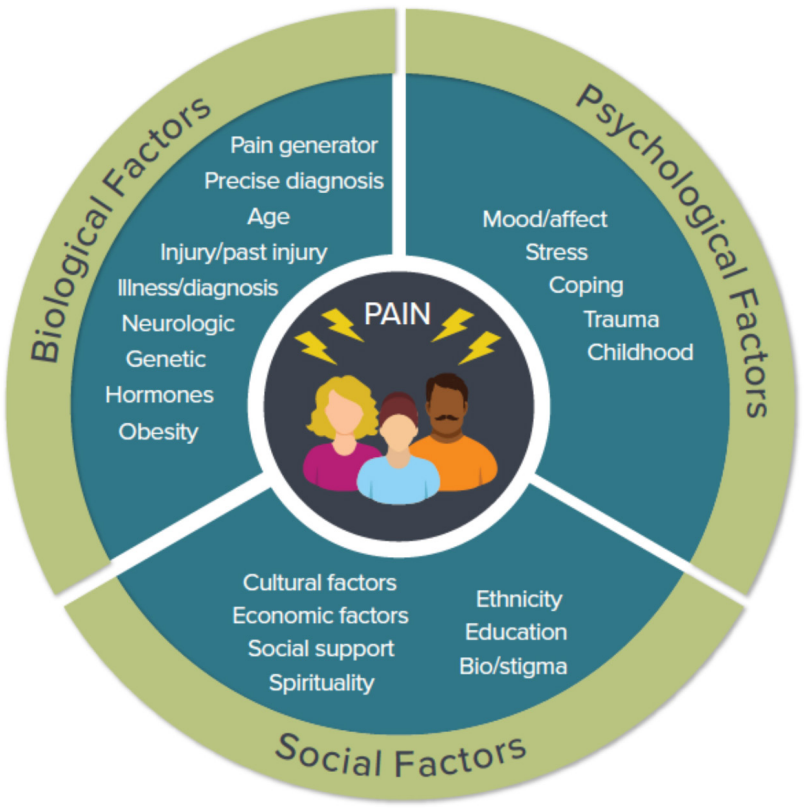
Evaluating pain

Take a history

The patient's self-report is the most reliable indicator of pain.[18] Physiological and behavioral signs of pain (e.g., tachycardia, grimacing) are neither sensitive nor specific for pain and should not replace patient self-report unless the patient is unable to communicate. Therefore, talking to patients and asking them about their pain (i.e., obtaining a "pain history") is integral to pain assessment.

The pain history usually is obtained as part of the patient history, which includes the patient's past medical history, medications, habits (e.g., smoking, alcohol intake), family history, and psychosocial history. Obtaining a comprehensive history provides many potential benefits, including improved management, fewer treatment side effects, improved function and quality of life, and better use of health care resources.

Figure 2. The Biopsychosocial Model of Pain[16]



Assessing the impact of pain on functional status and sleep and screening for mental health conditions potentially related to pain or treatment adherence (e.g., depression, anxiety, and memory issues) may provide useful information for pain management.[19] Depression in older patients, for example, sometimes presents with somatic complaints of pain. Pain complaints may resolve when the underlying depression is treated. Patients can also be screened for known risk factors for OUD (see below).

Tools

Many tools have been developed to document and assess pain. Initial approaches to assessing pain severity use a numerical rating scale (NRS) rating pain from 0 (no pain) to 10 (worst pain you can imagine) (some scales use a 0 to 100 scale). Such scales are often used in clinical trials of pain therapies, and the minimal clinically important difference using these scales is generally considered a 20%-30% change from baseline (i.e., 2-3 points on a 0-10 scale or 20-30 points on a 0-100 scale).[20]

Multidimensional tools, such as those described below, include questions relating to quality of life and participation in daily activities. Such tools can provide a more comprehensive approach to assessing pain and response to treatment. The selection of a pain assessment tool must balance the comprehensiveness of the assessment obtained with the time and energy required to use the tool in a real-world practice setting.

Brief pain inventory

The Brief Pain Inventory (BPI) is used frequently in clinical trials to assess pain. Specifically developed for patients with chronic pain, the BPI more fully captures the impact of pain on patient function and quality of life than simple VAS scales.[21] By including a pain map, the BPI allows tracking of the location of pain through the course of management. The BPI is self-administered but somewhat time-consuming, which may limit its role in a busy clinical practice.

PEG scale

The PEG scale (Pain average, interference with Enjoyment of life, and interference with General activity) is a three-item tool based on the BPI and is practical for clinical practice (Figure 3).

Figure 3: PEG scale[22]

What number best describes your pain on average in the past week?

0	1	2	3	4	5	6	7	8	9	10
No pain										Pain as bad as you can imagine

Zero-to-10 scales are used to assess pain, enjoyment of life, and general activity. PEG can be self-administered or done by the clinician and is relatively brief. [22]

Assessing acute pain

Acute pain intensity can be assessed with unidimensional tools such as the VAS and the Wong-Baker FACES Pain Rating Scale (faces depicting increasing levels of pain). While useful for a quick assessment, these scales alone may not appropriately identify patients with pain-related suffering driven by functional limitations, worry, or other factors, and may not detect some patients with clinically significant pain.[23]

Although developed for patients with chronic pain, the BPI is also applicable to patients with acute pain. Completed by the patient, the BPI captures ways that pain impacts function and quality of life, although, like most multidimensional questionnaires, it requires more time (about 10 minutes) and concentration to complete, which may limit its utility in some elderly patients.[21]

Pain in patients with dementia

Although patients with mild-to-moderate dementia can report their pain and its location, those with severe dementia are often unable to communicate their pain experience or request medication. In these patients, physicians need to observe pain behaviors, including facial expressions, verbal cues, body movements, changes in interpersonal interactions, activity patterns, and mental status. Caregiver observations and reports are critical to appropriate assessment and management of chronic pain conditions.[24]

BEFORE MOVING ONTO THE NEXT SECTION, PLEASE COMPLETE CASE STUDY 1.

Chronic pain that develops after acute pain

A number of factors have been associated with an increased risk for chronic pain following acute pain or surgery including older age, psychological problems, higher levels of pre-procedural pain or pain sensitivity, type and duration of surgery, severity and number of comorbidities, and use of post-procedural radiation or chemotherapy.[25]

Some tools have been developed to help clinicians predict the likelihood that a patient will experience chronic pain following acute injury or procedures. The 5-item PICKUP model, for example, showed moderate prognostic performance in a derivation study using data from 2,758 patients with acute low back pain.[26] And Sipila and colleagues developed a 6-item screening instrument for risk factors of persistent pain after breast cancer surgery based on a cohort of 489 women.[27]

Case Study 1

Instructions: Spend 5–10 minutes reviewing the case below and considering the questions that follow.

Maurianne is an 85-year-old woman living in a residence facility for people with Alzheimer disease. Her cognition has deteriorated slowly in the seven years she has lived at the facility and now her speech is often a rambling, incoherent stream-of-consciousness, that she only seldom recognizes as such. Maurianne fell and sustained a right femur fracture requiring internal fixation. On the second day after surgery, the hospital nurse noted that Maurianne had an order for acetaminophen every 6 hours as needed. Although Maurianne was lying still and did not appear to be in distress, the nurse contacted the nursing home nurse who reported that Maurianne rarely lies still. The nursing home nurse explained that they assess pain using the Pain Assessment in Advanced Dementia (PAINAD) tool and emailed a copy to the hospital nurse. A review of the medical chart indicated that Maurianne slept intermittently the previous night, and when she conducted a physical examination, Maurianne seemed rigid and exhibited shallow breathing at a rate of about 20 breaths per minute. The nurse used the PAINAD behavioral tool to assess Maurianne's pain and the result suggested a positive score for possible pain. The nurse immediately called the surgeon and received an order for 1-2 mg morphine every 8 hours over the next 3 days. After the first dose, Maurianne's body relaxed, and her breathing became regular at a rate of 14 per minute. Later that evening, Maurianne slept 7 hours.

1. **Do you think the initial script for acetaminophen was appropriate for this patient? If now, what would you have prescribed?**

2. **How might Maurianne's cognitive impairments affect her pain management plan?**

3. **What other tools or techniques might be used to characterize Maurianne's level of pain or her response to prescribed analgesics?**

Screen for opioid abuse risk factors

Screening and monitoring in pain management seeks to identify patients at risk of substance misuse and overdose as well as improve overall patient care. Evaluations of patient physical and psychological history can screen for risk factors and help characterize pain to inform treatment decisions. Screening approaches include efforts to assess for concurrent substance use and mental health disorders that may place patients at higher risk for OUD and overdose. This includes screening for drug and alcohol use and the use of urine drug testing, when clinically indicated. These approaches enable providers to identify high-risk patients so that they can consider whether to prescribe opioids, engage substance misuse and mental health interventions, and education materials to mitigate opioid misuse.[16]

Many tools have been developed for the formal assessment of a patient's risk of having a substance misuse problem, some of which are appropriate for routine clinical use because they are relatively brief and easily implemented. Table 1 lists the tools that appear to have good content and construct validity for assessing patient risks related to chronic opioid therapy, although to date, no single tool has been widely endorsed or thoroughly validated.[28]

The Screening, Brief Intervention and Referral to Treatment (SBIRT) is an evidence-based tool used to facilitate screening patients for OUD, which typically takes 5-10 minutes to administer.[29] SBIRT has been endorsed by the Substance Abuse and Mental Health Services Administration (SAMHSA), but should always be paired with referral to treatment.[30] SAMHSA recommends universal screening with oral or writing-based tools because of the high prevalence of substance use disorders in patients visiting primary care settings. In contrast, universal screening with urine, blood, or oral fluid tests are not recommended.[30] In the context of pain care, however, the 2016 CDC guidelines recommend urine drug testing before initiating opioid therapy and probably at least annually when prescribing opioids for chronic pain.[31]

Other tools for universal substance abuse screening include:

- Single screening question screening tool for drug use
- Drug Abuse Screening Test (DAST) 10
- Alcohol, Smoking, and Substance Involvement Screening Test (ASSIST)
- Tobacco, Alcohol, Prescription medication, and other Substance use (TAPS)
- the CAGE questionnaire adapted to include drugs (CAGE-AID)

Use drug monitoring programs

As of March, 2020, all U.S. states (except Missouri) and the District of Columbia have operational prescription drug monitoring programs (PDMPs).[32,33] Information available through PDMPs varies based on reporting requirements and restrictions, but may include DEA schedules reported, timeliness of pharmacy dispensing information, access, and required reviews.

Recommendations for using a PDMP include:

- Check the PDMP before starting anyone on opioid therapy.
- Review the PDMP periodically throughout opioid therapy (at least every 3 months).
- Look for prescriptions for other controlled substances, like benzodiazepines, that can increase risk of overdose death.
- Review the total MMED (Morphine Milligram Equivalent Dose).

Some states have specific requirements for PDMP use, such as requiring review prior to initial prescription or any time a specific prescription is written, such as for hydrocodone ER (Zohydro), therefore clinicians should remain updated about the specific requirements of their state PDMPs.

Urine drug testing

Urine drug testing (UDT) is recommended before prescribing any opioid and at least annually thereafter.[31] Providers using urine drug screens should be familiar with the metabolites and expected positive results based on the opioid prescribed. For example, a patient taking oxycodone may test positive for both oxycodone and oxymorphone (a metabolite).[34]

UDT often involves both presumptive (screen) testing, and definitive (quantitative) testing because many synthetic and semisynthetic opioids cannot be detected by presumptive testing alone.[35,36]

If the prescribed opioid is not detected, discuss the finding with the patient and, if diversion is confirmed or suspected, re-evaluate the pain management strategy or taper the opioid. If the patient tests positive for unprescribed drugs, schedule more frequent follow-up visits, consider opioid discontinuation, offer naloxone, or refer for treatment for substance use disorder. Decision tools and help with interpreting urine drug testing results are available at: http://mytopcare.org/udt-calculator/interpret-opiates-test-result.

Pain management overview

Many pharmacologic and non-pharmacologic approaches to treating pain are available to primary care providers.

These options should be employed using the following general principles:

- Identify and treat the source of the pain, if possible, although pain treatment can begin before the source of the pain is determined
- Select the simplest approach to pain management first. This generally means using non-pharmacologic approaches as much as possible and/or trying medications with the least severe potential side effects, and at the lowest effective doses
- Establish a function-based, individualized treatment plan if therapy is expected to be long-term

Non-drug approaches

Many nonpharmacologic and self-management treatment options have been found to be effective alone or as part of a comprehensive pain management plan, particularly for musculoskeletal pain and chronic pain.[37] Examples include, but are not limited to, psychological, physical rehabilitative and surgical approaches, procedural therapies (e.g., injections, nerve blocks), complementary therapies, and use of approved/cleared medical devices for pain management.

Table 1. Tools for patient risk assessment

Tool	Use	Who Administers?	Length
Current Opioid Misuse Measure (COMM)	Monitor for misuse by patients currently on long-term opioid therapy	Patient self-report	17 items
Diagnosis, Intractability, Risk, Efficacy (DIRE)	Screen for risk of opioid addiction	Clinician	7 items
Opioid Risk Tool (ORT)	Screen for risk of opioid addiction	Clinician or patient self-report	5 yes/no questions
Screener and Opioid Assessment for Patients with Pain, Version 1 and Revised (SOAPP, and SOAPP-R)	Screen for risk of opioid addiction	Patient self-report	24 items

Primary care clinicians should know about the range of treatment options available, the types of pain that may be responsive to those options, and when they should be used as part of a multidisciplinary approach to pain management.[37] Clinicians should also be aware that not all nonpharmacologic options have the same strength of evidence to support their utility in the management of pain, and some may be more applicable for some conditions than others.

Movement-based options

Movement therapies that may be helpful in patients with chronic pain include muscle-strengthening, stretching, and aerobic exercise (e.g., walking, aquatics). Recommended exercise programs typically occur one to three times a week for a total of 60-180 minutes per week, but any regimen must be carefully tailored to a patient's existing level of physical conditioning, comorbidities, and cognitive status.[38-40]

Additional movement-based options include:

- **Physical therapy** supervised by a licensed physical therapist, which can include resistance, aerobic, balance, and flexibility exercises as well as elements of massage, manipulation, or transcutaneous electrical nerve stimulation.
- **Tai chi**, a mind-body practice that combines controlled movements, meditation, and deep breathing. "Chair tai chi" can be an option for patients with limited mobility.
- **Yoga**, exercises or a series of postures designed to align muscle and bones, and increase strength and flexibility. It can also relax mind and body through breathing exercises and meditation. Gentler forms of yoga that may be more appropriate for older patients include Iyengar, Hatha, or Viniyoga.

Although these interventions may cause muscle soreness, increased back pain, or falls, movement-based options are generally considered safe.[40]

Weight loss

Some pain syndromes, such as knee osteoarthritis, are worsened by obesity. For some patients, pain due to this condition is improved by reducing body weight because of reduced loads and physical stresses on the affected joints. The goal of body weight reduction is a baseline weight loss of 7%-10% by calorie reduction and increased activity using a balanced diet with less than 30% of calories from fat, 15%-20% from protein, and 45%-60% from carbohydrates.[41]

Passive options

Acupuncture involves the stimulation of specific points on the body, most often involving skin penetration with fine metallic needles manipulated by hand but sometimes also including electrical stimulation or low intensity laser therapy. Potential adverse events include minor bruising and bleeding at needle insertion sites.[42]

Massage is the manual manipulation of the body to promote relaxation, reduce stress and improve well-being. Handheld devices may also provide relief for some patients. Some patients may report muscle soreness.[43]

Transcutaneous electrical nerve stimulation (TENS) is a machine that generates mild electrical pulses which are applied cutaneously. The electrical stimulation from TENS may block or disrupt pain signals to the brain, reducing pain perception. TENS machines can be used at home or in conjunction with other interventions like physical therapy.

Cognitive and behavioral options

Cognitive behavioral therapy (CBT) is a structured, time-limited (typically 3-10 weeks) intervention focused on how thoughts, beliefs, attitudes, and emotions influence pain and can help patients use their minds to control and adapt to pain. This therapy includes setting goals, often with recommendations to increase activity to reduce feelings of helplessness.[44]

Meditation

Mindfulness meditation programs typically include a time-limited (8 weeks; range 3-12 weeks) trainings with group classes and home meditation. The objective is to inculcate a long-term practice that helps patients refocus their minds on the present, increase awareness of self and surroundings, and reframe experiences.[45,46]

Non-opioid drug approaches

A wide range of medications can be used to treat pain, including:

- Acetaminophen
- NSAIDs (oral or topical)
- Antidepressants
  - serotonin and/or norepinephrine reuptake inhibitors
  - tricyclic antidepressants (TCAs)
  - selective serotonin reuptake inhibitors (SSRIs)
- Anticonvulsants
- Topical lidocaine or capsaicin
- Cannabinoid-based therapies
- Ketamine

Acetaminophen

Lower doses of acetaminophen are recommended to decrease risk of side effects. Patients should not exceed 1000 mg in a single dose. The maximum recommended dose for healthy adults is 4000 mg/day.[47]

The most severe potential side effect of acetaminophen is liver toxicity. Acetaminophen is the most common cause of acute liver failure, accounting for 46% of all cases.[48] Patients should stay within recommended doses to help prevent side effects and should only be prescribed one acetaminophen-containing product at a time.

NSAIDs

Chronic use of NSAIDs may be limited by gastrointestinal (GI) toxicity, including GI bleeding, upper GI symptoms, ulcers, and related complications. For high-risk patients, including the elderly, patients on warfarin or aspirin, and those with coagulopathies, adding a proton pump inhibitor (PPI) may help reduce the risk.[49,50] In addition to GI side effects, NSAIDs have been associated with an increased risk of renal and cardiac complications. Side effects with NSAIDs are typically lower with topical formulations.

Some early trials suggested that COX-2 inhibitors, as a class, were associated with higher risks for myocardial infarction and stroke compared to other NSAIDs, and the COX-2 inhibitor rofecoxib (Vioxx) was removed from the market in 2004 because of such concerns.[51] More recent trials and meta-analyses, however, provide strong evidence that the risks of CV events with celecoxib are no greater than those of other NSAIDs, and in 2018 two FDA advisory panels recommended that the FDA change its advice to physicians regarding celecoxib's safety.[52]

Selective serotonin norepinephrine reuptake inhibitors

SNRIs such as duloxetine, venlafaxine, and milnacipran are characterized by a mixed action on norepinephrine and serotonin, though their exact mechanism of action for pain reduction is unknown. These agents affect the descending pain pathways to facilitate pain relief. Side effects (e.g., nausea, dizziness, and somnolence) may limit treatment. Monitoring is suggested for blood pressure (duloxetine and venlafaxine), heart rate (venlafaxine), and drug interactions (duloxetine). SNRIs can be very helpful in patients who have central sensitization.

TCAs

TCAs inhibit reuptake of norepinephrine and serotonin. These agents act on descending pain pathways, but their mechanism of action for pain relief is unknown.

Examples of TCAs studied for the management of chronic pain include amitriptyline, desipramine, and nortriptyline. Side effects, such as anticholinergic effects (e.g., dry mouth, constipation, dizziness) and QTc prolongation limit the use of TCAs in elderly patients. The majority of side effects occur at the typically higher doses used to treat depression.

SSRIs

SSRIs, such as citalopram, fluoxetine, and paroxetine, block the reuptake of serotonin in the brain, making more serotonin available in the synapse. The mechanism of SSRIs for pain remains unknown. Compared to SNRIs and TCAs, there is relatively little evidence to support the use of SSRIs in treating chronic pain conditions.[28] Potential side effects of SSRIs include weight gain, sexual dysfunction, and QTc prolongation, especially with citalopram.

Anticonvulsants

Anticonvulsants, such as gabapentin, pregabalin, oxcarbazepine, and carbamazepine, are often prescribed for neuropathic pain and are thought to exert their analgesic effect by inhibiting neuronal calcium channels. Potential side effects include sedation, dizziness, and peripheral edema. Pregabalin and gabapentin have low abuse potential in the general population, are currently classified as Schedule V by the DEA, and prescriptions for these drugs are tracked by some state Prescription Drug Monitoring Programs (PDMPs). Anticonvulsants can be very helpful in patients who have central sensitization and neuropathic pain.

Topical lidocaine and capsaicin

Topical lidocaine inhibits the conduction of nociceptive nerve impulses. Irritation at the application site is the most common side effect. The most common products for chronic pain management are lidocaine 5% patches, available by prescription, and lidocaine 4% patches available OTC. Capsaicin is an active component of chili peppers and has moderate analgesic properties at 8% concentrations for neuropathic pain, specifically postherpetic neuralgia and diabetic neuropathic pain of the feet. [53] The most common side effect is a mild-to-severe burning sensation at the application site.

Cannabinoid preparations

With medical cannabis now legal in 36 states and recreational use legal in at least 10 states and the District of Columbia (as of 2020)[54], there has been increased interest among patients for the use of cannabis or cannabis derivatives (e.g., cannabidiol [CBD]) for pain relief. The CB1 and CB2 receptors have been shown to mediate the analgesic effects of cannabinoids[55] and some evidence suggests a potential benefit for chronic pain.

A 2017 National Academies of Science report, for example, concluded that "conclusive or substantial evidence" supports a beneficial role for cannabis or cannabinoids for treating chronic pain,[56] and a 2018 Cochrane review of the existing literature evaluating cannabinoids (cannabis, CBD, or combinations) suggests that these agents are moderately effective for neuropathic pain with adverse effects that are less than, or comparable to, existing non-opioid analgesics.[57]

But the evidence for a benefit of cannabinoids on acute pain, is extremely limited and mixed. A small double-blind, cross-over study in 18 females and experimentally-induced mild acute pain found no significant analgesic effect of oral cannabis extract.[58] Another randomized, double-blind study with 15 healthy volunteers using smoked cannabis found no analgesic effect with low doses of cannabis, a modest effect with moderate doses, and enhanced pain responses with high doses.[59] The authors of a 2017 review on cannabis and pain conclude that cannabis may have a narrow therapeutic window as a pharmacotherapy for chronic pain but that much more research is needed to inform physician recommendations to patients regarding the analgesic efficacy of cannabis.[60]

A systematic review of both randomized trials (47) and observational studies (57) in patients with chronic noncancer pain published through July 2017 found moderate evidence that cannabinoids can exert analgesia.[61] Cannabis preparations, however, may pose both short-term and long-term risks. Short-term effects include impaired memory, motor coordination, and judgment. Paranoid ideation and psychotic symptoms, while rare, may occur with high doses of THC. Possible long-term effects include impaired brain development in young adults, potential for habituation, and increased risk of anxiety or depression. Abrupt cessation of marijuana in long-term users may cause withdrawal symptoms such as anxiety, irritability, craving, dysphoria, and insomnia. There is an increased risk of chronic bronchitis, respiratory infections, and pneumonia with inhaled products.[62]

Nonetheless, the use of cannabis may have an opioid-sparing effect at a population level. The use of medical cannabis has been associated with a 25% reduction in opioid overdose mortality in states that legalized medical use.[63] However, a more recent study showed that states legalizing medical cannabis actually experienced a 22.7% increase in opioid overdose deaths.[64]

FDA-approved cannabinoids include dronabinol (Marinol), indicated for second-line treatment of chemotherapy-induced nausea and vomiting, and anorexia-associated weight loss in patients with HIV. Nabilone (Cesamet) is indicated for chemotherapy-induced nausea and vomiting. Common side effects include dizziness/vertigo and euphoria. Dronabinol may cause nausea/vomiting, abdominal pain, and abnormal thinking. Nabilone may cause ataxia and dry mouth.[62,65,66] None of these are indicated for the treatment of pain. When recommending cannabis for patients with chronic pain, clinicians may inform patients that the analgesic properties are due to both the CBD and THC components, which act on different pain pathways.[67]

Ketamine

Ketamine has been used as a general anesthetic since the 1960s, but its use in subanesthetic concentrations for analgesia has grown rapidly in recent years, due, in part, to efforts to reduce the risks of chronic opioid use.[68] Ketamine has been successfully used to treat such acute pain conditions as sickle cell crises, renal colic, and trauma.[68] Recently the American Society of Regional Anesthesia and Pain Medicine, the American Academy of Pain Medicine, and the American Society of Anesthesiologists released the first joint recommendations for subanesthetic ketamine (including transdermal ketamine) for acute pain.[68]. Ketamine infusions are used for the treatment of complex regional pain syndrome based on placebo-controlled trials, and topical ketamine may also be beneficial for the cutaneous hypersensitivity associated with this condition.[69]

Opioids

Mechanism of Action

Opioids exert their analgesic effects by acting on the mu, kappa, and delta opioid receptors. Individual agents may be classified as agonists or partial agonists of those receptors:[70]

- Agonists (e.g., morphine, codeine, hydromorphone, hydrocodone) stimulate at least one of the opioid receptors and provide continued analgesia with increasing doses.
- Partial agonists (e.g., buprenorphine) have high affinity at mu-receptors, have a ceiling for analgesic effect, and are less likely to cause respiratory depression.

Opioids are classified by the Drug Enforcement Agency (DEA) according to their presumed abuse and addiction potential, although the evidence base for making these differentiations continues to evolve. Tramadol, for example, is now known to have as much potential for abuse as opioids in more restrictive classes, although its DEA classification has not changed.[71]

Relative effectiveness

The analgesic efficacy of opioids for treating acute pain has been known for centuries and they continue to be reliable agents for moderate-to-severe acute pain, although they are not without risks. But the evidence for opioid efficacy for acute pain cannot be extended to chronic pain with a few exceptions that are discussed below. Neuronal and physiologic adaptations to long-term opioid use can result in reduced analgesic effectiveness, or even, paradoxically, increased pain or sensitivity to pain.[72] Opioid-induced hyperalgesia is different pharmacologically from the phenomenon of opioid tolerance, although both can lead to an increased need for opioids and disentangling the two, clinically, can be difficult.[73]

For chronic pain, the evidence that opioids reduce pain and improve function more than placebo is relatively weak. A 2018 systematic review and meta-analysis of 96 trials comparing various opioids vs. placebo or non-opioid analgesics in 26,169 patients with chronic noncancer pain found that opioids may slightly reduce pain and increase physical functioning compared to placebo, but not compared to non-opioids.[12] In 76 trials comparing opioids vs. placebo with follow-up ranging from 1 to 6 months, the reduction in pain scores with opioids (on a 10-point scale) was only 0.69 points, which is below the generally-accepted 2-point minimum clinically important difference for pain. Physical function scores (on a 100-point scale) improved with opioids by 2.04 points, which, again, may not be clinically important. The risk of vomiting with opioids, however, was more than 4 times higher than with placebo.[12]

The same meta-analysis compared opioids to non-opioid analgesics including NSAIDs, TCAs, anticonvulsants, and synthetic cannabinoids. No significant differences were found in physical functioning scores for any of the comparisons, and no significant differences were found in pain scores for comparisons with NSAIDs, TCAs, or cannabinoids.[12]

Exceptions: chronic opioid use in limited patient subsets

Sickle cell disease as an example for which chronic opioid therapy may be appropriate in some patients. The risk for opioid death in patients with sickle cell disease comprises a small fraction of the total number of opioid-related deaths.

From 1999 through 2013, there were 174,959 documents deaths attributed to opioid use. Of these 174, 959 deaths, 95 were patients with sickle cell disease (0.05%).[74] The pain experienced by patients includes both acute and chronic aspects through multiple mechanisms that are not completely understood. The American Society of Hematology 2020 guidelines endorses the use of chronic opioid therapy for patients with sickle cell disease with pain that is refractory to multiple other treatments using the lowest effective dose and with regular monitoring.[75,76]

Opioid formulations

Prescription opioids are available in immediate-release and extended-release/long-acting (ER/LA) formulations. Immediate-release agents are recommended in opioid-naïve patients and for all acute pain conditions, with ER/LA agents reserved for patients or conditions in which the longer duration of action and smoother pharmacodynamics are preferred.[31] A trial comparing immediate release to an ER/LA opioid did not find evidence that the continuous, time-scheduled use of ER/LA opioids was more effective or safer than intermittent use of the immediate-release opioid.[71]
According to the FDA, ER/LA opioids should only be used for patients who tolerate 60 morphine milligram equivalents per day (MMED) for at least one week.[78]

Efforts to create formulations with lower risks of abuse have met with limited success. For example, ER Oxymorphone was removed from the market after reports of intravenous abuse of the oral formulation.[79] Abuse-deterrent or tamper-resistant formulations do not prevent patients from developing opioid dependence, opioid use disorder, or simply taking too much of an opioid by mouth.[80,81]

BEFORE MOVING ONTO THE NEXT SECTION, PLEASE COMPLETE CASE STUDY 2 ON THE NEXT PAGE.

Atypical opoids: tramadol and tapentadol

Tramadol and tapentadol are mu receptor agonists and norepinephrine reuptake inhibitors. Their mechanisms of action are unknown, but their analgesic effects are similar to morphine. Patients taking tramadol should be monitored for nausea, vomiting, constipation, and drowsiness, all of which are similar to side effects with opioids.[82] There is potential risk of serotonin syndrome when tramadol is combined with SSRIs, SNRIs, or tricyclic antidepressants.[83]

As noted above, tramadol is classified as Schedule IV, which has led some to view it as less potent or safer than other opioids. The 2016 National Survey on Drug Use and Health, however, found that 1.7 million people in the U.S. aged > 12 years reported misusing tramadol products (e.g., Ultram, Ultram ER, Ultracet) in the previous year.[71] In addition, a 2019 cohort study of 88,902 patients with osteoarthritis showed increased risks of death at one year compared to NSAIDs naproxen, diclofenac, and celecoxib.[84]

Abrupt cessation of tramadol is associated with opioid withdrawal, restlessness, and drug cravings (similar to those associated with other opioids) as well as hallucinations, paranoia, extreme anxiety, panic attacks, confusion, and numbness/tingling in extremities (which are less typical of other opioids).[85]

Tapentadol is FDA-approved for treating neuropathic pain associated with diabetic peripheral neuropathy, although it is also used for musculoskeletal pain. A 2015 Cochrane review of 4 randomized trials with 4,094 patients with osteoarthritis or back pain found modest reductions in pain with tapentadol vs. placebo.[86]

Problematic opioid use

Although evidence for the long-term effectiveness of opioids for chronic pain is weak, evidence for opioid-related harms is abundant and strong. In a 2007 study assessing behaviors indicative of opioid misuse, many patients in primary care practices reported having engaged in aberrant behaviors with opioids one or more times (Table 2).[9] It is important to recognize and differentiate problematic use from adverse side effects of opioids. For instance, tolerance and opioid withdrawal occur with long term use of prescribed opioids. Clinicians should be able to differentiate this from problematic use.

Among adults without a prescription, 41% obtained prescription opioids from friends or relatives for their most recent episodes of misuse.[87]

For prescription opioids, long-term therapy is associated with an increased risk in accidental overdose and death. A retrospective study including 9,940 patients who received three or more opioid prescriptions within 90 days for chronic pain between 1997 and 2005 found that annual overdose rates rose significantly as doses exceeded 50 MMED (Figure 4).[88]

Combining opioids with sedating drugs such as benzodiazepines or alcohol increases the risk of respiratory depression and overdose death.[34] Benzodiazepines have been linked with overdose fatalities in 50-80% of heroin overdoses, and 40-80% in methadone-related deaths.[34,89] Patients prescribed benzodiazepines who are being initiated on opioids should have their benzodiazepine tapered and discontinued whenever possible. For patients being co-managed by mental health professionals, coordinate a plan regarding continuing or tapering benzodiazepines in the setting of opioid co-prescribing.

Case Study 2

Instructions: Spend 5–10 minutes reviewing the case below and considering the questions that follow.

Wayne is an 86-year-old who lives at home with his wife. He was diagnosed with ALS 6 months ago, with deterioration occurring first in his diaphragm. He has been experiencing increasing muscle weakness in his legs and uses a walker or a wheelchair to get around in his home. He uses a bilevel positive airway pressure device except when eating or bathing and finds it helpful. He takes the following medications: fish oil, a statin, a thiazide diuretic, and a non-benzodiazepine sedative to help him sleep. Lately he has been complaining of pain and stiffness in both of his knees and hips, which interferes with his sleep. He is physically deconditioned due to a lack of exercise, and has become increasingly withdrawn socially, which worries his wife and family members. He asks if you can prescribe something to ease his pain.

1. **Is Wayne a good candidate for an ER/LA opioid? Why, or why not?**

2. **Is he a better candidate for an immediate-release opioid? Why or why not?**

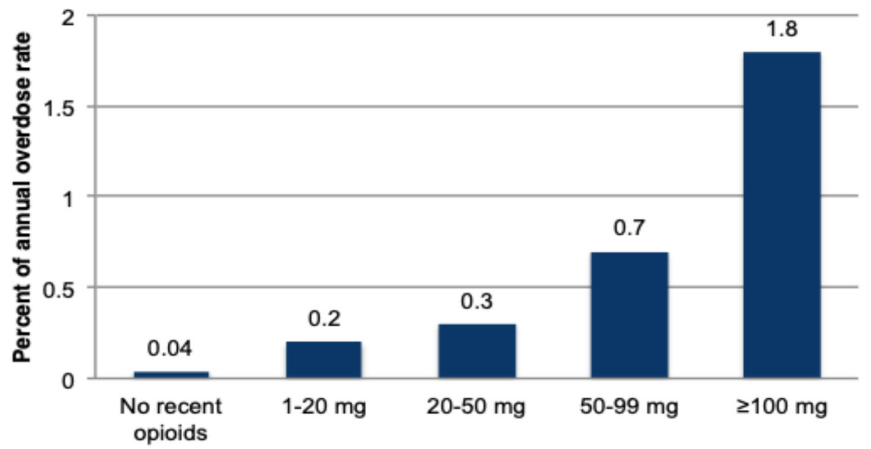
3. **Would Wayne's current medication need to be adjusted if he were to be prescribed an ER/LA opioid?**

4. **What kinds of non-opioid treatments might be tried to help Wayne with his pain?**

Table 2. Behaviors indicative of opioid misuse[9]

Behavior	Frequency in patients with opioid misuse
Requested early refills	47%
Increased dose on own	39%
Felt intoxicated from pain medication	35%
Purposely over sedated oneself	26%
Used opioids for purpose other than pain	18%

Figure 4. Risk of overdose rises with daily milligram morphine-equivalent dose.[88]



Other adverse events

In addition to risks of misuse, addiction, respiratory depression, and overdose death, there are many well-known side effects associated with chronic opioid use that can significantly compromise quality of life, including constipation, nausea or vomiting, sedation, pruritus, erectile dysfunction, menstrual changes, fracture, immunosuppression, hallucinations, and hyperalgesia.

Gastrointestinal side effects

Constipation is one of the most common opioid-related adverse events, affecting most patients to at least some degree, and which usually does not resolve with continued exposure.[28] To mitigate this side effect, patients should use a mild stimulant laxative such as senna or bisacodyl and increase the dosage in 48 hours if no bowel movement occurs. Physicians should perform a rectal examination if no bowel movement occurs in 72 hours. If there is no impaction, consider other therapies such as an enema, suppository, or magnesium citrate.[90]

Medications for refractory, opioid-induced constipation include naloxone derivatives: naloxegol (Movantik), methylnaltrexone (Relistor), or naldemedine (Symproic). Naloxegol is an oral tablet that is used daily while methylnaltrexone is a subcutaneous injection or oral tablet used daily. Naldemedine is taken by mouth daily (0.2 mg) and may cause side effects such as abdominal pain or discomfort, diarrhea, and nausea.[88] In the COMPOSE-1 trial, patients on naldemedine had significantly more spontaneous bowel movements (defined as ≥3 per week) than those on placebo (47.6% vs. 34.6%, P=0.002).[91]

For nausea or vomiting, physicians should consider a prophylactic antiemetic, add or increase non-opioid pain control agents (e.g., acetaminophen as an opioid-sparing drug), and decrease opioid dose by 25% if analgesic is satisfactory.

Sedation

Sedation is the first warning sign of a patient being at risk for opioid overdose. Take this symptom very seriously. If a patient complains of sedation, determine whether sedation is related to the opioid, eliminate nonessential depressants (such as benzodiazepines or alcohol), reduce dose by 10%-15% if analgesia is satisfactory, add or increase non-opioid or non-sedating adjuvant for additional pain to reduce opioid dose. There is insufficient evidence to recommend opioid rotation as a possible means of reducing sedation.[31] Patients should also be co-prescribed naloxone for opioid overdose reversal.

Fracture

A retrospective cohort study over seven years compared the risk of fracture associated with starting opioids vs. NSAIDs (2,436 older adults initiated on opioids and 4,874 older adults initiated on NSAIDs). Opioids significantly increased the risk of fracture in a dose-dependent fashion. The opioid formulation mattered with much of the risk in the first month after drug initiation for short-acting opioids, though fracture increased for both long- and short-acting opioids over time.[92]

Infection

Opioids may increase risk of infection in older adults. A case-control study of 3,061 older community dwelling adults ages 64-95 years evaluated the association between pneumonia and opioid use. Current prescription opioid users had a 38% increased risk of pneumonia compared with nonusers. The risk was highest for opioid users categorized as being immunosuppressed, such as those with cancer, recent cancer treatment, or chronic kidney disease, or those receiving immunosuppressive medications or medications for HIV.[93]

Myocardial Infarction (MI)

A case-control study assessed the risk of MI among adults on opioids for chronic pain in the UK General Practice Research Database (11,693 cases with up to four matched controls). Current opioid use was associated with a 28% increased risk of MI compared to non-use.[94]

Erectile Dysfunction (ED)

In a cross-sectional analysis of 11,327 men with back pain, 909 (8%) were receiving ED medications or testosterone (documented between 6 months before and 6 months after the study index visit). Prescriptions for an ED drug or testosterone were 54% greater for men using doses ≥120 MMEDs compared with those using doses of 1 to <20 MMED. In addition, the proportion of men receiving either of types of medications was 95% greater for those with chronic opioid use compared with those with no opioid use. These findings suggest that dose and duration of opioid use are associated with ED.[95]

Tamper-resistant/abuse-deterrent opioids

One strategy to mitigate the risk of opioid abuse has been the development of "abuse-deterrent" formulations of opioids that make it more difficult to alter for non-oral consumption (e.g., injecting, snorting, or smoking).[96] However, these opioids are more aptly named as "tamper-resistant" formulations instead of "abuse-deterrent" since they are no less potentially addictive than regular opioids when taken by mouth.

Tamper-resistant formulations often contain a higher opioid dose than immediate-release preparations. Furthermore, most are extended-release and also considerably more expensive than generic, off-patent opioids.[96] As of this writing, only one immediate-release opioid is available in an abuse deterrent formulation (oxycodone hydrochloride [RoxyBond]).[96]

Patient education

Before prescribing an opioid for pain, clinicians should discuss with patients the risks and benefits of such therapy. An important consideration in framing treatment, and a key message to communicate to patients, is that the goal is not "zero pain" but, rather, a level of analgesia that maximizes a patient's physical and mental functioning.[97] A multi-modal approach, using both drug and non-drug treatments, should be encouraged.

In addition, patients should be educated about the safe storage and disposal of opioid medications. Safe use means following clinician instructions about dosing, avoiding potentially dangerous drug interactions (e.g., alcohol), and assuring full understanding of how the medication should be consumed or applied. Remind patients that opioid pain medications are sought after by many people, and, therefore, opioids should be stored in a locked cabinet or, if a locked unit is not available a place that is not obvious or easily accessed by others.

Proper disposal methods should be explained:

- Follow any specific disposal instructions on the prescription drug labeling or patient information that accompanies the medication
- Do not flush medicines down the sink or toilet unless the prescribing information specifically instructs to do so.
- Return medications to a pharmacy, health center, or other organization with a take-back program.
- Mix the medication with an undesirable substance (e.g., used coffee grounds or kitty litter) and put it in the trash, or use special drug deactivation pouches that your health care provider may recommend.

Managing acute pain

It is now becoming clear that many of the problems and risks associated with managing chronic pain with opioids are also at work in the management of acute pain with opioids. For example, a number of studies demonstrate increased risk of new persistent opioid use in opioid-naïve patients after having been prescribed opioids for acute pain.[98-101] Although the risk of opioid misuse in patients prescribed opioids for acute post-surgical or post-procedural pain is relatively small (roughly 0.6% per year)[102], the volume of such procedures (approximately 48 million ambulatory surgeries or procedures in 2010)[103] translates into large numbers of patients (i.e., approximately 160,000) who may develop dependence, abuse, or overdose every year.

A central tenet of pain management, whether acute or chronic, is that the goal of treatment is a tolerable level of pain that allows the patient maximum physical and emotional functioning with the lowest risk of side effects, progression to chronic pain, or misuse or abuse[104] This requires an adroit balancing of patient-related factors (e.g., comorbidities, medical history, risk of abuse) and drug-related factors (e.g., potency, mechanism of action, expected side effects). A commonly-recommended way to achieve this balance is with multimodal analgesia, in which several therapeutic approaches are used, each acting at different sites of the pain pathway, which can reduce dependence on a single medication and may reduce or eliminate the need for opioids and attendant risks/side effects.[105]

Multimodal analgesia (e.g., using drugs from two or more classes, or a drug plus a non-drug treatment) can produce synergistic effects, reduce side effects, or both. One example of multimodal analgesia is the use of both an NSAID and acetaminophen, plus physical approaches (e.g., cold, compression, or elevation) to manage postoperative pain. Demonstrated benefits of multimodal analgesia include earlier ambulation, earlier oral intake, and earlier hospital discharge for postoperative patients, as well as higher levels of participation in activities necessary for recovery (e.g., physical therapy).[105]

Non-pharmacological treatments for acute pain

When possible, non-pharmacologic methods should be used, alone or in combination with analgesics, to manage acute pain.[106] The degree to which this is possible depends on the severity, type, and origin of the pain, but many non-pharmacological approaches can be very effective and their use avoids the potential side effects and risks associated with pharmacological interventions.

Physical methods of pain management can be helpful in all phases of care, including immediately after tissue trauma (e.g., rest, application of cold, compression, elevation) and later in the healing period (e.g., exercises to regain strength and range of motion).

Physical therapy may be useful for a range of musculoskeletal issues and can be helpful in recovering from acute pain-producing traumas initially treated with other methods. A 2018 study reported that patients with low back pain who first consulted a physical therapist were less likely to receive an opioid prescription compared to those who first saw their primary care physician.[107]

Exercise therapy can take many forms, including walking, swimming or in-water exercise, weight training, or use of aerobic or strength-training equipment. According to a CDC review, conditions that may improve with exercise therapy include low back pain, neck pain, hip and knee osteoarthritis pain, fibromyalgia, and migraine.[108]

BEFORE MOVING ONTO THE NEXT SECTION, PLEASE COMPLETE CASE STUDY 3.

Case Study 3

Instructions: Spend 5-10 minutes reviewing the case below and considering the questions that follow.

Hannah, a 64-year-old female presents with severe pain in both anterior-lateral thighs and lateral shoulders, rated at 7/10 on the VAS. She reports that the pain is constant and that she gets only mild relief from NSAIDs. She cannot walk without a cane or walker. She had been diagnosed six years ago with severe peripheral neuropathy in her legs for which she was prescribed gababentin. She reports that gababentin gives her intense "brain fog" and forgetfulness, however, and that she has stopped taking it because of these side effects. The patient also has type 2 diabetes, initially treated with metformin but lately also with 50 units of insulin per day.

The patient was given a treatment plan that included chiropractic adjustments and exercise rehabilitation exercises. She also adopted a "Paleo" diet, which she followed strictly for three months, although it did not significantly lower her hemoglobin A1c levels. She has come to you because the pain is eroding her quality of life, interrupting her sleep, and contributing to tensions with her partner.

1. **Given the subjective nature of pain, how can a clinician more objectively assess the kind of pain reported by patients such as this?**

2. **Is it reasonable to believe that the gabapentin was responsible for her reported side effects?**

3. **Would Hannah be a good candidate for an opioid analgesic? Why or why not?**

4. **What non-pharmacological treatments might be tried for reducing this patient's pain?**

Non-opioid pharmacologic treatments for acute pain

Acetaminophen and NSAIDs

In general, mild-to-moderate acute pain responds well to oral non-opioids (e.g., acetaminophen, NSAIDs, and topical agents). Although they are weaker analgesics than opioids, acetaminophen and NSAIDs do not produce tolerance, physical dependence, or addiction and they do not induce respiratory depression or constipation. Acetaminophen and NSAIDs are often added to an opioid regimen for their opioid-sparing effect. Since non-opioids relieve pain via different mechanisms than opioids, combination therapy can provide improved relief with fewer side effects.

The choice of medication may be driven by patient risk factors for drug-related adverse effects (e.g., NSAIDs increase the rate of gastrointestinal, renal, and cardiovascular events). If acetaminophen or NSAIDs are contraindicated or have not sufficiently eased the patient's pain or improved function despite maximal or combination therapy, other drug classes (e.g., opioids) are sometimes used.

Non-opioid analgesics are not without risk, particularly in older patients. Potential adverse effects of NSAIDs include gastrointestinal problems (e.g., stomach upset, ulcers, perforation, bleeding, liver dysfunction), bleeding (i.e., antiplatelet effects), kidney dysfunction, hypersensitivity reactions, and cardiovascular concerns, particularly in the elderly.[109] The threshold dose for acetaminophen liver toxicity has not been established; however, the Food and Drug Administration (FDA) recommends that the total adult daily dose not exceed 4,000 mg in patients without liver disease (with a lower ceiling for older adults with certain conditions).[110]

The FDA currently sets a maximum limit of 325 mg of acetaminophen in prescription combination products (e.g., hydrocodone and acetaminophen) in an attempt to limit liver damage and other potential ill effects of these products.[32]

Topical agents

Topical capsaicin and salicylates can both be effective for short term cutaneous pain relief and generally have fewer side effects than oral analgesics, but their long-term efficacy is not well studied.[111,,112] Topical aspirin, for example, can help reduce pain from acute herpes zoster infection.[107] Topical NSAIDs and lidocaine may also be effective for short-term relief of superficial pain with minimal side effects. Topical agents can be simple and effective for reducing pain associated with wound dressing changes, debridement of leg ulcers, and other sources of superficial pain.[103]

Anticonvulsants

Anticonvulsants, such as gabapentin, pregabalin, oxcarbazepine, and carbamazepine, are often prescribed for chronic neuropathic pain (e.g., post-herpetic neuralgia and diabetic neuropathy) although evidence for efficacy in acute pain conditions is weak.[114] A 2017 trial, for example, randomized 209 patients with sciatica pain to pregabalin 150 mg/day titrated to a maximum of 600 mg/day vs. placebo for 8 weeks.[115] At 8 weeks there was no significant difference in pain between groups (mean leg pain intensity on a 0-10 scale 3.7 with pregabalin vs. 3.1 with placebo, P=0.19).

Opioids for acute pain: use caution

Opioids are commonly prescribed for pain, with nearly two thirds (64%) of the public reporting being prescribed an opioid for pain at some point in their lives.[116] However, this approach is not as safe and effective as once thought, and high-dose prescriptions or prolonged use not only increase the risk of misuse, addiction, or overdose, they may actually *increase* pain and pain sensitivity.[117,118]

Recent evidence suggests that opioids may not be more effective for moderate to severe acute pain than non-opioid pain regimens.[119,120] A randomized trial of 416 patients with acute extremity pain found no clinically important differences in pain reduction at two hours after single-dose treatment with ibuprofen and acetaminophen vs. three different opioid and acetaminophen combination analgesics.[113]

Physical dependence can readily occur after use of opioids at a sufficient dose (e.g., 30mg of oxycodone) for just a few days. In addition, side effects of opioid use can include constipation, confusion/gait instability, respiratory depression, pruritus, erectile dysfunction, and fractures, all of which may be more problematic in older patients and occur at higher rates than with non-opioid analgesics.

A cross-sectional study compared common side effects experienced during the first week of treatment with opioid analgesics vs. non-opioid analgesics in patients over age 65 with acute musculoskeletal pain.[121] The intensity of six common opioid-related side effects were significantly higher with opioids. (A limitation of this study is that it could not assess severe but less common adverse events associated with NSAIDs and acetaminophen, including the risk for gastrointestinal bleeding, acute kidney injury, and hepatotoxicity.)

In a retrospective study of 12,840 elderly patients with arthritis, opioid use was associated with an increased risk relative to non-opioids for cardiovascular events, fracture, events requiring hospitalization, and all-cause mortality.[122]

The risk of prolonged opioid use is particularly high after arthroscopic joint procedures. In a 2019 case-control study of 104,154 opioid-naïve adults, 8,686 (8.3%) developed new prolonged opioid use (continued opioid use between 91 and 180 days after shoulder arthroscopy).[123]

Subgroups at higher risk for long-term use included women, those with a history of alcohol use disorder, those with a mood disorder, and those with an anxiety disorder.

Opioid choices for acute pain

If an opioid is deemed necessary to treat moderate-to-severe acute pain, the following general principles are recommended when starting an opioid:

- Avoid extended-release and long-acting opioids such as methadone, fentanyl patches, and ER/LA versions of opioids such as oxycodone or oxymorphone.
- Avoid co-prescribing opioids with other drugs known to depress central nervous system function (e.g., benzodiazepines)
- Limit the dose and quantity of opioids to address the expected duration and severity of pain (usually less than 7 days).
- Combine opioids with other treatments (e.g., non-pharmacologic options such as exercise or cognitive behavioral therapy, NSAIDs, or acetaminophen).
- Closely monitor patients with impaired hepatic or kidney function if they are prescribed opioids, and adjust the dose or duration accordingly

Immediate-release agents are strongly preferred because of the higher risk of overdose associated with ER/LA agents. A cohort study of 840,000 opioid-naïve patients over a 10-year span found that unintentional overdose was 5 times more likely in patients prescribed ER/LA agents compared to immediate-release opioids.[124]

Opioid dosing for acute pain

The amount of opioid prescribed should relate to the level of pain expected from the injury or procedure. Injuries or procedures involving bones and joints tend to be more painful than those involving soft tissues.[125] Table 3 illustrates the wide range of expected pain and associated recommended opioid doses for some common surgeries or procedures.

Table 3. Opioid dose recommendations for post-procedural pain[126]	
Procedure	**Number of oxycodone 5 mg tablets (or equivalent)**
Dental extraction	0
Thyroidectomy	5
Breast biopsy or lumpectomy	5
Lumpectomy plus sentinel lymph node biopsy	5
Hernia repair (minor or major)	10
Sleeve gastrectomy	10
Prostatectomy	10
Open cholecystectomy	15
Cesarean delivery	15
Hysterectomy (all types)	15
Cardiac surgery via median sternotomy	15
Open small bowel resection	20
Simple mastectomy with or without sentinel lymph node biopsy	20
Total hip arthroplasty	30
Total knee arthroplasty	50

Managing chronic non-cancer pain

Management of chronic non-cancer pain begins by establishing individualized treatment goals, exploring non-opioid treatment options, and addressing comorbid depression and anxiety, if present. Pain management goals may include both pain and functional targets, with the understanding that being 100% pain free is not realistic. Functional goals should focus on activities that are meaningful to the patient and attainable based on the severity of the painful condition. Multi-modal approaches that include non-drug (procedures, integrative treatments) and drug interventions are recommended.[28]

Be aware that comorbid conditions such as depression and anxiety can impact pain management. (In a study of 250 patients with chronic pain and moderate depression, using antidepressant therapy reduced pain levels before analgesic interventions were added.[127])

For patients with intractable, moderate-to-severe chronic noncancer pain unresponsive to non-opioid treatment options, a trial of opioids may be indicated guided by the following principles (each detailed below):

- Discuss risks and benefits of opioid use
- Establish a written treatment agreement
- Check or monitor opioid use with the prescription drug monitoring program
- Use caution with dose escalation
- Prescribe naloxone if at risk for overdose
- Screen for opioid misuse or abuse using history and, ideally, a validated questionnaire, as well as urine drug testing
- Taper or discontinue opioids when possible

Establishing a written treatment agreement

Written documentation of all aspects of a patient's care, including assessments, informed consent, treatment plans, and provider/patient agreements, are a vital part of opioid prescription "best practices." Such documentation provides a transparent and enduring record of a clinician's rationale for a particular treatment and provides a basis for ongoing monitoring and, if needed, modifications of a treatment plan.[104]

Many computerized systems are now available for the acquisition, storage, integration, and presentation of medical information. Most offer advantages that will benefit both patients and prescribers, such as maintaining up-to-date records, and providing instant availability of information relevant to prescribing or treatment. Although automation can help, clear documentation is not dependent on electronic record-keeping; it merely requires a commitment to creating clear and enduring communication in a systematic fashion. Good documentation can be achieved with the most elaborate electronic medical record systems, with paper and pen, or with dictated notes. Clinicians must decide for themselves how thoroughly, and how frequently, their documentation of a patient's treatment should be.

Informed Consent

Informed consent is a fundamental part of planning for any treatment, but it is particularly important in long-term opioid therapy, given the potential risks of such therapy. At its best, consent also fortifies the clinician/patient relationship.

Prescribers must be able to answer with confidence four key questions when obtaining informed consent in the context of treatment with opioids:[122]

1. Does the patient understand the various options for treatment?
2. Has the patient been reasonably informed of the potential benefits and risks associated with each of those options?
3. Is the patient free to choose among those options, free from coercion by the healthcare professional, the patient's family, or others?
4. Does the patient have the capacity to communicate his or her preferences—verbally or in other ways (e.g., if the patient is deaf or mute)?
5. Is there a proxy available if the patient cannot provide consent due to cognitive impairment?

Documentation related to these key areas can be accomplished by creating a separate paper or electronic informed consent form or by incorporating informed consent language into a larger treatment plan or patient/provider agreement.

Patient-Provider Agreements

A written agreement between a clinician and a patient about the specifics of their pain treatment with opioids can help clarify the plan with the patient, the patient's family, and other clinicians who may become involved in the patient's care.[104]

Such agreements can also reinforce expectations about the appropriate and safe use of opioids. Caution must be exercised, however, to ensure that patient/provider agreements are not used in a coercive way to unethically place patients in the position of having to agree to its terms or else lose an important component of their treatment (or even lose *all* treatment).[128]

Although evidence is lacking about the most effective methods to convey the information included in most patient-provider agreements, such agreements have been widely used and are recommended by regulators and many experts on treatment guidelines for long-term opioid therapy.[28] The Veterans Administration and U.S. Department of Defense chartered an expert panel to undertake a systematic review of existing medical literature on this subject. In the clinical practice guidelines resulting from that work, the panel concluded that opioid treatment agreements are a standard of care when prescribing long-term opioid therapy.[128]

Clinicians should strive to craft agreements that serve their patients' best interests and avoid coercive or punitive language. Thus, agreements should avoid:

1. Putting all burden on the patient rather than sharing it between patient and clinician
2. Framing the agreement in terms of punishments for possible future crimes or difficulties

3. Using language that is stigmatizing, dominating, or pejorative
4. Using coercion in any way
5. Imposing limitations for the clinician's convenience without clear and substantial benefit for the patient.
6. Insisting on behaviors unrelated to actual use of medications Using the term "fired" to describe termination of treatment.
7. Threatening abandonment or suggesting that patients will not have continued access to non-opioid pain-relieving treatments if opioids are terminated

To be effective, written agreements must be clearly understood by the patient. This may require the provision of agreements in multiple languages. All agreements should be written at the sixth- to seventh-grade level or even lower.[129] Translators may need to be provided for speakers of other languages to ensure patient understanding and effective informed consent. A patient who does not fully understand the potential risks and benefits of a treatment cannot be truly "informed" as required by the legal and ethical guidelines for medical practice. Time must be allowed for patients to ask questions, and for prescribers to ensure patients understand what they are being told. Some, or all, of these tasks may be handled by trained personnel (or staff members) rather than clinicians.

Although the term "agreement" is generally perceived as being more patient-friendly than the word "contract," clinicians should understand that, from a legal standpoint, any written or oral agreement between a prescriber and a patient may be considered a binding "contract."[130] Clinicians should ensure that the terms in any agreement are understood by the patient, and are acceptable, attainable, and consistent with high-quality practice.

BEFORE MOVING ON THE NEXT SECTION, PLEASE COMPLETE CASE STUDY 4 ON THE NEXT PAGE.

Creating individualized function-based pain treatment plans

Once a patient has been assessed and accepted as a candidate for chronic opioid therapy, and after informed consent has been obtained for such treatment, a written plan for implementing the treatment should be drafted. Such plans typically include a statement of the goals of therapy. These goals should be written carefully in light of the inherent subjectivity of pain. Since pain itself cannot be measured objectively, framing treatment goals solely in terms of pain relief means that such goals cannot be objectively confirmed.

Although a patient's subjective pain and suffering are obviously important factors, only the functional impact of the pain can be measured and used to create objective treatment goals. This impact takes many forms, but typically chronic pain erodes foundations of daily life, such as physical activity, concentration, emotional stability, interpersonal relationships, and sleep. This can, in turn, degrade functioning at work or in the home, which can lead to depression, anxiety, insomnia, and even suicide. Clinicians should know that even relatively modest reductions in pain can translate into significant functional improvements as pain rating declines.[104] A 20% reduction in a pain score (i.e., roughly two points on the standard 0-10 pain scale) may be acceptable if it produces significant functional benefits for a patient.

Framing treatment goals in terms of improved patient functioning, rather than merely pain relief, offers two primary advantages to clinicians:

- Prescribing decisions (or decisions to terminate treatment) are based on outcomes that can be objectively demonstrated to both clinician and patient (and, possibly, to the patient's family)
- Individual differences in pain tolerance become secondary to the setting and monitoring of treatment goals, since subjectively perceived levels of pain are not the primary focus in determining functionality.

Basing treatment plans on functional goals is especially valuable in the context of prescribing opioid pain medications, because such goals may help determine whether a patient has an opioid use disorder because patients with OUD often have decreased functioning, while effective pain relief typically improves functioning.

Functional decline itself may result from a range of problems, including inadequate pain relief, non-adherence to a regimen, function-limiting side effects, or untreated affective disorders. Sometimes impaired functioning is the result of OUD, and these objective results may shed valuable light on an otherwise confusing presentation of a patient's pain symptoms.

Functional treatment goals should be realistic. Progress in restoring function is usually slow and gains are typically incremental. Chronic non-cancer pain is often marked by long-standing physical and psychological deconditioning, and recovery may require reconditioning that may take weeks, months, or years. It is much better to set goals that are slightly too low than slightly too high. Raising goals after a patient has "succeeded" in achieving them is far more motivational and encouraging than lowering goals after a patient has "failed." Table 4 illustrates some simple functional goals and ways they might be verified.

The responsibility for obtaining evidence of success in meeting a functional goal lies with the patient and should be made explicit in the prescribing agreement. If a patient is unable to document or achieve the progress outlined in a treatment plan, this may suggest a need for goal readjustment.

Initiating therapy

When initiating a trial of opioids, start with immediate-release formulations because their shorter half-life reduces the risk of inadvertent overdose. Prescribe low doses on an intermittent, as-needed basis. For elderly patients who have comorbidities, start at an even lower dose (25-50% of usual adult dose).

Long-term opioid use often begins with treatment for acute pain, and research shows that opioids are often over-prescribed for acute pain. For example, a study of 1,416 patients in a 6-month period found that surgeons prescribed a mean of 24 pills (standardized to 5 mg oxycodone) but patients reported using a mean of only 8.1 pills (utilization rate 34%).[125] For acute pain, only enough opioids should be prescribed to address the expected duration and severity of pain from an injury or procedure (or to cover pain relief until a follow-up appointment). Several guidelines about opioid prescribing for acute pain from emergency departments[131,132] and other settings[133,134] have recommended prescribing $\leq$ 3 days of opioids in most cases, whereas others have recommended $\leq$ 7 days,[135] or $\leq$ 14 days.[136] CDC guidelines suggest that for most painful conditions (barring major surgery or trauma) a 3-day supply should be enough, although many factors must be taken into account (for example, some patients might live so far away from a health care facility or pharmacy that somewhat larger supplies might be justified) and clinician judgment is an important factor in determining the supply.[31]

Monitoring opioid use

Follow-up appointments should occur one to four weeks after initiation of opioids or with dose changes; maintenance therapy visits should occur at least every three months. Each visit should include an assessment using a pain and function tool, questions about side effects, evaluation of overdose risk, and discussions about how the medication is being used.[34]

Many strategies to monitor opioid use and ensure patient safety have been recommended. However, simply asking patients how they are using the medication, how often they take it, how many pills they take at one time, and what triggers them to take the medication, can identify patients who may be misusing opioids or need changes to their pain management plan.

Case Study 4

Instructions: Spend 5–10 minutes reviewing the case below and considering the questions that follow.

Inessa is 72 and lives in an urban area, having immigrated from Russia as a young woman. She grew up on a farm and worked in the fields or tending animals starting as a child. She blames these early labors for the arthritis she now has in her hands and wrists, and for the pain she feels in her lower back. Although Inessa lives alone, following the death of her husband from a heart attack 5 years ago, she relies on a young man who lives in a small apartment attached to her house for help with activities of daily living and simply for company.

According to Inessa, the pain medication she was prescribed for her arthritis (short-acting hydrocodone/acetaminophen) is no longer working and she has come to you asking for either a different medication or a higher dose of the existing medication. Despite her reported pain, Inessa is ambulatory and appears cognitively intact. She takes a range of herbal supplements including St. John's wort, turmeric, and a "joint support" supplement, the ingredients of which she is unsure. She has a very insistent, demanding personality and is convinced she needs the new, or higher-dose, opioid medication.

1. **How would you respond to Inessa's request?**

2. **What alternatives to an opioid analgesic could you offer to Inessa?**

3. **If you end up prescribing an opioid analgesic for Inessa, would you require that she sign a patient-provider agreement? If so, what specific caveats would you include in the agreement?**

4. **Would it be prudent to include the young man who cares for her in discussions about treatment?**

Table 4: Example of functional goals and evidence used to assess progress[104]

Functional Goal	Evidence
Begin physical therapy	Letter from physical therapist
Sleeping in bed as opposed to lounge chair	Report by family member or friend (either in-person or in writing)*
Participation in pain support group	Letter from group leader
Increased activities of daily living	Report by family member or friend
Walk around the block	Pedometer recordings or written log of activity
Increased social activities	Report by family member or friend
Resumed sexual relations	Report by partner
Returned to work	Pay stubs from employer or letter confirming the patient is off of disability leave
Daily exercise	Gym attendance records or report from family member or friend

* Involving other persons requires explicit permission from the patient, and this permission should be documented.

Other ways to objectively monitor opioid use are checking prescription drug monitoring programs, completing urine drug tests/oral fluid tests, or random pill counts.

Relatively infrequent urine monitoring may be appropriate for low-risk patients on a stable dose of opioids (i.e., 1-2 times a year). More frequent or intense monitoring is appropriate for patients during the initiation of therapy or if the dose, formulation, or opioid medication is changed. Patients who may need more frequent or intense monitoring (i.e., 4-6 times a year) include:[104]

- Those with a prior history of an addictive disorder, past abuse, or other aberrant use
- Those in an occupation demanding mental acuity
- Older adults
- Patients with an unstable or dysfunctional social environment
- Those with comorbid psychiatric or medical conditions

It is important to recognize that urine drug testing is expensive and not all insurance companies will pay for frequent testing. Discuss the cost of testing with patients. Also, only order the test that is necessary. It is not necessary to order quantitative (definitive test) testing on all patients as this test can be very expensive. For low-risk patients urine drug screening (presumptive test), even done as a point of care test, may be sufficient. However, if the urine drug screen will not detect the drug of interest, then a quantitative test will be needed.

Trust is a necessary part of any patient/clinician relationship, but studies suggest that in the context of controlled substances, it is unwise to rely on a patient's word that medications are being consumed as prescribed. Although the use of more objective ways to monitor adherence to medication regimens is an imperfect science, such methods remain an essential component of periodic review. Multiple objective methods to assess adherence exist, but there is no single "best" approach and all such methods have both advantages and potential drawbacks.

In the context of family practice settings (and even pain specialist settings) unobserved urine collection is usually an acceptable procedure for drug testing. Prescribers, however, should be aware of the many ways in which urine specimens can be adulterated. Specimens should be shaken to determine if soap products have been added, for example. The urine color should be noted on any documentation that accompanies the specimen for evaluation, since unusually colored urine could indicate adulteration. Urine temperature and pH should be measured immediately after collection when possible.[131]

Prescribers should be familiar with the metabolites associated with each opioid that may be detected in urine, since the appearance of a metabolite can be misleading. A patient prescribed codeine, for example, may test positive for morphine because morphine is a metabolite of codeine. Similar misunderstandings may occur for patients prescribed hydrocodone who appear positive for hydromorphone or oxycodone and oxymorphone.

Opioid rotation and equianalgesic dosing

"Opioid rotation" means switching from one opioid to another in order to better balance analgesia and side effects. Rotation may be needed because of a lack of efficacy (often related to tolerance), bothersome or unacceptable side effects, increased dosing that exceeds the recommended limits of the current opioid (e.g., dose limitations of co-compounded acetaminophen), or inability to absorb the medication in its present form (i.e., if there is a change in the patient's ability to swallow, switch to a formulation that can be absorbed by a different route such as transdermal.)

Because of the large number of variables involved in how any given opioid will affect any given patient, opioid rotation must be approached cautiously, particularly when converting from an immediate-release formulation to an ER/LA product. As noted previously, equianalgesic charts must be used carefully, and titration must be done carefully and with appropriate monitoring. In some cases, because of the risk of potential harm during the time of rotating from one chronic opioid regimen to another, it may be wise to initially use lower doses of an ER/LA opioid than might be suggested by equianalgesic charts, while temporarily liberalizing, as needed, the use of a short-acting opioid.[138] This would then be followed by gradual titration of the LA opioid to the point where the as-needed short-acting opioid is incrementally reduced, until no longer necessary.

Equianalgesic dosing charts help clinicians determine the appropriate starting dose of an opioid when changing routes of administration or when changing from one opioid drug to another. Such charts must be used carefully, however. A high degree of variation has been found across the various charts and online calculator tools, and may account for some overdoses and fatalities.[132] The optimal dose for a specific patient must be determined by careful titration and appropriate monitoring, and clinicians must be mindful that patients may exhibit incomplete cross-tolerance to different types of opioids because of differences in the receptors or receptor sub-types to which different opioids bind.[138] In addition, the patient's existing level of opioid tolerance as well as concurrent medications that depress the central nervous system must be taken into account. Printed equianalgesic charts are common, and online calculators are also freely available (a common one can be accessed at clincalc.com/Opioids). Always work with a clinical pharmacist if you do not have a lot of experience with opioid rotation as this can be a risk factor for unintentional opioid overdose.

Recognizing patients with opioid use disorder

Whenever a clinician considers treating pain with a controlled substance, such as an opioid, risk of misuse or diversion is always a possibility, no matter how remote, and must be assessed. Some patient characteristics are predictive of a potential for drug abuse, misuse, or other aberrant behaviors. The factor that appears to be most strongly predictive in this regard is a personal or family history of alcohol or drug abuse.[28] Some studies have also shown that younger age and the presence of psychiatric conditions are also associated with aberrant drug-related behaviors.[28]

In evaluating patients with chronic pain for risk of addiction or signs that they may be abusing a controlled substance, it may be helpful to consider the sets of characteristics listed in Table 5.

Signs of physical dependence include the appearance of an abstinence syndrome with abrupt cessation or diminution of chronic drug administration and is not the same as OUD, a condition where patients lose control of their opioid use or compulsively use opioids. The nature and time of onset of this syndrome vary with drug actions and half-life. Slow tapering of the drug (e.g., 10-15% reduction in dosage per day or every other day) usually avoids the appearance of an abstinence syndrome.

Managing Non-Adherent Patients

Patients who exhibit aberrant drug-related behaviors or non-adherence to an opioid prescription should be monitored more closely than compliant patients. Concern that a patient is non-adherent should prompt a thorough evaluation.
The way clinicians interact with patients can affect the relationship (for better or worse) and influence treatment outcomes. A clinician's negative reactions to non-adherence might include anger at the patient, disappointment and sadness at the apparent betrayal of trust, or fear that the patient's behavior could expose the provider to legal jeopardy.[104]

The use of patient–provider agreements and/or informed consent documents can help clinicians navigate the uncertainties that can arise in cases of real or apparent non-adherence, and may help make the process less confrontational. Consultation with an addiction medicine specialist or psychiatrist may be necessary if addiction is suspected or if a patient's behavior becomes so problematic that it jeopardizes the clinician/patient relationship.

Table 5: Chronic pain patients vs. patients with an OUD[137]	
Patient with chronic pain	**Patient with an opioid use disorder**
Medication use is not out of control	Medication use is out of control
Medication use improves quality of life	Medication use impairs quality of life
Wants to decrease medication if adverse effects develop	Medication use continues or increases despite adverse effects
Is concerned about the physical problem being treated with the drug	Unaware of or in denial about any problems that develop as a result of drug treatment
Follows the practitioner-patient agreement for use of the opioid	Does not follow opioid agreement
May have left over medication	Does not have leftover medication
	Loses prescriptions
	Always has a story about why more drug is needed

Treatment Termination

Reasons for discontinuing an opioid analgesic can include the healing of or recovery from an injury, medical procedure, or condition; intolerable side effects; lack of response; or discovery of misuse of medications. Regardless of the reason, termination should be accomplished so as to minimize unpleasant withdrawal symptoms by tapering the opioid medication slowly, by carefully changing to a new formulation, or by effectively treating an opioid use disorder if it has developed. Approaches to weaning range from a slow 10% reduction per week to a more aggressive 25 to 50% reduction every few days.[28] In general, a slower taper will produce fewer unpleasant symptoms of withdrawal; however, this may not be the safe course of action for a patient experiencing side effects or who has OUD.

Opioid therapy must be discontinued or re-evaluated whenever the risk of therapy is deemed to outweigh the benefits being provided.

A clinician may choose to continue opioid treatment with intensified monitoring, counseling, and careful documentation if it is deemed in the best interest of the patient. This requires, however, careful consideration and a well-documented risk management plan that addresses the greater resources necessary for opioid continuation following evidence of misuse.

If termination of the physician/patient relationship is deemed necessary (though it rarely is), clinicians must ensure that the patient is transferred to the care of another physician or provider and ensure that the patient has adequate medications to avoid unnecessary risk, such as from uncontrolled or unpleasant withdrawal. Practitioners can be held accountable for patient abandonment if medical care is discontinued without justification or adequate provision for subsequent care.

Caution with dose escalation

When escalating opioid doses, be aware of two possible critical daily thresholds—50 and 90 MMED.[34] According to the CDC, doses >50 MMED are associated with more than double the risk of overdose compared to patients on <50 MMED.[31] For patients on >90 MMED, a 9-fold increase in mortality risk was observed compared with the lowest opioid doses. Ninety MMED is considered by several guidelines as a "red flag" dose beyond which careful assessment, more frequent monitoring, and documentation of expected benefits are required (note, however, that this limit doesn't apply to patients with severe cancer pain or end-of-life pain). The total MMED for all prescribed opioids should be used (MMED is automatically calculated on many state PDMP reports). Physician clinical judgment is also important in determining daily thresholds and the CDC limits can be used as a guide.

Role of ER/LA opioids and methadone

ER/LA opioids include methadone, transdermal fentanyl, and extended-release versions of opioids such as oxycodone, oxymorphone, hydrocodone, and morphine. A 2015 study found a higher risk for overdose among patients initiating treatment with ER/LA opioids than among those initiating treatment with immediate-release opioids.[124] As noted above, continuous, time-scheduled use of ER/LA opioids is not more effective or safer than intermittent use of immediate-release opioids, and ER/ LA opioids increase risks for opioid misuse or addiction.[31]

The 2016 CDC guidelines suggest that ER/LA opioids should be reserved for severe, continuous pain and should be considered only for patients who have received immediate-release opioids daily for at least 1 week.[31] Additional caution is required when prescribing ER/LA opioids in older adults or patients with renal or hepatic dysfunction because decreased clearance of drugs among these patients can lead to accumulation of drugs to toxic levels and persistence in the body for longer durations.

When an ER/LA opioid is prescribed in the primary care setting, using an agent with predictable pharmacokinetics and pharmacodynamics is preferred to minimize unintentional overdose risk (i.e., the unusual characteristics of methadone and transdermal fentanyl make safe prescribing of these medications for pain more challenging).[31]

The use of methadone for chronic pain in primary care should generally be avoided because of higher methadone-related risks for QTc prolongation and fatal arrhythmias.[31]

Equianalgesic dose ratios are highly variable with methadone, making conversion from other opioids difficult, with attendant increased risk of overdose. While methadone-related death rates decreased 9% from 2014 to 2015 overall, the rate increased in people ≥65 years of age.[139] If methadone or transdermal fentanyl is considered, refer patients to pain management specialists with expertise in using this medication.

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Protecting against opioid-induced adverse events

Prophylaxis for constipation—the most common opioid-induced adverse event—has been facilitated by the approval of methylnaltrexone subcutaneous administration and naloxegol oral administration for patients with chronic non-cancer pain. Other, less expensive medications like senna and docusate, are also effective to guard against constipation.

Both male and female patients on long-term opioid therapy are at risk for hypogonadism, thus current guidelines suggest that the endocrine function of all patients should be assessed at the start of long-term opioid therapy and at least annually thereafter.

Naloxone for opioid overdose

Naloxone (e.g., Narcan) is an opioid antagonist that quickly reverses the effects of opioid overdose. Naloxone is increasingly available to first responders, patients, and friends and family members of those prescribed opioids, and a generic formulation of nasal-spray naloxone was approved by the FDA in April, 2019.[141]

Case Study 5

Instructions: Spend 5–10 minutes reviewing the case below and considering the questions that follow.

Jeremiah has been your patient since he was a young boy. Now 33 years old, you have seen Jeremiah grow up into a physically strong, but emotionally vulnerable young man. Jeremiah struggled in school and chose to enter a training program for masons rather than pursue college. A self-described "partyer" who reports regular use of alcohol and cannabis, Jeremiah nonetheless has not reported any impacts of his substance use on his personal or work life. He has, in fact, been successful in both, earning a good living as a mason and supporting his wife and two sons.

But Jeremiah is currently on workman's compensation to recover from a compound fracture of his left foot and ankle sustained when a large section of a chimney he was working on collapsed and fell. He also tore the rotator cuff in his right shoulder when he fell backwards against the scaffolding poles during the accident. Both injuries required surgical interventions and his recovery has been slow. Jeremiah was prescribed a short-acting opioid after each surgery, which he has continued to use.

He has been regularly attending physical therapy sessions to restore strength in his left leg and to increase the range of motion in his right shoulder, but he complains that the therapy sessions are painful and that he doesn't think they're helping. He says his boss suggested that a long-acting opioid would be easier to use and would provide him more steady pain relief.

1. **How would Jeremiah's substance use affect your decision-making process related to his request for an ER/LA medication?**

2. **What steps might you take before agreeing to a trial of an ER/LA medication for Jeremiah?**

3. **What specific kind/dose of ER/LA medication might be most appropriate for Jeremiah if no contraindications were found in the pain and substance abuse assessment?**

4. **Name three specific functional goals that might be used as the basis for a pain management agreement with Jeremiah.**

Primary care providers should prescribe naloxone to patients at risk of overdose, including those:

- With renal or hepatic dysfunction
- Taking opioid doses >50 MMED
- Co-prescribed benzodiazepines or other sedating medications
- With a history of overdose or OUD
- Starting treatment for opioid use disorder

Many states allow patients, family members, caregivers, and/or friends to request naloxone from their local pharmacist. Anyone receiving naloxone should be taught how to use the device and about the common signs of overdose (slow or shallow breathing, gasping for air, unusual snoring, pale or bluish skin, not waking up or responding, pin point pupils, slow heart rate).

A variety of naloxone products are available. The intranasal device with atomizer and intramuscular (IM) shots require the most manipulation in order to administer. Intranasal naloxone and the auto-IM injector are easier to use, but vary greatly in terms of price and insurance coverage.

Successful opioid tapering

Patients who do not achieve functional goals on stable or increasing opioid doses or those with unacceptable side effects, should have the opioid tapered or discontinued. Patients sometimes resist tapering or discontinuation, fearing increased pain. However, a 2017 systematic review found that dose reduction or discontinuation resulted in reduced pain (eight studies), improved function (five studies) and improved quality of life (three studies), although the evidence was not strong because the analysis included poor-quality studies with uncontrolled designs and the interventions and outcome measures were heterogeneous.[142]

Recommendations for tapering schedules vary. One source recommends a 10% decrease weekly based on years of opioid use (i.e., 10% decrease monthly for patients using opioids ≥4 years). For patients on high-dose opioids (i.e., ≥90 MMED), taper 10% until patient is taking 30% of the total initial dose, then recalculate 10% taper based on the new total opioid dose to slow taper.[143] The rate of opioid taper should be adjusted based on patient-specific factors such as the severity of withdrawal symptoms.

Table 6: Recommendations for preventing or treating opioid-induced side effects[140]	
Constipation	Methylnaltrexone or naloxegol Prophylactic mild peristaltic stimulant (e.g. bisacodyl or senna) If no bowel movement for 48 hours, increase dose of bowel stimulant If no bowel movement for 72 hours, perform rectal exam If not impacted, provide additional therapy (suppository, enema, magnesium citrate, etc.)
Nausea or vomiting	Consider prophylactic antiemetic therapy Add or increase non-opioid pain control agents (e.g. acetaminophen) If analgesia is satisfactory, decrease dose by 25% Treat based on cause
Sedation	Determine whether sedation is due to the opioid – if so, lower opioid dose immediately Eliminate nonessential CNS depressants (such as benzodiazepines) Reduce dose by 20-30% Add or increase non-opioid or non-sedating adjuvant for additional pain relief (such as NSAID or acetaminophen)so the opioid can be reduced Change opioid Prescribe naloxone
Pruritus	Consider treatment with antihistamines Change opioid
Hallucination or dysphoria	Evaluate underlying cause Eliminate nonessential CNS acting medications
Sexual dysfunction	Reduce dose Testosterone replacement therapy may be helpful (for men) Erection-enhancing medications (e.g., sildenafil)

In 2019 the FDA, recognizing the risks associated with abrupt discontinuation of opioid analgesics, required new labeling for opioid analgesics to guide prescribers about safe tapering practices.[138]

The key elements include:[144]

- Do not abruptly discontinue opioid analgesics in patients physically dependent on opioids. Counsel patients not to discontinue their opioids without first discussing the need for a gradual tapering regimen.
- Abrupt or inappropriately rapid discontinuation of opioids is associated with serious withdrawal symptoms, uncontrolled pain, and suicide.
- Ensure ongoing care of the patient and mutually agree on an appropriate tapering schedule and follow-up plan.
- In general, taper by an increment of no more than 10-20% every 2-4 weeks.
- Pause taper if the patient experiences significantly increased pain or serious withdrawal symptoms.
- Use a multimodal approach to pain management, including mental health support (if needed).
- Reassess the patient regularly to manage pain and withdrawal symptoms that emerge and assess for suicidality or mood changes.
- Refer patients with complex comorbidities or substance use disorders to a specialist.

Opioid use disorder (OUD)

OUD is a problematic pattern of opioid use that causes significant impairment or distress.[145] As with other chronic diseases, OUD usually involves cycles of relapse and remission. DSM-5 diagnosis of OUD is based on clinical evaluation and determination that a patient has problematic opioid use leading to clinically significant impairment or distress involving at least two of the following within a 12-month period:[145]

- Opioids taken in larger amounts, or for longer periods, than intended
- Persistent desire or unsuccessful attempts to control or reduce use
- Significant time lost obtaining, consuming, and recovering from opioids
- Craving or a strong desire or urge to use opioids
- Failure to complete obligations (i.e., work, home, or school) due to opioids
- Persistent or recurrent social or interpersonal problems due to opioids
- Giving up enjoyable social, work, or recreational activities due to opioids
- Recurrent opioid use in situations in which it is physically hazardous (e.g., driving)
- Continued use despite a physical or psychological problem caused by or worsened by opioid use
- Tolerance (unless opioids are being taken as prescribed)
- Using opioids to prevent withdrawal symptoms (unless opioids are being taken as prescribed)

OUD is not a binary diagnosis, rather it exists as a continuum, with DSM-5 describing 3 levels of severity:

- Mild OUD (2-3 criteria)
- Moderate OUD (4-5 criteria)
- Severe OUD (≥ 6 criteria)

More than 2 million Americans have OUD, and the number is growing.[70] OUD can be effectively managed with medication-assisted treatment (MAT), but only an estimated 20% of adults with OUD currently receive such treatment.[146]

Medications to treat OUD

The FDA has approved three medications for treating OUD: buprenorphine, methadone, and extended-release naltrexone (Table 7). Buprenorphine and methadone can reduce opioid cravings and all three can prevent misuse.[141] Each medication has a unique mechanism of action and involve different formulations, methods of induction and maintenance, patterns of administration, and regulatory requirements.

Methadone

Methadone is a synthetic, long-acting opioid agonist that fully activates mu-opioid receptors in the brain.[148] This activity reduces the unpleasant/dysphoric symptoms of opioid withdrawal, and, at therapeutic doses, it blunts the "highs" of shorter-acting opioids such as heroin, codeine, and oxycodone. Patients do not have to experience opioid withdrawal before starting methadone.

Table 7. FDA-approved medications for OUD[147]
Buprenorphine • Buprenorphine/naloxone buccal film (Bunavail) • Buprenorphine/naloxone sublingual film (Suboxone, generics) • Buprenorphine/naloxone sublingual tablets (Zubsolv, generics) • Buprenorphine sublingual tablets (generics) • Buprenorphine subdermal implant (Probuphine) • Buprenorphine extended-release subcutaneous injection (Sublocade)
Methadone • Tablets (Dolophine, MethaDose, generics) • Oral concentrate (MethaDose, generics)
Naltrexone extended-release injection (Vivitrol)

It may, however, take days to weeks to achieve a therapeutic dose, which requires individualized monitoring in order to minimize cravings and reduce the risk of relapse.

As a full agonist, methadone sustains opioid tolerance and physical dependence, thus missing doses may precipitate opioid withdrawal. Overdose risk is highest in the first two weeks of methadone treatment,[149] after which risk is significantly lower compared to people who are not in treatment.[150,151]

Common side effects of methadone are constipation, vomiting, sweating, dizziness, and sedation. Although respiratory depression can be induced by methadone, the FDA advises that methadone not be withheld from patients taking benzodiazepines or other central nervous system depressants because the risk of overdose is even higher among patients not on methadone for OUD.[152] The other potential harms of methadone include hypogonadism, which is a potential side effect of chronic use of any opioid, and QTc segment prolongation.

Buprenorphine

Buprenorphine is a high-affinity partial opioid agonist at the mu-opioid receptor as well as an antagonist of the kappa opioid receptor.[153] Like methadone, buprenorphine can relieve opioid withdrawal symptoms, and, because of its partial agonist effect, it can reduce the rewarding effect of other opioids used simultaneous with buprenorphine. Buprenorphine's partial agonist status also translates into a lower risk of respiratory depression compared to methadone and other opioids,[148] and a therapeutic dose may be achieved within a few days.[155]

Buprenorphine is available as sublingual tablets, sublingual/buccal films, subdermal implants, or extended-release subcutaneous injection (Table 10). Some film and tablet formulations are combined with the opioid antagonist naloxone to discourage misuse by crushing and injecting the medication. (A buprenorphine-only patch [Butrans] is only FDA-approved as an analgesic.)

Some forms of buprenorphine can be self-administered by patients after filling their prescription at regular pharmacies.

In order to prescribe buprenorphine, physicians in the United States must complete an 8-hour training and apply for a waiver (informally called an X-waiver) from the Drug Enforcement Administration (for details see "Obtaining an X-waiver" section below). The Comprehensive Addiction and Recovery Act of 2016 authorized nurse practitioners and physician assistants to be eligible to apply for training and X-waivers, although the associated required training is 24 hours.[156]

As with methadone, buprenorphine sustains opioid tolerance and physical dependence in patients, so discontinuation can lead to withdrawal—although buprenorphine's withdrawal syndrome may be less severe. The most common side effects are constipation, vomiting, headache, sweating, insomnia, and blurred vision. One risk of buprenorphine (as well as naltrexone) is the risk of precipitating opioid withdrawal at first dose if the patient has recently used either prescription or illicit drugs, due to buprenorphine's partial-agonist properties high binding affinity for the opioid receptor.[141] Thus, a patient must be in mild to moderate withdrawal prior to initiation to avoid precipitating withdrawal. The risk of opioid overdose declines immediately when patients with OUD initiate buprenorphine treatment.[145] The risk of hypogonadism is lower with buprenorphine compared to methadone, and buprenorphine is not associated with QTc prolongation or cardiac arrhythmias.[157]

The various non-oral routes of buprenorphine avoid the significant hepatic metabolism inherent with oral administration, and appear to be largely equivalent in their efficacy for maintaining abstinence and reducing risk of overdose. For example, a randomized trial comparing buprenorphine implant to sublingual buprenorphine found higher levels of negative urine screens and abstinence with the implant, but the differences did not reach statistical significance.[158] (Note that use of implantable agents require stabilization on sublingual doses first.)

"Buprenorphine treatment provides one of the rare opportunities in primary care to see dramatic clinical improvement: it's hard to imagine a more satisfying clinical experience than helping a patient escape the cycle of active addiction."

--Wakeman et al. NEJM 2018;379(1):1-4

Extended-release naltrexone

Naltrexone is not an opioid. It is a full antagonist of the mu-opioid receptor, which blocks both the euphoric and analgesic effects of all opioids, including endogenous opioids (i.e., endorphins) and also reduces cravings for opioids.[153] Naltrexone does not cause physical dependence, nor does it produce any of the rewarding effects of opioids. Patients may try to use opioids while on extended-release naltrexone, but it is unlikely that they will experience any rewarding effects from such use, unless the binding affinity of naltrexone is overcome.[147] The most common side effects of extended-release naltrexone are injection site pain, nasopharyngitis, insomnia, and toothache.

Treatment initiation requires a 7-10 day period during which the patient is free from all opioids, including methadone and buprenorphine. This is usually achieved with medicallysupervised withdrawal followed by at least 4 to 7 days without any opioids (including methadone and buprenorphine). This process is a very significant barrier to naltrexone use.[147]

Naltrexone is currently available both as a once-daily oral tablet and in a once monthly, extended-release depot injection. The oral formulation, however, was found to be no better than placebo in a 2011 Cochrane review of 13 trials with 1,158 participants,[159] and only the extended-release formulation has been approved for OUD by the FDA. Patients may have an increased risk of overdose when they approach the end of the 28-day period of the extended-release formulation.[160]

Naloxone vs. Naltrexone: What's the difference?

Naloxone (Narcan) is an opioid antagonist given by injection or nasal spray to reverse overdoses. It acts within minutes and lasts for only about an hour due to rapid metabolism.

Naltrexone has a very similar chemical structure to Naloxone and is also an opioid antagonist, but it acts more slowly and lasts longer. Extended-release naltrexone is used clinically to block cravings for opioids and other drugs.

Does MAT really work?

Abundant evidence from decades of randomized trials, clinical studies, and meta-analyses suggests that agonist or partial-agonist opioid treatment used for an indefinite period of time is the safest option for treating OUD.[147, 155] (The evidence base for extended-release naltrexone is much less robust.)[147]

A small randomized trial and a large cohort study demonstrated that people with OUD treated with methadone or buprenorphine are less likely to die, less likely to overdose, and more likely to remain in treatment. [153,161] MAT is also associated with lower risks for HIV and other infections, and improved social functioning and quality of life compared to people not on MAT.[30]

Data suggest that MAT is more effective than psychotherapeutic interventions alone, and is just as effective whether psychotherapeutic interventions are used concurrently with medication treatment or not. For example, data from Massachusetts Medicaid beneficiary claims between 2004 and 2010 show significantly lower relapse rates with both buprenorphine and methadone compared to a behavioral health intervention alone.[162]

Although the evidence base for intramuscular naltrexone is less robust than for methadone or buprenorphine, it has been shown to significantly decrease opioid misuse in patients with mild-to-moderate OUD.[147] For example, one trial randomized 250 patients with OUD who completed inpatient detoxification (≥ 7 days off all opioids) to 24 weeks of naltrexone intramuscular injection (380 mg/month) vs. placebo.[163] At follow-up, 90% in the naltrexone group were abstinent compared to 35% in the placebo group.

Psychosocial treatments

Psychosocial and/or behavioral interventions can be used in combination with medications in order to treat the "whole patient" (e.g., comorbid psychiatric symptoms, social support needs). The National Academy of Sciences, however, notes that psychosocial services may not be available to all patients and recommends that the lack of such supports should not be a barrier to using MAT.[147]

For example, a 2012 trial randomized 230 adults with OUD to one of three groups: methadone without extra counseling vs. methadone with standard counseling vs. methadone with counseling in the context of smaller caseloads.[164] At one-year follow-up there were no significant differences between the groups in rates of retention in treatment or urine tests positive for opioids. Three other randomized trials comparing buprenorphine with medical management alone vs. buprenorphine plus cognitive behavioral therapy or extra counseling sessions also found no significant differences in key opioid-related outcomes.[165-167]

Nonetheless, psychosocial, behavioral, and peer-support interventions may have many profoundly important benefits for patients beyond strictly opioid-related outcomes, such as improving self-confidence, self-advocacy, general quality of life, and improvements in legal, interpersonal, and occupational functioning.[141] Some guidelines and authors advocate for the use of psychosocial interventions, but suggest that the lack of such interventions at a given place or time should not be a barrier to the use of MAT.[147,169]

Tapering protocols

OUD guidelines do not recommend a duration of MAT treatment, which could be for an indefinite period of time because of the high risk of relapse with discontinuation.[147] For example, a population-based retrospective study of 14,602 patients who discontinued methadone treatment found that only 13% had successful outcomes (no treatment re-entry, death, or opioid-related hospitalization) within 18 months of taper.[169]

Nonetheless, some patients may want to stop opioid agonist therapy. An ideal time frame for a trial of MAT tapering has not been established. Tapering should always be at the patient's discretion, and all decisions should be based on a thorough dialogue between patient and provider. Goals should be framed functionally, for example maintaining employment, avoiding using illicit opioids or other drugs, continuing with social/emotional support programs, etc.

Misconceptions about OUD Treatment

Stigma and misunderstanding surround the issues of addiction in general and OUD in particular.[147] These include counterproductive ideologies that portray addiction as a failure of will or a moral weakness, as opposed to understanding OUD as a chronic disease of the brain requiring medical management, which is no different, in principle, from the approach used to manage other chronic diseases such as diabetes or hypothyroidism. Some stigma and misunderstanding may arise from a lack of awareness of how treatment of OUD has evolved in the past 15 years.[170] Table 8 summarizes some common misconceptions about OUD treatment.

Addressing stigma

High levels of stigma persist among some medical professionals and recovery communities toward people with OUD and medications used to treat OUD.[147] A 2016 national opinion survey (n=264) found that 54% of respondents thought people addicted to opioid pain relievers were to blame for their addiction, 46% felt such people are irresponsible, and 45% said they would be unwilling to work closely with such people.[162]

A 2014 survey of 1,010 primary care physicians found similar, or even higher, levels of stigma related to people with OUD.[167] Interviews with patients using methadone for OUD confirm that this group experiences high rates of stigma and discrimination related to their medication use in interactions with the public and with health care professionals,[174] which erodes their psychological well-being and may inhibit them from entering treatment.[147]

Table 8. Misconceptions vs. realities of OUD treatment[171]

Misconceptions	Reality
Buprenorphine treatment is more dangerous than other chronic disease management.	Buprenorphine treatment is less risky than many other routine treatments, such as titrating insulin or starting anticoagulation and easier to administer. It is also safer than prescribing many opioids (e.g., oxycodone, morphine).
Using methadone or buprenorphine is simply a "replacement" addiction.	Addiction is compulsive use of a drug despite harm. When taken as prescribed, methadone and buprenorphine improve function, autonomy, and quality of life and patients using these drugs do not meet the definition of addiction.
Detoxification for OUD is effective.	No data show that detoxification programs are effective for OUD, and, in fact, such interventions may increase the risk of overdose death by eliminating tolerance.
Prescribing buprenorphine is time consuming and burdensome.	Buprenorphine treatment can be readily managed in a primary care setting, and in-office induction or intensive behavioral therapy are not required for effective treatment.

Health care professionals can combat stigma by examining their own attitudes and beliefs and by consciously and consistently using neutral, "person-first," and non-stigmatizing language such as "being in recovery" instead of "being clean" or "person with opioid use disorder" rather than "addict," "user," or "drug abuser."[175]

Pregnancy and OUD

Pregnant women with untreated OUD have up to six times more maternal complications than women without OUD, including low birth weight and fetal distress, while neonatal complications among babies born to mothers with OUD range from neonatal abstinence syndrome and neurobehavioral problems to a 74-fold increase in sudden infant death syndrome.[177]

Both methadone and buprenorphine are recommended for treating OUD in pregnancy to improve outcomes for both mother and newborn.[141] The efficacy and safety of methadone treatment for OUD in pregnant women was established in the 1980s, showing that maternal and neonatal outcomes in women on methadone treatment during pregnancy are similar to women and infants not exposed to methadone.[177] More recent research suggests that buprenorphine treatment has similar, or superior, benefits in this population.[178]

The safety of extended-release naltrexone has not yet been established for pregnant women, and naltrexone is currently not recommended for the treatment of OUD in pregnant women.[147]

Despite this solid evidence base, most pregnant women with OUD do not receive any treatment with medications.[179] Among women who do receive treatment during pregnancy, many fall out of treatment during the post-partum period due to gaps in insurance coverage and other systemic barriers. An integrated approach with close collaboration between OUD treatment providers and prenatal providers has been described as the "gold standard" for care, and further research is needed to investigate interventions that could help to increase treatment retention.[147]

Treating acute pain in patients on MAT

Some physicians may not prescribe effective opioid analgesia for patients with OUD on MAT due to concerns about respiratory depression, overdose, or drug diversion. As a result, this population is at particular risk of under-treatment for acute pain.

Physicians may also mistakenly assume that acute pain is adequately controlled with the long-term opioid agonist (i.e., methadone) or partial agonist (i.e., buprenorphine). Although potent analgesics, methadone and buprenorphine have an analgesic duration of action (four to eight hours) that is substantially shorter than their suppression of opioid withdrawal (24 to 48 hours).[180]

Non-opioid analgesics (e.g., acetaminophen and NSAIDs) are first-line options for treating acute pain in this population. For moderate-to-severe pain not adequately controlled with non-opioids, however, judicious use of opioid analgesics should be considered. Patients on MAT generally have a high cross-tolerance for analgesia, leading to shorter durations of analgesic effects. Higher opioid doses administered at shorter intervals may thus be necessary. Concomitant opioids can be given for pain to a patient prescribed buprenorphine, but typically hydromorphone or fentanyl may be the most effective due to competitive binding at the opioid receptor.

Since extended-release naltrexone will block the effects of any opioid analgesics, acute pain in such patients (e.g., that associated with dental work, surgery, or traumatic injury) should be treated with regional analgesia, conscious sedation, non-opioid analgesics, or general anesthesia.[30]

Palliative Care

Palliative care is specialized medical care for people with serious illness focused on relieving symptoms and improving quality of life for both the patient and the family. Palliative care involves three key areas: symptom management (e.g., pain, nausea, constipation), supporting patients and their loved ones as they cope with illness and death, and communication and education about the illness through advance care planning (ACP).[181] The field of palliative care emerged from a hospice tradition but in the past decade a more nuanced model of care has been introduced, which integrates palliative care with disease-modifying care across the duration of an illness and includes consideration of those affected by the death of the individual.

Pain control is a central focus of palliative care, but the goal of pain management is not simply the elimination of all pain, it is the control of pain sufficient for a given patient to achieve his or her highest quality of life in the moment.[182] In the palliative care setting, clinicians may need to manage acute pain (e.g., post-surgical or post-treatment pain) or chronic pain or both types of pain simultaneously.

Clinicians can avail themselves of a wide range of pharmacologic and non-pharmacologic approaches for pain management, which should be employed using the following general principles:

- Identify and treat the source of the pain, if possible, although pain treatment can begin before the source of the pain is determined
- Select the simplest approach first. This generally means using non-pharmacologic approaches as much as possible and/or trying medications with the least severe potential side effects, and at the lowest effective doses
- Establish a function-based management plan if treatment is expected to be long-term

A range of non-pharmacological treatments may help patients manage chronic pain, which can be used alone or in combination with pharmacological treatments:

- Physical therapy
- Yoga
- Acupuncture
- Massage
- Transcutaneous electrical nerve stimulation
- Cognitive behavioral therapy
- Mindfulness meditation
- Weight loss

Medications used to treat chronic pain in palliative settings include:

- acetaminophen
- non-steroidal anti-inflammatory drugs (NSAIDs)
- antidepressants
- anticonvulsants
- topical lidocaine or capsaicin
- cannabinoid-based therapies
- opioids

Opioids are classified by the Drug Enforcement Agency according to their presumed abuse and addiction potential, although the evidence base for making these differentiations continues to evolve. Tramadol, for example, is now known to have as much potential for abuse as opioids in more restrictive classes.[171]

Managing end-of-life pain

Although pain relief is often considered—and may sometimes be—an end unto itself, pain management and control of symptoms at the end of life may be more appropriately viewed as means of achieving the more primary goal of improving or maintaining a patient's overall quality of life. For some patients, mental alertness sufficient to allow maximal interactions with loved ones may be more important than physical comfort. Optimal pain management, in such cases, may mean lower doses of an analgesic and the experience, by the patient, of higher levels of pain.

The end of life is often characterized by a reduced level of consciousness or complete lack of consciousness. This can make assessments of pain very challenging. If a patient is not alert enough to communicate, nonverbal signs or cues must be used to determine if the patient is experiencing pain and to what degree an analgesic approach is effective. Signs of discomfort that are accompanied by more rapid breathing or heart rate should be taken more seriously.

Opioids are often valuable for providing effective analgesia at the end of life, and opioid formulations are available in such variety in the U.S. that, typically, a pain regimen can be tailored to each patient. Because there is great between-patient variability in response to particular opioid agents no specific agent is superior to another as first-line therapy. Opioid-related side effects must be considered in advance of treatment and steps must be taken to minimize these effects to the extent possible, since adverse effects contribute significantly to analgesic nonadherence. This is particularly true for constipation and sedation.

A stimulant, such as methylphenidate or dextroamphetamine, might be added to offset sedative effects, typically starting at a dose of 5 to 10 mg once or twice daily. Other adverse effects, including respiratory depression, are greatly feared and may lead to clinician under-prescribing and reluctance by patients to take the medication, despite the rarity of this event in persons with cancer.[183] Despite this fear, studies have revealed no correlation between opioid dose, timing of opioid administration, and time of death.[184]

A wide range of complementary and alternative therapies (CAT) are commonly used in end-of-life care. CAT interventions are aimed at reducing pain, inducing relaxation, and enhancing a sense of control over the pain or the underlying disease. Breathing exercises, relaxation, imagery, hypnosis, and other behavioral therapies are among the modalities shown to be potentially helpful to patients.[185] Psychosocial interventions for end-of-life pain may include cancer pain education, hypnosis and imagery based methods, and coping skills training. Educational programs are one of the most common interventions to address cancer pain barriers, and current studies provide high-quality evidence that pain education is feasible, cost-effective, and practical in end-of-life settings.[186]

Conclusions

Managing pain is particularly challenging in an era when society is grappling with an epidemic of opioid misuse and overdose. This learning activity has reviewed an evidence-based path forward, based on a biopsychosocial model of pain, and an emphasis on holistic assessment, individualized treatment planning, and multi-modal therapeutic approaches.

Physicians and caregivers need to base pain treatment plans on realistic functional goals and the level of pain management needed to reach those goals using a shared decision-making approach. As detailed in this activity, chronic pain syndromes respond differently to available pharmacologic and non-pharmacologic treatments, but, in general, non-drug options (which can be as effective as drug options) should be tried first when possible. When drug options are considered, it is important to maximize non-opioid options before prescribing opioids. For selected patients requiring opioids, the risk of long-term opioid treatment should be minimized through patient education, screening of high-risk patients for OUD, continuous monitoring, use of alternative non-opioid options, and careful tapering when appropriate.

Since much acute pain is self-limiting and remits with healing (typically within a month), helping patients frame expectations about acute pain and pain relief can provide reassurance and reduce fear, worry, and distress. Multimodal approaches should be used to manage acute pain, combining non-drug (e.g. interventional procedures, physical rehabilitation, and psychological support) as well as appropriate drug-based options. Opioid analgesics should be reserved for severe pain that does not respond to all other approaches, and then should be used at the lowest doses, and shortest durations, appropriate for the pain intensity expected with the precipitating event.

This activity has laid out the evidence supporting these conclusions and provides the basis for improved treatment and reduced risk, both for patients and society at large.

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Self-Assessment

Choose the best possible answer for each question and mark your answers on the self-assessment answer sheet at the end of this book. There is a required score of 70% or better to receive a certificate of completion.

11. Nonpharmacologic and self-management treatment options have been found to be effective alone or as part of a comprehensive pain management plan for which types of pain?

A. Nociceptive and neuropathic pain.
B. Acute pain > 48 hours after tissue trauma.
C. Neuropathic and chronic pain.
D. Musculoskeletal and chronic pain.

12. What is the maximum recommended daily dose of acetaminophen for healthy adult patients?

A. 2500 mg.
B. 3000 mg.
C. 3500 mg.
D. 4000 mg.

13. Which non-opioid analgesic has been successfully used to treat such acute pain conditions as sickle cell crises, renal colic, and trauma?

A. Ketamine.
B. Cannabis.
C. Capsaicin.
D. Anticonvulsants.

14. Which of the following topics should be routinely covered as part of patient education about opioid analgesics?

A. Background information about acute vs. chronic pain.
B. Criteria for Opioid Use Disorder.
C. Safe medication disposal.
D. Difference between nociceptive and neuropathic pain.

15. Which of the following is an example of a functional goal?

A. Reduced anxiety about pain.
B. Reduced need for rescue analgesia.
C. Reduced daily dose of opioid analgesic.
D. Resumed sexual relations.

16. Which of the following is a possible reason for prescribing naloxone to a patient who has been prescribed an opioid analgesic?

A. The patient is taking a dose of an opioid > 50 MMED.
B. The patient has recently entered prison.
C. The patient has history of hypertension.
D. The patient has a concurrent prescription for an SSRI antidepressant.

17. According to the Centers for Disease Control and Prevention, what amount of opioid analgesic is appropriate for most painful conditions?

A. 2-day supply.
B. 3-day supply.
C. 5-day supply.
D. 7 day supply.

18. Which of the following medications is a full mu-receptor agonist used to treat Opioid Use Disorder?

A. Methadone.
B. Buprenorphine.
C. Extended-release naltrexone.
D. Naloxone.

19. Which of the following medications can be self-administered by patients with a medication obtained from a regular pharmacy?

A. Methadone.
B. Buprenorphine.
C. Extended-release naltrexone.
D. Naloxone.

20. For which of the following must clinicians obtain a special waiver from the DEA prior to being able to prescribe the medication?

A. Methadone.
B. Buprenorphine.
C. Extended-release naltrexone.
D. Naloxone.

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Guidance on Professional Boundaries and Sexual Misconduct

	A	B	C	D
1	○	○	○	○
2	○	○	○	○
3	○	○	○	○
4	○	○	○	○
5	○	○	○	○
6	○	○	○	○
7	○	○	○	○
8	○	○	○	○
9	○	○	○	○
10	○	○	○	○

Effective Management of Acute and Chronic Pain with Opioid Analgesics

	A	B	C	D
11	○	○	○	○
12	○	○	○	○
13	○	○	○	○
14	○	○	○	○
15	○	○	○	○
16	○	○	○	○
17	○	○	○	○
18	○	○	○	○
19	○	○	○	○
20	○	○	○	○

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LEARNER RECORDS: EVALUATION

You must complete the program evaluation and applicable activity evaluation(s) in order to earn *AMA PRA Category 1 Credits*™, MOC points, or participation in MIPS. For each of the objectives determine if the activity increased your:

A Competence B Performance C Outcome D No Change

COURSE 1 - GUIDANCE ON PROFESSIONAL BOUNDARIES AND SEXUAL MISCONDUCT:

		A	B	C	D
1.	Utilize best practices during intimate examinations, including use of chaperones and respectful communication with patient.	○	○	○	○
2.	Recognize and report suspected sexual misconduct or assault	○	○	○	○

3. Please identify a specific change, if any, you will make in your practice related to professional boundaries and sexual misconduct.

_____

_____

4. What do you see as a barrier to making these changes?

_____

_____

COURSE 2 - EFFECTIVE MANAGEMENT OF ACUTE & CHRONIC PAIN WITH OPIOID ANALGESICS:

		A	B	C	D
5.	Assess non-pharmacological, non-opioid, and opioid analgesic therapies in comprehensive pain plans for patients with acute or chronic pain.	○	○	○	○
6.	Identify and manage patients with opioid use disorder and recognize when to incorporate emergency opioid antagonists into prescribing practice.	○	○	○	○

7. Please identify a specific change, if any, you will make in your practice related to safe prescribing of opioid analgesics.

_____

_____

8. What do you see as a barrier to making these changes?

_____

_____

OVERALL PROGRAM:

		Yes	No	If no, please explain:
9.	The program was balanced, objective & scientifically valid	○	○	_____
10.	Do you feel the program was scientifically sound & free of commercial bias or influence?	○	○	_____

11. How can this program be improved? _____

_____

12. Based on your educational needs, please provide us with suggestions for future program topics & formats. _____

_____

13. For which activities would you like to use your participation as a clinical practice improvement activity (CPIA) for MIPS?

○ Course 1 ○ Course 2 ○ None

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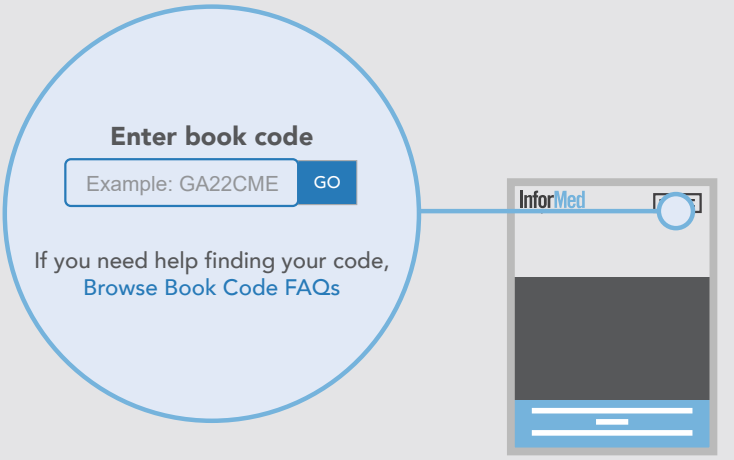

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