Oregon Pain Management Commission

April 28, 2016

Clackamas Community College
Wilsonville Training Center, Room 112
29373 SW Town Center Loop E,
Wilsonville, Oregon 97070

Pain Management Commission Meeting
Agenda

April 28, 2016

Clackamas Community College, Wilsonville Training Center, Room 112
29353 SW Town Center Loop E, Wilsonville, OR 97070
Tele-Conference: 1-888-251-2909 Participant Code: 344574

Item/ Topic	Introduced by	Action	Time Allotted
Welcome & Introductions		None	5 minutes
Minutes & Agenda • Approval of 2/25/16 minutes • Approval and/or additions to agenda.		Review, Discussion & Vote	10 minutes
Pain Coordinator Report • Member Recruitment • Updates o Web site o Back and Spine Lines o Upcoming Events • Coordinator Activity • National Pain Strategy • PCAC Joint Statement	Denise	Information Sharing & Discussion	30 minutes
OHP Prioritized List: Implementation of the Back & Spine Lines • Opioid Guideline Note Revisions			15 minutes
Legislative Concept • Professionals added • Change in required frequency • Update/ progress from legislative coordinator		Information Sharing & Discussion	30 minutes
Pain Education: State-wide case review – ECO type	Nora Stern	Information Sharing & Discussion	30 minutes
OPMC On-line Module • Presentation of format for CEUs	Denise	Review, discussion &	30 minutes
Open Forum		Information Sharing & Discussion	30 minutes

Back Conditions Implementation Delay
Technical summary posted 8/10/2015; updated 3/29/16

Implementation delay:

This document enumerates changes to the Prioritized List of Health Services, which had been planned for implementation January 1, 2016. However, the implementation of these changes has been delayed by OHA leadership in order to address implementation concerns.

This document also contains additional revisions made at the January 14, 2016 HERC meeting. These changes include removal of epidural steroid injections from line 407 as well as reverting criteria for Guideline Note D4, Advanced Imaging for Back Pain, to their previous state as well as correction of some ICD-10-CM diagnosis codes and removal of ICD-9 diagnosis codes.

Finally, a few codes are shown in italics (the addition of psychotherapy codes to line 366 and the removal of ICD-10-CM diagnosis code M99.1 from line 407). These proposed changes will be considered for adoption by HERC at their May 19, 2016 meeting.

Information on the delay has been posted on the CCO Quality and Health Outcomes Committee web site.

For a narrative description of the changes and details about the process leading to the changes see the Back Policy Changes Fact Sheet.

Note: Line numbers refer to the January 1, 2016 Prioritized List.

Changes to Line Items

Line: 351
CONDITION: CONDITIONS OF THE BACK AND SPINE WITH URGENT SURGICAL INDICATIONS
TREATMENT: SURGICAL THERAPY

ICD-10: G83.4 (cauda equina), M43.1 (spondylolisthesis), M47.0 (anterior spinal artery compression syndroms, vertebral artery compression syndromes), M47.1 (spondylosis with myelopathy), M48.0 (spinal stenosis), M50.0 (cervical disc disorders with myelopathy), M51.0 (intervertebral disc disorder with myelopathy), M53.2X (spinal instabilities), Q76.2 (spondylolisthesis)
CPT: 20660-20665, 20930-20938, 21720, 21725, 22206-22226, 22532-22865, 29000-29046, 29710-29720, 62287 (percutaneous disc compression),63001-63091, 63170, 63180-63200, 63270-63273, 63295-63610, 63650, 63655, 63685, 96150-4 (health and behavior assessment codes), 97001-97004, 97022, 97110-97124, 97140, 97150, 97530, 97535 (PT/OT evaluation and treatment), 98966-98968, 98969, 99051, 99060, 99070, 99078, 99201-99215 (outpatient medical visits), 99217-99239 (hospital), 99281-99285 (ER), 99291-99292 (critical care), 99304-99337 (SNF care), 99401-99404 (risk factor reduction intervention), 99408, 99409, 99411, 99412, 99441-99444, 99446-99449 (telephone/Internet consults), 99468-99480, 99605-99607
HPCPS: G0157-G0160 (PT/OT), G0396-G0397 (SBRT), G0406-G0408 (inpatient consultation), G0425-G0427 (telehealth), G0463, G0466, G0467 (FQHC), S2350-S2351 (discectomy with decompression of spinal cord)

Line: 366
CONDITION: SCOLIOSIS

TREATMENT: MEDICAL AND SURGICAL THERAPY

ICD-10: M41 (scoliosis), M96.5 (postradiation scoliosis), Q67.5 (congenital deformity of spine), Q76.3 (congenital scoliosis due to congenital bony formation), Z47.82 (encounter for other orthopedic aftercare following scoliosis surgery)

CPT: 20660-20665, 20930-20938, 21720, 21725, 22206-22226, 22532-22855, 29000-29046, 29710-29720, 62287, 63001-63091, 63170, 63180-63200, , 63295-63610, 63650, 63655, 63685, *90785, 90832-90838,90853 (mental health visits, counseling),* 96150-96154 (health and behavior assessment codes), 97001-97004, 97022, 97110-97124, 97140, 97150, 97530, 97535 (PT/OT evaluation and treatment), 97760, 97762, 97810-97814 (acupuncture), 98925-98929 (osteopathic manipulation), 98940-98942 (chiropractic manipulation), 98966-98968, 98969, 99051, 99060, 99070, 99078, 99201-99215 (outpatient medical visits), 99217-99239 (hospital), 99281-99285 (ER), 99291-99292 (critical care), 99304-99337 (SNF care), 99401-99404 (risk factor reduction intervention), 99408, 99409, 99411, 99412, 99441-99444, 99446-99449 (telephone/Internet consults), 99468-99480, 99605-99607

HPCPS: G0157-G0160 (PT/OT), G0396-G0397 (SBRT), G0406-G0408 (inpatient consultation), G0425-G0427 (telehealth), G0463, G0466, G0467 (FQHC)

Line: 407

CONDITION: CONDITIONS OF THE BACK AND SPINE

TREATMENT: RISK ASSESSMENT, PHYSICAL MODALITIES, COGNITIVE BEHAVIORAL THERAPY, MEDICAL THERAPY

ICD-10: F45.42 (Pain disorder with related psychological factors), G83.4, G95.0, M24.08, M25.78, M40, M42.0, M43, M45, M46.1, M46.4-M46.9, M47, M48.00-M48.38, M48.8-M48.9, M49.8, M50, M51, M53.2-M3.9, M54, M62.830, M96.1-M96.4, M99.0, ~~*M99.12-M99.13*~~, M99.20-M99.79, M99.81-M99.84, Q06.0-Q06.3, Q06.8-Q06.9, Q76.0-Q76.2, Q76.4, S13.0XXA-S13.0XXD, S13.4XXA-S13.4XXD, S13.8XXA-S13.8XXD, S13.9XXA-S13.9XXD, S16.1XXA-S16.1XXD, S23.0XXA-S23.0XXD, S23.100A-S23.100D, S23.101A-S23.101D, S23.110A-S23.110D, S23.111A-S23.111D, S23.120A-S23.120D, S23.121A-S23.121D, S23.122A-S23.122D, S23.123A-S23.123D, S23.130A-S23.130D, S23.131A-S23.131D, S23.132A-S23.132D, S23.133A-S23.133D, S23.140A-S23.140D, S23.141A-S23.141D, S23.142A-S23.142D, S23.143A-S23.143D, S23.150A-S23.150D, S23.151A-S23.151D, S23.152A-S23.152D, S23.153A-S23.153D, S23.160A-S23.160D, S23.161A-S23.161D, S23.162A-S23.162D, S23.163A-S23.163D, S23.170A-S23.170D, S23.171A-S23.171D, S23.3XXA-S23.3XXD, S23.8XXA-S23.8XXD, S23.9XXA-S23.9XXD, S33.0XXA-S33.0XXD, S33.100A-S33.100D, S33.101A-S33.101D, S33.110A-S33.110D, S33.111A-S33.111D, S33.120A-S33.120D, S33.121A-S33.121D, S33.130A-S33.130D, S33.131A-S33.131D, S33.140A-S33.140D, S33.141A-S33.141D, S33.5XXA-S33.5XXD, S33.8XXA-S33.8XXD, S33.9XXA-S33.9XXD, S34.3XXA-S34.3XXD, S39.092A-S39.092D, S39.82XA-S39.82XD, S39.92XA-S39.92XD

CPT: 62311, 90785,90832-90838,90853 (mental health visits, counseling), 96150-96154 (health and behavior assessment codes), 97001-97004, 97022, 97110-97124, 97140, 97150, 97530, 97535 (PT/OT evaluation and treatment), 97810-97814 (acupuncture), 98925-98929, 98940-98942 (OMT/CMT), 98966-98968, 98969, 99051, 99060, 99070, 99078, 99201-99215 (outpatient medical visits), 99281-99285 (ER), 99304-99337 (SNF care), 99340-99359, 99366-99404 (risk factor reduction intervention), 99408, 99409, 99411, 99412, 99441-99449, 99487-99490, 99605-99607

HPCPS: G0157-G0160 (PT/OT), G0396-G0397 (SBRT), G0425-G0427 (telehealth), G0463, G0466, G0467, G0469, G0470 (FQHC)

Line: 532

CONDITION: CONDITIONS OF THE BACK AND SPINE WITHOUT URGENT SURGICAL INDICATIONS

TREATMENT: SURGICAL THERAPY

ICD-10: G95.0, M40, M42, M43.0- M43.2, M43.8, M45, M46.4-M46.99,M47.2-M47.9, M48.0 (spinal stenosis), M48.1, M48.3, M48.8-M48.9, M49, M50.1-M50.9, M51.1-M51.9, M53.8-M53.9, M54.1, M96.1-M96.4, M99.2-M99.7, M99.81-M91.85, Q06.0-Q06.3,Q06.8-Q06.9, Q76.0-Q76.2, Q76.4, S13.0XXA-S13.0XXD,S23.0XXA-S23.0XXD,S23.100A-S23.100D,S23.110A-S23.110D,S23.120A-S23.120D,S23.122A-S23.122D,S23.130A-S23.130D,S23.132A-S23.132D,S23.140A-S23.140D,S23.142A-S23.142D,S23.150A-S23.150D,S23.152A-S23.152D,S23.160A-S23.160D,S23.162A-S23.162D,S23.170A-S23.170D,S33.0XXA-S33.0XXD,S33.100A-S33.100D,S33.110A-S33.110D,S33.120A-S33.120D,S33.130A-S33.130D,S33.140A-S33.140D,S34.3XXA-S34.3XXD

CPT: 20660-20665, 20930-20938, 21720, 21725, 22206-22226, 22532-22865, 27035, 29000-29046, 29710-29720, 62287, 63001-63091, 63170, 63180-63200, 63270-63273, 63295-63610, 63650, 63655, 63685, 96150-96154 (health and behavior assessment codes), 97001-97004, 97022, 97110-97124, 97140, 97150, 97530, 97535 (PT/OT evaluation and treatment), 98966-98968, 98969, 99051, 99060, 99070, 99078, 99201-99215 (outpatient medical visits), 99217-99239 (hospital), 99281-99285 (ER), 99291-99292 (critical care), 99304-99337 (SNF care), 99401-99404 (risk factor reduction intervention), 99408, 99409, 99411, 99412, 99441-99444, 99446-99449 (telephone/Internet consults), 99468-99480, 99605-99607

HPCPS: G0157-G0160 (PT/OT), G0396-G0397 (SBRT), G0406-G0408 (inpatient consultation), G0425-G0427 (telehealth), G0463, G0466, G0467 (FQHC), S2350-S2351 (discectomy with decompression of spinal cord)

New Guideline Notes

GUIDELINE NOTE 56, NON-INTERVENTIONAL TREATMENTS FOR CONDITIONS OF THE BACK AND SPINE

Lines 366, 407

Patients seeking care for back pain should be assessed for potentially serious conditions ("red flag") symptoms requiring immediate diagnostic testing, as defined in Diagnostic Guideline D4. Patients lacking red flag symptoms should be assessed using a validated assessment tool (e.g. STarT Back Assessment Tool) in order to determine their risk level for poor functional prognosis based on psychosocial indicators.

For patients who are determined to be low risk on the assessment tool, the following services are included on this line:

- Office evaluation and education,
- Up to 4 total visits, consisting of the following treatments: OMT/CMT, acupuncture, and PT/OT. Massage, if available, may be considered.
- First line medications: NSAIDs, acetaminophen, and/or muscle relaxers. Opioids may be considered as a second line treatment, subject to the limitations on coverage of opioids in Guideline Note 60 OPIOID PRESCRIBING FOR CONDITIONS OF THE BACK AND SPINE. See evidence table.

For patients who are determined to be high risk on the validated assessment tool, the following treatments are included on this line:

- Office evaluation, consultation and education
- Cognitive behavioral therapy. The necessity for cognitive behavioral therapy should be re-evaluated every 90 days and coverage will only be continued if there is documented evidence of decreasing depression or anxiety symptomatology, improved ability to work/function, increased self-efficacy, or other clinically significant, objective improvement.
- Medications, subject to the limitations on coverage of opioids in Guideline Note 60 OPIOID PRESCRIBING FOR CONDITIONS OF THE BACK AND SPINE. See evidence table.
- The following evidence-based therapies, when available, are encouraged: yoga, massage, supervised exercise therapy, intensive interdisciplinary rehabilitation
- A total of 30 visits per year of any combination of the following evidence-based therapies when available and medically appropriate. These therapies are only covered if provided by a provider licensed to provide the therapy and when there is documentation of measurable clinically significant progress toward the therapy plan of care goals and objectives using evidence based objective tools (e.g. Oswestry, Neck Disability Index, SF-MPQ, and MSPQ).
    1) Rehabilitative therapy (physical and/or occupational therapy), if provided according to GUIDELINE NOTE 6, REHABILITATIVE SERVICES. Rehabilitation services provided under this guideline also count towards visit totals in Guideline Note 6
    2) Chiropractic or osteopathic manipulation
    3) Acupuncture

Back Conditions Implementation Delay
Technical summary posted 8/10/2015; updated 3/29/16

These coverage recommendations are derived from the State of Oregon Evidence-based Guideline on the Evaluation and Management of Low Back Pain available here: http://www.oregon.gov/oha/herc/Pages/blog-low-back-non-pharmacologic-intervention.aspx

Evidence Table of Effective Treatments for the Management of Low Back Pain

Intervention Category*	Intervention	Acute < 4 Weeks	Subacute & Chronic > 4 Weeks
Self-care	Advice to remain active	●	●
	Books, handout	●	●
	Application of superficial heat	●	
Nonpharmacologic therapy	Spinal manipulation	●	●
	Exercise therapy		●
	Massage		●
	Acupuncture		●
	Yoga		●
	Cognitive-behavioral therapy		●
	Progressive relaxation		●
Pharmacologic therapy (Carefully consider risks/harms)	Acetaminophen	●	●
	NSAIDs	●(▲)	●(▲)
	Skeletal muscle relaxants	●	
	Antidepressants (TCA)		●
	*Benzodiazepines***	●(▲)	●(▲)
	*Tramadol, opioids***	●(▲)	●(▲)
Interdisciplinary therapy	Intensive interdisciplinary rehabilitation		●

- ● Interventions supported by grade B evidence (at least fair-quality evidence of moderate benefit, or small benefit but no significant harms, costs, or burdens). No intervention was supported by grade "A" evidence (good-quality evidence of substantial benefit).

▲ *Carries greater risk of harms than other agents in table.*

NSAIDs = nonsteroidal anti-inflammatory drugs; TCA = tricyclic antidepressants.

*These are general categories only. Individual care plans need to be developed on a case by case basis. For more detailed information please see: http://www.annals.org/content/147/7/478.full.pdf

**Associated with significant risks related to potential for abuse, addiction and tolerance. This evidence evaluates effectiveness of these agents with relatively short term use studies. Chronic use of these agents may result in significant harms.

GUIDELINE NOTE 60, OPIOID PRESCRIBING FOR CONDITIONS OF THE BACK AND SPINE

Lines 351, 366, 407, 532

The following restrictions on opioid treatment apply to all diagnoses included on these lines.

For acute injury, acute flare of chronic pain, or after surgery:

1) During the first 6 weeks after the acute injury, flare or surgery, opioid treatment is included on these lines ONLY
    a. When each prescription is limited to 7 days of treatment, AND
    b. For short acting opioids only, AND
    c. When one or more alternative first line pharmacologic therapies such as NSAIDs, acetaminophen, and muscle relaxers have been tried and found not effective or are contraindicated, AND
    d. When prescribed with a plan to keep active (home or prescribed exercise regime) and with consideration of additional therapies such as spinal manipulation, physical therapy, yoga, or acupuncture, AND
    e. There is documented lack of current or prior opioid misuse or abuse.
2) Treatment with opioids after 6 weeks, up to 90 days, requires the following
    a. Documented evidence of improvement of function of at least thirty percent as compared to baseline based on a validated tools.
    b. Must be prescribed in conjunction with therapies such as spinal manipulation, physical therapy, yoga, or acupuncture.
    c. Verification that the patient is not high risk for opioid misuse or abuse. Such verification may involve
        i. Documented verification from the state's prescription monitoring program database that the controlled substance history is consistent with the prescribing record
        ii. Use of a validated screening instrument to verify the absence of a current substance use disorder (excluding nicotine) or a history of prior opioid misuse or abuse
        iii. Administration of a baseline urine drug test to verify the absence of illicit drugs and non-prescribed opioids.
    d. Each prescription must be limited to 7 days of treatment and for short acting opioids only
3) Further opioid treatment after 90 days may be considered ONLY when there is a significant change in status, such as a clinically significant verifiable new injury or surgery. In such cases, use of opioids is limited to a maximum of an additional 7 days. In exceptional cases, use up to 28 days may be covered, subject to the criteria in #2 above.

For patients with chronic pain from diagnoses on these lines currently treated with long term opioid therapy, opioids must be tapered off, with a taper of about 10% per week recommended. By the end of 2016, all patients currently treated with long term opioid therapy must be tapered off of long term opioids for diagnoses on these lines. If a patient has developed dependence and/or addiction related to their opioids, treatment is available on line 4 SUBSTANCE USE DISORDER.

GUIDELINE NOTE 37, SURGICAL INTERVENTIONS FOR CONDITIONS OF THE BACK AND SPINE OTHER THAN SCOLIOSIS

Lines 351, 532

Surgical consultation/consideration for surgical intervention are included on these lines only for patients with neurological complications, defined as showing objective evidence of one or more of the following:

A) Markedly abnormal reflexes
B) Segmental muscle weakness
C) Segmental sensory loss
D) EMG or NCV evidence of nerve root impingement
E) Cauda equina syndrome
F) Neurogenic bowel or bladder
G) Long tract abnormalities

Spondylolithesis (ICD-10 M43.1, Q76.2) is included on line 351 only when it results in spinal stenosis with signs and symptoms of neurogenic claudication. Otherwise, these diagnoses are included on line 532.

Surgical correction of spinal stenosis (ICD-10 M48.0) is only included on line 351 for patients with:

1) MRI evidence of moderate to severe central or foraminal spinal stenosis AND
2) A history of neurogenic claudication, or objective evidence of neurologic impairment consistent with MRI findings.

Only decompression surgery is covered for spinal stenosis; spinal fusion procedures are not covered for this diagnosis. Otherwise, these diagnoses are included on line 532.

The following interventions are not covered due to lack of evidence of effectiveness for back pain, with or without radiculopathy:

- facet joint corticosteroid injection
- prolotherapy
- intradiscal corticosteroid injection
- local injections
- botulinum toxin injection
- intradiscal electrothermal therapy
- therapeutic medial branch block
- radiofrequency denervation
- sacroiliac joint steroid injection
- coblation nucleoplasty
- percutaneous intradiscal radiofrequency thermocoagulation
- radiofrequency denervation
- epidural steroid injections

GUIDELINE NOTE 41 SCOLIOSIS

Line 366

Non-surgical treatments of scoliosis (ICD-10 M41) are included on line 366 when

1) the scoliosis is considered clinically significant, defined as curvature greater than or equal to 25 degrees or
2) there is curvature with a documented rapid progression.

Surgical treatments of scoliosis are included on line 366

1) only for children and adolescents (age 20 and younger) with
2) a spinal curvature of greater than 45 degrees

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Changes to Existing Guideline Notes

DIAGNOSTIC GUIDELINE D4, ADVANCED IMAGING FOR LOW BACK PAIN

In patients with non-specific low back pain and no "red flag" conditions [see Table D4], imaging is not a covered service; otherwise work up is covered as shown in the table. Repeat imaging is only covered when there is a substantial clinical change (e.g. progressive neurological deficit) or new clinical indication for imaging (i.e. development of a new red flag condition). Repeat imaging for acute exacerbations of chronic radiculopathic pain is not covered.

Electromyelography (CPT 96002-4) is not covered for non-specific low back pain.

Table D4
Low Back Pain - Potentially Serious Conditions ("Red Flags") and Recommendations for Initial Diagnostic Work-up

Possible cause	Key features on history or physical examination	Imaging[1]	Additional studies[1]
Cancer	• History of cancer with new onset of LBP	MRI	ESR
	• Unexplained weight loss • Failure to improve after 1 month • Age >50 years • Symptoms such as painless neurologic deficit, night pain or pain increased in supine position	Lumbosacral plain radiography	
	• Multiple risk factors for cancer present	Plain radiography or MRI	
Spinal column infection	• Fever • Intravenous drug use • Recent infection	MRI	ESR and/or CRP
Cauda equina syndrome	• Urinary retention • Motor deficits at multiple levels • Fecal incontinence • Saddle anesthesia	MRI	None
Vertebral compression fracture	• History of osteoporosis • Use of corticosteroids • Older age	Lumbosacral plain radiography	None
Ankylosing spondylitis	• Morning stiffness • Improvement with exercise • Alternating buttock pain • Awakening due to back pain during the second part of the night • Younger age	Anterior-posterior pelvis plain radiography	ESR and/or CRP, HLA-B27
Nerve compression/ disorders (e.g. herniated disc with radiculopathy)	• Back pain with leg pain in an L4, L5, or S1 nerve root distribution present < 1 month • Positive straight-leg-raise test or crossed straight-leg-raise test	None	None
	• Radiculopathic signs[2] present >1 month • Severe/progressive neurologic deficits (such as foot drop), progressive motor weakness	MRI[3]	Consider EMG/NCV
Spinal stenosis	• Radiating leg pain • Older age • Pain usually relieved with sitting (Pseudoclaudication a weak predictor)	None	None
	• Spinal stenosis symptoms present >1 month	MRI[4]	Consider EMG/NCV

[1] Level of evidence for diagnostic evaluation is variable
[2] Radiculopathic signs are defined for the purposes of this guideline defined as the presence of any of the following:
A. Markedly abnormal reflexes
B. Segmental muscle weakness
C. Segmental sensory loss
D. EMG or NCV evidence of nerve root impingement
E. Cauda equina syndrome,
F. Neurogenic bowel or bladder
G. Long tract abnormalities
[3] Only if patient is a potential candidate for surgery

Red Flag: Red flags are findings from the history and physical examination that may be associated with a higher risk of serious disorders. CRP = C-reactive protein; EMG = electromyography; ESR = erythrocyte sedimentation rate; MRI = magnetic resonance imaging; NCV = nerve conduction velocity.

Extracted and modified from Chou R, Qaseem A, Snow V, et al: Diagnosis and Treatment of Low Back Pain: A Joint Clinical Practice Guideline from the American College of Physicians and the American Pain Society. Ann Intern Med. 2007; 147:478-491.

The development of this guideline note was informed by a HERC coverage guidance. See http://www.oregon.gov/oha/herc/Pages/blog-adv-imaging-low-back.aspx

GUIDELINE NOTE 92, ACUPUNCTURE

Lines 1,207,414,468,546,407

Inclusion of acupuncture (CPT 97810-97814) on the Prioritized List has the following limitations:

Line 1 PREGNANCY
Acupuncture pairs on Line 1 for the following conditions and codes.

Hyperemesis gravidarum
ICD-10-CM code: O21.0, O21.1
Acupuncture pairs with hyperemesis gravidarum when a diagnosis is made by the maternity care provider and referred for acupuncture treatment for up to 12 sessions of acupressure/acupuncture.

Breech presentation
ICD-10-CM code: O32.1
Acupuncture (and moxibustion) is paired with breech presentation when a referral with a diagnosis of breech presentation is made by the maternity care provider, the patient is between 33 and 38 weeks gestation, for up to 6 visits.

Back and pelvic pain of pregnancy
ICD-10-CM code: O99.89
Acupuncture is paired with back and pelvic pain of pregnancy when referred by maternity care provider/primary care provider for up to 12 sessions.

Line 207 DEPRESSION AND OTHER MOOD DISORDERS, MILD OR MODERATE
Acupuncture is paired with the treatment of post-stroke depression only. Treatments may be billed to a maximum of 30 minutes face-to-face time and limited to 12 total sessions, with documentation of meaningful improvement.

Line 407-CONDITIONS OF THE BACK AND SPINE
Acupuncture is included this line with visit limitations as in Guideline Note 56.

Line 414 MIGRAINE HEADACHES
Acupuncture pairs on Line 414 for migraine (ICD-10-CM G43.0, G43.1, G43.5, G43.7, G43.8, G43.9), when referred, for up to 12 sessions.

Line 468 OSTEOARTHRITIS AND ALLIED DISORDERS
Acupuncture pairs on Line 468 for osteoarthritis of the knee only (ICD-10-CM M17), for up to 12 sessions.

Line 546 TENSION HEADACHES
Acupuncture is included on Line 546 for treatment of tension headaches G44.2x, for up to 12 sessions.

Deleted Guideline Notes

~~**GUIDELINE NOTE 37, DISORDERS OF SPINE WITH NEUROLOGIC IMPAIRMENT**~~

~~*Lines 374,545*~~

~~Diagnoses are included on Line 374 when objective evidence of neurologic impairment or radiculopathy is present, as defined as:~~

~~A) Markedly abnormal reflexes~~
~~B) Segmental muscle weakness~~
~~C) Segmental sensory loss~~
~~D) EMG or NCV evidence of nerve root impingement~~
~~E) Cauda equina syndrome,~~
~~F) Neurogenic bowel or bladder~~
~~G) Long tract abnormalities~~

~~Otherwise, disorders of spine not meeting these criteria (e.g. pain alone) fall on Line 545.~~

~~**GUIDELINE NOTE 41, SPINAL DEFORMITY, CLINICALLY SIGNIFICANT**~~

~~*Line 412*~~

~~Clinically significant scoliosis is defined as curvature greater than or equal to 25 degrees or curvature with a documented rapid progression. Clinically significant spinal stenosis is defined as having MRI evidence of moderate to severe central or foraminal spinal stenosis in addition to a history of neurogenic claudication, or objective evidence of neurologic impairment consistent with MRI findings (see Guideline Note 37).~~

GUIDELINE NOTE 56, ACUTE AND CHRONIC DISORDERS OF SPINE WITHOUT NEUROLOGIC IMPAIRMENT

Line 545

Disorders of spine without neurologic impairment include any conditions represented on this line for which objective evidence of one or more of the criteria stated in Guideline Note 37 is not available

GUIDELINE NOTE 60, SPINAL DEFORMITY, NOT CLINICALLY SIGNIFICANT

Line 588

Scoliosis not defined as clinically significant included curvature less than 25 degrees that does not have a documented progression of at least 10 degrees

GUIDELINE NOTE 94, EVALUATION AND MANAGEMENT OF LOW BACK PAIN

Lines 374,545

Procedures for the evaluation and management of low back pain are included on these lines when provided subject to the State of Oregon Evidence-based Clinical Guidelines dated 10/2011 located at:
http://www.oregon.gov/oha/OHPR/pages/herc/evidence-based-guidelines.aspx.

GUIDELINE NOTE 105, EPIDURAL STEROID INJECTIONS FOR LOW BACK PAIN
Line 407

Epidural lumbar steroid injections (CPT 62311, 64483, 64484) are included on this line for patients with persistent radiculopathy due to herniated lumbar disc, where radiculopathy is defined as lower extremity pain in a nerve root distribution, with or without weakness or sensory deficits, showing objective evidence of one or more of the following:

A) Markedly abnormal reflexes
B) Segmental muscle weakness
C) Segmental sensory loss
D) EMG or NCV evidence of nerve root impingement

One epidural steroid injection is included on these lines this line; a second epidural steroid injection may be provided after 3-6 months only if objective evidence of 3 months of sustained pain relief was provided by the first injection. It is recommended that shared decision-making regarding epidural steroid injection include a specific discussion about inconsistent evidence showing moderate short-term benefits, and lack of long-term benefits. Epidural lumbar steroid injections are not included on these lines this line for spinal stenosis or for patients with low back pain without radiculopathy. Epidural steroid injections are only included on this line when the patient is also participating in an active therapy such as physical therapy or home exercise therapy.

Guideline Note 60, OPIOID PRESCRIBING FOR CONDITIONS OF THE BACK AND SPINE

Lines 351, 366, 407, 532

The following restrictions on opioid treatment apply to all diagnoses included on these lines.

For acute injury, acute flare of chronic pain, or after surgery:

1) During the first 6 weeks after the acute injury, flare or surgery, opioid treatment is included on these lines ONLY
   a) When each prescription is limited to 7 days of treatment, AND
   b) For short acting opioids only, AND
   c) When one or more alternative first line pharmacologic therapies such as NSAIDs, acetaminophen, and muscle relaxers have been tried and found not effective or are contraindicated, AND
   d) When prescribed with a plan to keep active (home or prescribed exercise regime) and with consideration of additional therapies such as spinal manipulation, physical therapy, yoga, or acupuncture, AND
   e) There is documented lack of current or prior opioid misuse or abuse.
2) Treatment with opioids after 6 weeks, up to 90 days, requires the following
   a) Documented evidence of improvement of function of at least thirty percent as compared to baseline based on a validated tools.
   b) Must be prescribed in conjunction with therapies such as spinal manipulation, physical therapy, yoga, or acupuncture.
   c) Verification that the patient is not high risk for opioid misuse or abuse. Such verification may involve
      i) Documented verification from the state's prescription monitoring program database that the controlled substance history is consistent with the prescribing record
      ii) Use of a validated screening instrument to verify the absence of a current substance use disorder (excluding nicotine) or a history of prior opioid misuse or abuse
      iii) Administration of a baseline urine drug test to verify the absence of illicit drugs and non-prescribed opioids.
   d) Each prescription must be limited to 7 days of treatment and for short acting opioids only

3) Further opioid treatment after 90 days may be considered ONLY when there is a significant change in status, such as a clinically significant verifiable new injury or surgery. In such cases, use of opioids is limited to a maximum of an additional 7 days. In exceptional cases, use up to 28 days may be covered, subject to the criteria in #2 above.

For patients with chronic pain from diagnoses on these lines currently treated with long term opioid therapy, opioids must be tapered off, with a taper of about 10% per week recommended. By the end of 2016, all patients currently treated with long term opioid therapy must be tapered off of long term opioids for diagnoses on these lines. If a patient has developed dependence and/or addiction related to their opioids, treatment is available on line 4 SUBSTANCE USE DISORDER.

2017 Agency Legislative Concept Request

Agency #/Concept #:

Placeholder? ☐ Yes ☐ No

(TEXT BOXES EXPAND AS NEEDED)

Date:

Agency: Oregon Health Authority

Division/Program: Health Policy and Analytics/Oregon Pain Management Commission

Concept Subject or Title: Oregon Pain Education Provider Requirement

Concept Contact Person: Denise Taray

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1. Problem (Completely describe the problem you propose to solve.)

Pain management should be a collaborative and integrated approach rather than provided by a single specialist whose preferred approaches might not work best for all patients they provide care for. Any health care professional that is responsible for assessing the needs of a patient with acute and/or chronic pain should have the information and confidence to treat safely and effectively.

- Oregon's Prescription Drug Monitoring Program reported in 2012 that twenty percent of Oregonians (about 760,000) live with chronic pain.
- Substance Abuse and Mental Health Services Administration's National Survey on Drug Use and Health reports Oregon was first in the nation for non-medical use of prescription pain relievers in 2010-2011.
- Drug Enforcement Agency changed hydrocodone-combination drugs to a Schedule II drug under the Controlled Substances Act effective October 2014.
- 2015 Legislative session approved SB 152 that added the ability to prescribe the Schedule II hydrocodone-combination drugs to optometrist's scope of practice.
- Health Evidence Review Commission approved revisions to the OHP Prioritized List that will result in coverage of evidence-based, effective therapies to treat painful back conditions based on a bio-psycho-social model of care.

2. Proposed Solution (Completely describe what the concept does to fix the problem. Do not include proposed statute changes here.)

Statewide efforts are being made to mitigate the risks and associated harms of opioid prescription medications. Concurrently, alternative care models are being recommended for the treatment and management of pain.

This measure would identify additional health care professionals required to complete the one-hour web-based pain education module developed by the Oregon Pain Management Commission (OPMC). Information is essential to successful pain management and expanding the pain education requirement will improve the care of patients with pain in Oregon.

The OPMC recommends that all provider types that have the potential to interact with and/or treat patients in pain should have knowledge about pain and pain management. Existing statute (ORS 413.590) identifies ten health care professionals required to complete continuing education related to pain and pain management prior to renewal of licensure. Based on current models of care that support a bio-psycho-social and integrative approach for the treatment of pain, the commission recommends the following additional health care professional be required to complete the one-hour web-based training offered by the Commission:

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- Optometrists
- Social workers
- Professional counselors and marriage & family therapists
- Massage therapists
- Pharmacy technicians
- Expanded practice dental hygienist

The one-hour web-based pain educational module is already available online and maintained by the OPMC. The one-hour educational module does not have any associated fees to the health care professional to complete.

Oversight for the completion of the continuing education would be through each of the professional licensing boards similar to current mechanisms; most already have a professional continuing education requirement.

3. Proposed Changes to Statute (Please attach your best attempt at proposing changes to statute to accomplish your goal; however, Legislative Counsel may draft alternate language.)

See attached.

4. Has this been introduced in a prior session? ☒ No ☐ Yes Years(s) Bill#(s)

Does this amend current law or programs? ☐ No ☒ Yes (Specify) **ORS 413.590: Pain management education required of certain licensed health care professionals; duties of Oregon Medical Board; rules.** Amended as above in Proposed Changes to Statute.

Is this related to a legal decision? ☒ No ☐ Yes (Case cite, AGO No. date, etc. – *attach copies*)

5. Equity Analysis (Describe any known racial or ethnic inequities associated with the problem and how the proposed statutory changes are culturally and linguistically appropriate *and* specifically address the inequities.)

No racial or ethnic inequities known at this time.

6. Stakeholders and/or Other Affected Agencies who are Aware of Your Concept

Agency: **Contact Person:** **Phone:**

7. Known Support or Opposition (Please elaborate.)

Oregon Pain Management Commission

8. Increases fees or assessments? ☒ No ☐ Yes

Concept has other fiscal, revenue or position (FTE) impacts? ☒ No ☐ Yes Provide Fiscal Form

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9. For PLACEHOLDERS – ALL additional substantive information is due to DAS no later than June 24. This concept is a PLACEHOLDER. ☒ No ☐ Yes (approximate delivery date)

10. Additional Information or Attachments (Briefly describe attachments - draft language, opinions, etc.)

11. Approved for Drafting:

_____	_____	_____	_____
Governor's Office	**Date**	**Department of Administrative Services**	**Date**

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Oregon Pain Education Provider Requirement LC
Proposed Changes to Statute

413.590 Pain management education required of certain licensed health care professionals; duties of Oregon Medical Board; rules. (1) A physician assistant licensed under ORS chapter 677, a nurse licensed under ORS chapter 678, a psychologist licensed under ORS 675.010 to 675.150, a chiropractic physician licensed under ORS chapter 684, a naturopath licensed under ORS chapter 685, an acupuncturist licensed under ORS 677.759, a pharmacist **and pharmacy technician** licensed under ORS chapter 689, a dentist licensed under ORS chapter 679, **a dental hygienist licensed under ORS 680, an optometrist licensed under ORS 676, a social worker licensed under ORS 676.530, a professional counselor and therapists licensed under ORS 675.705-675.835, a massage therapist licensed under ORS 687,** an occupational therapist licensed under ORS 675.210 to 675.340 and a physical therapist licensed under ORS 688.010 to 688.201 must complete ~~*one*~~ **the** pain management education program described under ORS 413.572 **once every four (4) years**.

(2) The Oregon Medical Board, in consultation with the Pain Management Commission, shall identify by rule physicians licensed under ORS chapter 677 who, on an ongoing basis, treat patients in chronic or terminal pain and who must complete ~~*one*~~ **the** pain management education program established under ORS 413.572. The board may identify by rule circumstances under which the requirement under this section may be waived. [Formerly 409.560]

Centers for Disease Control and Prevention
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CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

CONTENTS

Disclosure of Relationship

The Core Expert Group (CEG) members disclose that they have no financial conflicts of interest. Experts disclose the following activities related to the content of this guideline: Pam Archer discloses authorship of the Oklahoma Emergency Department and Urgent Care Clinic Opioid Prescribing Guidelines and the Opioid Prescribing Guidelines for Oklahoma Health Care Providers in the Office Based Setting; Bonnie Burman discloses authorship of the Ohio Guidelines for Prescribing Opioids for the Treatment of Chronic, Non-Terminal Pain; Jane Ballantyne discloses that she has served as a paid consultant to Cohen Milstein Sellers & Toll, PLLC, and has special advisory committee responsibilities on the Food and Drug Administration (FDA) Risk Evaluation and Mitigation Strategies committee; Phillip Coffin discloses that in 2012 he provided expert testimony to the California State Assembly regarding a bill to expand naloxone access and reports that he is the principal investigator on a research study of methamphetamine dependence that receives donated injectable naltrexone from Alkermes, Inc.; Gary Franklin discloses authorship of the AMDG Interagency Guideline on Prescribing Opioids for Pain; Erin Krebs discloses that she represented the American College of Physicians at a 2014 Food and Drug Administration meeting on Abuse Deterrent Opioid Formulations; Lewis Nelson discloses his ad-hoc membership on the FDA Drug Safety and Risk Management Advisory Committee; Trupti Patel discloses authorship of the Arizona Opioid Prescribing Guidelines; Robert "Chuck" Rich discloses that he was an author of the 2013 American Academy of Family Physicians position paper on opioids and pain management; Joanna Starrels discloses that she received honoraria from the Betty Ford Institute; Thomas Tape discloses that he was an author of the 2013 American College of Physicians policy position paper on prescription drug abuse. CDC provided 100% of the funding for the supplemental evidence review tasks and meeting support. No foundation or industry support was accepted.

The Opioid Guideline Workgroup (OGW) members disclose that they have no financial conflicts of interest. Experts disclose the following activities related to the content of this guideline: Anne Burns discloses that she participated in a congressional briefing sponsored by Reps. Carter and DeSaulnier on the pharmacist's role of furnishing Naloxone and that she participates on the National Advisory Board for the Prescription Drug Abuse and Heroin Summit. Chinazo Cunningham discloses that her husband is employed by Quest Diagnostics and Dr. Cunningham was recused from any discussion related to urine drug testing. Traci Green discloses that she was previously employed by Inflexxion, a small business that conducts Small Business Innovation Research on behavioral interventions for behavioral health and chronic pain and created several psychometric tools for conducting risk assessment for prescription opioid abuse potential. Dr. Green also discloses that while at the hospital where she is employed, she provided consultation to Purdue Pharma Ltd to design overdose prevention brochures for persons who use diverted prescription opioids non-medically with an emphasis on persons who inject prescription drugs, and not for patients using opioid therapy for pain. Dr. Green was recused from any discussion related to risk assessment tools and patient education materials. Erin Krebs discloses that she served on the CDC Opioid Prescribing Guideline CEG. Christina Porucznik discloses that she served on the CDC Opioid Prescribing Guideline CEG. Greg Terman discloses that he serves as the President of the American Pain Society. Mark Wallace discloses that he served on a Kempharma advisory panel for an abuse-deterrent hydrocodone formulation to treat acute postoperative pain and Dr. Wallace was recused form any discussion related to abuse-deterrent drugs.

The NCIPC Board of Scientific Counselors (BSC) members disclose that they have no financial conflicts of interest. Two BSC members, Traci Green and Christina Porucznik, served on the Opioid Guideline Workgroup. Traci Green discloses that she was previously employed by Inflexxion, a small business that conducts Small Business Innovation Research on behavioral interventions for behavioral health and chronic pain and created several psychometric tools for conducting risk assessment for prescription opioid abuse potential. Dr. Green also discloses that while at the hospital where she is employed, she provided consultation to Purdue Pharma Ltd to design overdose prevention brochures for persons who use diverted prescription opioids non-medically with an emphasis on persons who inject prescription drugs, and not for patients using opioid therapy for pain. Dr. Green was recused from any discussion related to risk assessment tools and patient education materials. Christina Porucznik discloses that she served on the CDC Opioid Prescribing Guideline CEG.

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CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016

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Summary

This guideline provides recommendations for primary care clinicians who are prescribing opioids for chronic pain outside of active cancer treatment, palliative care, and end-of-life care. The guideline addresses 1) when to initiate or continue opioids for chronic pain; 2) opioid selection, dosage, duration, follow-up, and discontinuation; and 3) assessing risk and addressing harms of opioid use. CDC developed the guideline using the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) framework, and recommendations are made on the basis of a systematic review of the scientific evidence while considering benefits and harms, values and preferences, and resource allocation. CDC obtained input from experts, stakeholders, the public, peer reviewers, and a federally chartered advisory committee. It is important that patients receive appropriate pain treatment with careful consideration of the benefits and risks of treatment options. This guideline is intended to improve communication between clinicians and patients about the risks and benefits of opioid therapy for chronic pain, improve the safety and effectiveness of pain treatment, and reduce the risks associated with long-term opioid therapy, including opioid use disorder, overdose, and death. CDC has provided a checklist for prescribing opioids for chronic pain (http://stacks.cdc.gov/view/cdc/38025) as well as a website (http://www.cdc.gov/drugoverdose/prescribingresources.html) with additional tools to guide clinicians in implementing the recommendations.

Introduction

Background

Opioids are commonly prescribed for pain. An estimated 20% of patients presenting to physician offices with noncancer pain symptoms or pain-related diagnoses (including acute and chronic pain) receive an opioid prescription (*1*). In 2012, health care providers wrote 259 million prescriptions for opioid pain medication, enough for every adult in the United States to have a bottle of pills (*2*). Opioid prescriptions per capita increased 7.3% from 2007 to 2012, with opioid prescribing rates increasing more for family practice, general practice, and internal medicine compared with other specialties (*3*). Rates of opioid prescribing vary greatly across states in ways that cannot be explained by the underlying health status of the population, highlighting the lack of consensus among clinicians on how to use opioid pain medication (*2*).

Prevention, assessment, and treatment of chronic pain are challenges for health providers and systems. Pain might go unrecognized, and patients, particularly members of racial and ethnic minority groups, women, the elderly, persons with cognitive impairment, and those with cancer and at the end of life, can be at risk for inadequate pain treatment (*4*). Patients can experience persistent pain that is not well controlled. There are clinical, psychological, and social consequences associated with chronic pain including limitations in complex activities, lost work productivity, reduced quality of life, and stigma, emphasizing the importance of appropriate and compassionate patient care (*4*). Patients should receive appropriate pain treatment based on a careful consideration of the benefits and risks of treatment options.

Chronic pain has been variably defined but is defined within this guideline as pain that typically lasts >3 months or past the time of normal tissue healing (*5*). Chronic pain can be the result of an underlying medical disease or condition, injury, medical treatment, inflammation, or an unknown cause (*4*). Estimates of the prevalence of chronic pain vary, but it is clear that the number of persons experiencing chronic pain in the United States is substantial. The 1999–2002 National Health and Nutrition Examination Survey estimated that 14.6% of adults have current widespread or localized pain lasting at least 3 months (*6*). Based on a survey conducted during 2001–2003 (*7*), the overall prevalence of common, predominantly musculoskeletal pain conditions (e.g., arthritis, rheumatism, chronic back or neck problems, and frequent severe headaches) was estimated at 43% among adults in the

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United States, although minimum duration of symptoms was not specified. Most recently, analysis of data from the 2012 National Health Interview Study showed that 11.2% of adults report having daily pain (*8*). Clinicians should consider the full range of therapeutic options for the treatment of chronic pain. However, it is hard to estimate the number of persons who could potentially benefit from opioid pain medication long term. Evidence supports short-term efficacy of opioids for reducing pain and improving function in noncancer nociceptive and neuropathic pain in randomized clinical trials lasting primarily ≤12 weeks (*9*,*10*), and patients receiving opioid therapy for chronic pain report some pain relief when surveyed (*11*–*13*). However, few studies have been conducted to rigorously assess the long-term benefits of opioids for chronic pain (pain lasting >3 months) with outcomes examined at least 1 year later (*14*). On the basis of data available from health systems, researchers estimate that 9.6–11.5 million adults, or approximately 3%–4% of the adult U.S. population, were prescribed long-term opioid therapy in 2005 (*15*).

Opioid pain medication use presents serious risks, including overdose and opioid use disorder. From 1999 to 2014, more than 165,000 persons died from overdose related to opioid pain medication in the United States (*16*). In the past decade, while the death rates for the top leading causes of death such as heart disease and cancer have decreased substantially, the death rate associated with opioid pain medication has increased markedly (*17*). Sales of opioid pain medication have increased in parallel with opioid-related overdose deaths (*18*). The Drug Abuse Warning Network estimated that >420,000 emergency department visits were related to the misuse or abuse of narcotic pain relievers in 2011, the most recent year for which data are available (*19*). Although clinical criteria have varied over time, opioid use disorder is a problematic pattern of opioid use leading to clinically significant impairment or distress. This disorder is manifested by specific criteria such as unsuccessful efforts to cut down or control use and use resulting in social problems and a failure to fulfill major role obligations at work, school, or home (*20*). This diagnosis has also been referred to as "abuse or dependence" and "addiction" in the literature, and is different from tolerance (diminished response to a drug with repeated use) and physical dependence (adaptation to a drug that produces symptoms of withdrawal when the drug is stopped), both of which can exist without a diagnosed disorder. In 2013, on the basis of DSM-IV diagnosis criteria, an estimated 1.9 million persons abused or were dependent on prescription opioid pain medication (*21*). Having a history of a prescription for an opioid pain medication increases the risk for overdose and opioid use disorder (*22*–*24*), highlighting the value of guidance on safer prescribing practices for clinicians. For example, a recent study of patients aged 15–64 years receiving opioids for chronic noncancer pain and followed for up to 13 years revealed that one in 550 patients died from opioid-related overdose at a median of 2.6 years from their first opioid prescription, and one in 32 patients who escalated to opioid dosages >200 morphine milligram equivalents (MME) died from opioid-related overdose (*25*).

This guideline provides recommendations for the prescribing of opioid pain medication by primary care clinicians for chronic pain (i.e., pain conditions that typically last >3 months or past the time of normal tissue healing) in outpatient settings outside of active cancer treatment, palliative care, and end-of-life care. Although the guideline does not focus broadly on pain management, appropriate use of long-term opioid therapy must be considered within the context of all pain management strategies (including nonopioid pain medications and nonpharmacologic treatments). CDC's recommendations are made on the basis of a systematic review of the best available evidence, along with input from experts, and further review and deliberation by a federally chartered advisory committee. The guideline is intended to ensure that clinicians and patients consider safer and more effective treatment, improve patient outcomes such as reduced pain and improved function, and reduce the number of persons who develop opioid use disorder, overdose, or experience other adverse events related to these drugs. Clinical decision making should be based on a relationship between the clinician and patient, and an understanding of the patient's clinical situation, functioning, and life context. The recommendations in the guideline are voluntary, rather than prescriptive standards. They are based on emerging evidence, including observational studies or randomized clinical trials with notable limitations. Clinicians should consider the circumstances and unique needs of each patient when providing care.

Rationale

Primary care clinicians report having concerns about opioid pain medication misuse, find managing patients with chronic pain stressful, express concern about patient addiction, and report insufficient training in prescribing opioids (*26*). Across specialties, physicians believe that opioid pain medication can be effective in controlling pain, that addiction is a common consequence of prolonged use, and that long-term opioid therapy often is overprescribed for patients with chronic noncancer pain (*27*). These attitudes and beliefs, combined with increasing trends in opioid-related overdose, underscore the need for better clinician guidance on opioid prescribing. Clinical practice guidelines focused on prescribing can improve clinician knowledge, change prescribing practices (*28*), and ultimately benefit patient health.

Professional organizations, states, and federal agencies (e.g., the American Pain Society/American Academy of Pain Medicine, 2009; the Washington Agency Medical Directors Group, 2015; and the U.S. Department of Veterans Affairs/Department of Defense, 2010) have developed guidelines for opioid prescribing (*29–31*). Existing guidelines share some common elements, including dosing thresholds, cautious titration, and risk mitigation strategies such as using risk assessment tools, treatment agreements, and urine drug testing. However, there is considerable variability in the specific recommendations (e.g., range of dosing thresholds of 90 MME/day to 200 MME/day), audience (e.g., primary care clinicians versus specialists), use of evidence (e.g., systematic review, grading of evidence and recommendations, and role of expert opinion), and rigor of methods for addressing conflict of interest (*32*). Most guidelines, especially those that are not based on evidence from scientific studies published in 2010 or later, also do not reflect the most recent scientific evidence about risks related to opioid dosage.

This CDC guideline offers clarity on recommendations based on the most recent scientific evidence, informed by expert opinion and stakeholder and public input. Scientific research has identified high-risk prescribing practices that have contributed to the overdose epidemic (e.g., high-dose prescribing, overlapping opioid and benzodiazepine prescriptions, and extended-release/long-acting [ER/LA] opioids for acute pain) (*24*,*33*,*34*). Using guidelines to address problematic prescribing has the potential to optimize care and improve patient safety based on evidence-based practice (*28*), as well as reverse the cycle of opioid pain medication misuse that contributes to the opioid overdose epidemic.

Scope and Audience

This guideline is intended for primary care clinicians (e.g., family physicians and internists) who are treating patients with chronic pain (i.e., pain lasting >3 months or past the time of normal tissue healing) in outpatient settings. Prescriptions by primary care clinicians account for nearly half of all dispensed opioid prescriptions, and the growth in prescribing rates among these clinicians has been above average (*3*). Primary care clinicians include physicians as well as nurse practitioners and physician assistants. Although the focus is on primary care clinicians, because clinicians work within team-based care, the recommendations refer to and promote integrated pain management and collaborative working relationships with other providers (e.g., behavioral health providers, pharmacists, and pain management specialists). Although the transition from use of opioid therapy for acute pain to use for chronic pain is hard to predict and identify, the guideline is intended to inform clinicians who are considering prescribing opioid pain medication for painful conditions that can or have become chronic.

This guideline is intended to apply to patients aged ≥18 years with chronic pain outside of palliative and end-of-life care. For this guideline, palliative care is defined in a manner consistent with that of the Institute of Medicine as care that provides relief from pain and other symptoms, supports quality of life, and is focused on patients with serious advanced illness. Palliative care can begin early in the course of treatment for any serious illness that requires excellent management of pain or other distressing symptoms (*35*). End-of-life care is defined as care for persons with a terminal illness or at high risk for dying in the near future in hospice care, hospitals, long-term care settings, or at home. Patients within the scope of this guideline include cancer survivors with chronic pain who have completed cancer treatment, are in clinical remission, and are under cancer surveillance only. The guideline is not intended for patients undergoing active cancer treatment, palliative care, or end-of-life care because of the unique therapeutic goals, ethical considerations, opportunities for medical supervision, and balance of risks and benefits with opioid therapy in such care.

The recommendations address the use of opioid pain medication in certain special populations (e.g., older adults and pregnant women) and in populations with conditions posing special risks (e.g., a history of substance use disorder). The recommendations do not address the use of opioid pain medication in children or adolescents aged <18 years. The available evidence concerning the benefits and harms of long-term opioid therapy in children and adolescents is limited, and few opioid medications provide information on the label regarding safety and effectiveness in pediatric patients. However, observational research shows significant increases in opioid prescriptions for pediatric populations from 2001 to 2010 (*36*), and a large proportion of adolescents are commonly prescribed opioid pain medications for conditions such as headache and sports injuries (e.g., in one study, 50% of adolescents presenting with headache received a prescription for an opioid pain medication [*37*,*38*]). Adolescents who misuse opioid pain medication often misuse medications from their own previous prescriptions (*39*), with an estimated 20% of adolescents with currently prescribed opioid medications reporting using them intentionally to get high or increase the effects of alcohol or other drugs (*40*). Use of prescribed opioid pain medication before high school graduation is associated with a 33% increase in the risk of later opioid misuse (*41*). Misuse of opioid pain medications in adolescence strongly predicts later onset of heroin use (*42*). Thus, risk of opioid medication use in pediatric populations is of great concern. Additional clinical trial and observational research is needed,

and encouraged, to inform development of future guidelines for this critical population.

The recommendations are not intended to provide guidance on use of opioids as part of medication-assisted treatment for opioid use disorder. Some of the recommendations might be relevant for acute care settings or other specialists, such as emergency physicians or dentists, but use in these settings or by other specialists is not the focus of this guideline. Readers are referred to other sources for prescribing recommendations within acute care settings and in dental practice, such as the American College of Emergency Physicians' guideline for prescribing of opioids in the emergency department (*43*); the American Society of Anesthesiologists' guideline for acute pain management in the perioperative setting (*44*); the Washington Agency Medical Directors' Group Interagency Guideline on Prescribing Opioids for Pain, Part II: Prescribing Opioids in the Acute and Subacute Phase (*30*); and the Pennsylvania Guidelines on the Use of Opioids in Dental Practice (*45*). In addition, given the challenges of managing the painful complications of sickle cell disease, readers are referred to the NIH National Heart, Lung, and Blood Institute's Evidence Based Management of Sickle Cell Disease Expert Panel Report for management of sickle cell disease (*46*).

Guideline Development Methods

Guideline Development Using the Grading of Recommendations Assessment, Development, and Evaluation Method

CDC developed this guideline using the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) method (http://www.gradeworkinggroup.org). This method specifies the systematic review of scientific evidence and offers a transparent approach to grading quality of evidence and strength of recommendations. The method has been adapted by the CDC Advisory Committee on Immunization Practices (ACIP) (*47*). CDC has applied the ACIP translation of the GRADE framework in this guideline. Within the ACIP GRADE framework, the body of evidence is categorized in a hierarchy. This hierarchy reflects degree of confidence in the effect of a clinical action on health outcomes. The categories include type 1 evidence (randomized clinical trials or overwhelming evidence from observational studies), type 2 evidence (randomized clinical trials with important limitations, or exceptionally strong evidence from observational studies), type 3 evidence (observational studies or randomized clinical trials with notable limitations), and type 4 evidence (clinical experience and observations, observational studies with important limitations, or randomized clinical trials with several major limitations). Type of evidence is categorized by study design as well as limitations in study design or implementation, imprecision of estimates, variability in findings, indirectness of evidence, publication bias, magnitude of treatment effects, dose-response gradient, and a constellation of plausible biases that could change observations of effects. Type 1 evidence indicates that one can be very confident that the true effect lies close to that of the estimate of the effect; type 2 evidence means that the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different; type 3 evidence means that confidence in the effect estimate is limited and the true effect might be substantially different from the estimate of the effect; and type 4 evidence indicates that one has very little confidence in the effect estimate, and the true effect is likely to be substantially different from the estimate of the effect (*47*,*48*). When no studies are present, evidence is considered to be insufficient. The ACIP GRADE framework places recommendations in two categories, Category A and Category B. Four major factors determine the category of the recommendation: the quality of evidence, the balance between desirable and undesirable effects, values and preferences, and resource allocation (cost). Category A recommendations apply to all persons in a specified group and indicate that most patients should receive the recommended course of action. Category B recommendations indicate that there should be individual decision making; different choices will be appropriate for different patients, so clinicians must help patients arrive at a decision consistent with patient values and preferences, and specific clinical situations (*47*). According to the GRADE methodology, a particular quality of evidence does not necessarily imply a particular strength of recommendation (*48*–*50*). Category A recommendations can be made based on type 3 or type 4 evidence when the advantages of a clinical action greatly outweigh the disadvantages based on a consideration of benefits and harms, values and preferences, and costs. Category B recommendations are made when the advantages and disadvantages of a clinical action are more balanced. GRADE methodology is discussed extensively elsewhere (*47*,*51*). The U.S. Preventive Services Task Force (USPSTF) follows different methods for developing and categorizing recommendations (http://www.uspreventiveservicestaskforce.org). USPSTF recommendations focus on preventive services and are categorized as A, B, C, D, and I. Under the Affordable Care Act, all "nongrandfathered" health plans (that is, those health plans not in existence prior to March 23, 2010 or those with significant changes to their coverage) and expanded Medicaid plans are required to cover

preventive services recommended by USPSTF with a category A or B rating with no cost sharing. The coverage requirements went into effect September 23, 2010. Similar requirements are in place for vaccinations recommended by ACIP, but do not exist for other recommendations made by CDC, including recommendations within this guideline.

A previously published systematic review sponsored by the Agency for Healthcare Research and Quality (AHRQ) on the effectiveness and risks of long-term opioid treatment of chronic pain (*14*,*52*) initially served to directly inform the recommendation statements. This systematic clinical evidence review addressed the effectiveness of long-term opioid therapy for outcomes related to pain, function, and quality of life; the comparative effectiveness of different methods for initiating and titrating opioids; the harms and adverse events associated with opioids; and the accuracy of risk-prediction instruments and effectiveness of risk mitigation strategies on outcomes related to overdose, addiction, abuse, or misuse. For the current guideline development, CDC conducted additional literature searches to update the evidence review to include more recently available publications and to answer an additional clinical question about the effect of opioid therapy for acute pain on long-term use. More details about the literature search strategies and GRADE methods applied are provided in the Clinical Evidence Review (http://stacks.cdc.gov/view/cdc/38026). CDC developed GRADE evidence tables to illustrate the quality of the evidence for each clinical question.

As identified in the AHRQ-sponsored clinical evidence review, the overall evidence base for the effectiveness and risks of long-term opioid therapy is low in quality per the GRADE criteria. Thus, contextual evidence is needed to provide information about the benefits and harms of nonpharmacologic and nonopioid pharmacologic therapy and the epidemiology of opioid pain medication overdose and inform the recommendations. Further, as elucidated by the GRADE Working Group, supplemental information on clinician and patient values and preferences and resource allocation can inform judgments of benefits and harms and be helpful for translating the evidence into recommendations. CDC conducted a contextual evidence review to supplement the clinical evidence review based on systematic searches of the literature. The review focused on the following four areas: effectiveness of nonpharmacologic and nonopioid pharmacologic treatments; benefits and harms related to opioid therapy (including additional studies not included in the clinical evidence review such as studies that evaluated outcomes at any duration or used observational study designs related to specific opioid pain medications, high-dose opioid therapy, co-prescription of opioids with other controlled substances, duration of opioid use, special populations, risk stratification/mitigation approaches, and effectiveness of treatments for addressing potential harms of opioid therapy); clinician and patient values and preferences; and resource allocation. CDC constructed narrative summaries of this contextual evidence and used the information to support the clinical recommendations. More details on methods for the contextual evidence review are provided in the Contextual Evidence Review (http://stacks.cdc.gov/view/cdc/38027).

On the basis of a review of the clinical and contextual evidence (review methods are described in more detail in subsequent sections of this report), CDC drafted recommendation statements focused on determining when to initiate or continue opioids for chronic pain; opioid selection, dosage, duration, follow-up, and discontinuation; and assessing risk and addressing harms of opioid use. To help assure the draft guideline's integrity and credibility, CDC then began a multistep review process to obtain input from experts, stakeholders, and the public to help refine the recommendations.

Solicitation of Expert Opinion

CDC sought the input of experts to assist in reviewing the evidence and providing perspective on how CDC used the evidence to develop the draft recommendations. These experts, referred to as the "Core Expert Group" (CEG) included subject matter experts, representatives of primary care professional societies and state agencies, and an expert in guideline development methodology.* CDC identified subject matter experts with high scientific standing; appropriate academic and clinical training and relevant clinical experience; and proven scientific excellence in opioid prescribing, substance use disorder treatment, and pain management. CDC identified representatives from leading primary care professional organizations to represent the audience for this guideline. Finally, CDC identified state agency officials and representatives based on their experience with state guidelines for opioid prescribing that were developed with multiple agency stakeholders and informed by scientific literature and existing evidence-based guidelines.

Prior to their participation, CDC asked potential experts to reveal possible conflicts of interest such as financial relationships with industry, intellectual preconceptions, or previously stated public positions. Experts could not serve if they had conflicts that might have a direct and predictable effect on the recommendations. CDC excluded experts who had a financial or promotional relationship with a company

* A list of the members appears at the end of this report. The recommendations and all statements included in this guideline are those of CDC and do not necessarily represent the official position of any persons or organizations providing comments on the draft guideline.

that makes a product that might be affected by the guideline. CDC reviewed potential nonfinancial conflicts carefully (e.g., intellectual property, travel, public statements or positions such as congressional testimony) to determine if the activities would have a direct and predictable effect on the recommendations. CDC determined the risk of these types of activities to be minimal for the identified experts. All experts completed a statement certifying that there was no potential or actual conflict of interest. Activities that did not pose a conflict (e.g., participation in Food and Drug Administration [FDA] activities or other guideline efforts) are disclosed.

CDC provided to each expert written summaries of the scientific evidence (both the clinical and contextual evidence reviews conducted for this guideline) and CDC's draft recommendation statements. Experts provided individual ratings for each draft recommendation statement based on the balance of benefits and harms, evidence strength, certainty of values and preferences, cost, recommendation strength, rationale, importance, clarity, and ease of implementation. CDC hosted an in-person meeting of the experts that was held on June 23–24, 2015, in Atlanta, Georgia, to seek their views on the evidence and draft recommendations and to better understand their premeeting ratings. CDC sought the experts' individual opinions at the meeting. Although there was widespread agreement on some of the recommendations, there was disagreement on others. Experts did not vote on the recommendations or seek to come to a consensus. Decisions about recommendations to be included in the guideline, and their rationale, were made by CDC. After revising the guideline, CDC sent written copies of it to each of the experts for review and asked for any additional comments; CDC reviewed these written comments and considered them when making further revisions to the draft guideline. The experts have not reviewed the final version of the guideline.

Federal Partner Engagement

Given the scope of this guideline and the interest of agencies across the federal government in appropriate pain management, opioid prescribing, and related outcomes, CDC invited its National Institute of Occupational Safety and Health and CDC's federal partners to observe the expert meeting, provide written comments on the full draft guideline after the meeting, and review the guideline through an agency clearance process; CDC reviewed comments and incorporated changes. Interagency collaboration will be critical for translating these recommendations into clinical practice. Federal partners included representatives from the Substance Abuse and Mental Health Services Administration, the National Institute on Drug Abuse, FDA, the U.S. Department of Veterans Affairs, the U.S. Department of Defense, the Office of the National Coordinator for Health Information Technology, the Centers for Medicare and Medicaid Services, the Health Resources and Services Administration, AHRQ, and the Office of National Drug Control Policy.

Stakeholder Comment

Given the importance of the guideline for a wide variety of stakeholders, CDC also invited review from a Stakeholder Review Group (SRG) to provide comment so that CDC could consider modifications that would improve the recommendations' specificity, applicability, and ease of implementation. The SRG included representatives from professional organizations that represent specialties that commonly prescribe opioids (e.g., pain medicine, physical medicine and rehabilitation), delivery systems within which opioid prescribing occurs (e.g., hospitals), and representation from community organizations with interests in pain management and opioid prescribing.* Representatives from each of the SRG organizations were provided a copy of the guideline for comment. Each of these representatives provided written comments. Once input was received from the full SRG, CDC reviewed all comments and carefully considered them when revising the draft guideline.

Constituent Engagement

To obtain initial perspectives from constituents on the recommendation statements, including clinicians and prospective patients, CDC convened a constituent engagement webinar and circulated information about the webinar in advance through announcements to partners. CDC hosted the webinar on September 16 and 17, 2015, provided information about the methodology for developing the guideline, and presented the key recommendations. A fact sheet was posted on the CDC Injury Center website (http://www.cdc.gov/injury) summarizing the guideline development process and clinical practice areas addressed in the guideline; instructions were included on how to submit comments via email. CDC received comments during and for 2 days following the first webinar. Over 1,200 constituent comments were received. Comments were reviewed and carefully considered when revising the draft guideline.

Peer Review

Per the final information quality bulletin for peer review (https://www.whitehouse.gov/sites/default/files/omb/memoranda/fy2005/m05-03.pdf), peer review requirements applied to this guideline because it provides influential

scientific information that could have a clear and substantial impact on public- and private-sector decisions. Three experts independently reviewed the guideline to determine the reasonableness and strength of recommendations; the clarity with which scientific uncertainties were clearly identified; and the rationale, importance, clarity, and ease of implementation of the recommendations.* CDC selected peer reviewers based on expertise, diversity of scientific viewpoints, and independence from the guideline development process. CDC assessed and managed potential conflicts of interest using a process similar to the one as described for solicitation of expert opinion. No financial interests were identified in the disclosure and review process, and nonfinancial activities were determined to be of minimal risk; thus, no significant conflict of interest concerns were identified. CDC placed the names of peer reviewers on the CDC and the National Center for Injury Prevention and Control Peer Review Agenda websites that are used to provide information about the peer review of influential documents. CDC reviewed peer review comments and revised the draft guideline accordingly.

Public Comment

To obtain comments from the public on the full guideline, CDC published a notice in the *Federal Register* (80 FR 77351) announcing the availability of the guideline and the supporting clinical and contextual evidence reviews for public comment. The comment period closed January 13, 2016. CDC received more than 4,350 comments from the general public, including patients with chronic pain, clinicians, families who have lost loved ones to overdose, medical associations, professional organizations, academic institutions, state and local governments, and industry. CDC reviewed each of the comments and carefully considered them when revising the draft guideline.

Federal Advisory Committee Review and Recommendation

The National Center for Injury Prevention and Control (NCIPC) Board of Scientific Counselors (BSC) is a federal advisory committee that advises and makes recommendations to the Secretary of the Department of Health and Human Services, the Director of CDC, and the Director of NCIPC.* The BSC makes recommendations regarding policies, strategies, objectives, and priorities, and reviews progress toward injury and violence prevention. CDC sought the BSC's advice on the draft guideline. BSC members are special government employees appointed as CDC advisory committee members; as such, all members completed an OGE Form 450 to disclose relevant interests. BSC members also reported on their disclosures during meetings. Disclosures for the BSC are reported in the guideline.

To assist in guideline review, on December 14, 2015, via Federal Register notice, CDC announced the intent to form an Opioid Guideline Workgroup (OGW) to provide observations on the draft guideline to the BSC. CDC provided the BSC with the draft guideline as well as summaries of comments provided to CDC by stakeholders, constituents, and peer reviewers, and edits made to the draft guideline in response. During an open meeting held on January 7, 2016, the BSC recommended the formation of the OGW. The OGW included a balance of perspectives from audiences directly affected by the guideline, audiences that would be directly involved with implementing the recommendations, and audiences qualified to provide representation. The OGW comprised clinicians, subject matter experts, and a patient representative, with the following perspectives represented: primary care, pain medicine, public health, behavioral health, substance abuse treatment, pharmacy, patients, and research.* Additional sought-after attributes were appropriate academic and clinical training and relevant clinical experience; high scientific standing; and knowledge of the patient, clinician, and caregiver perspectives. In accordance with CDC policy, two BSC committee members also served as OGW members, with one serving as the OGW Chair. The professional credentials and interests of OGW members were carefully reviewed to identify possible conflicts of interest such as financial relationships with industry, intellectual preconceptions, or previously stated public positions. Only OGW members whose interests were determined to be minimal were selected. When an activity was perceived as having the potential to affect a specific aspect of the recommendations, the activity was disclosed, and the OGW member was recused from discussions related to that specific aspect of the recommendations (e.g., urine drug testing and abuse-deterrent formulations). Disclosures for the OGW are reported. CDC and the OGW identified ad-hoc consultants to supplement the workgroup expertise, when needed, in the areas of pediatrics, occupational medicine, obstetrics and gynecology, medical ethics, addiction psychiatry, physical medicine and rehabilitation, guideline development methodology, and the perspective of a family member who lost a loved one to opioid use disorder or overdose.

The BSC charged the OGW with reviewing the quality of the clinical and contextual evidence reviews and reviewing each of the recommendation statements and accompanying rationales. For each recommendation statement, the OGW considered the quality of the evidence, the balance of benefits and risks, the values and preferences of clinicians and patients, the cost feasibility, and the category designation

of the recommendation (A or B). The OGW also reviewed supplementary documents, including input provided by the CEG, SRG, peer reviewers, and the public. OGW members discussed the guideline accordingly during virtual meetings and drafted a summary report of members' observations, including points of agreement and disagreement, and delivered the report to the BSC.

NCIPC announced an open meeting of the NCIPC BSC in the Federal Register on January 11, 2015. The BSC met on January 28, 2016, to discuss the OGW report and deliberate on the draft guideline itself. Members of the public provided comments at this meeting. After discussing the OGW report, deliberating on specific issues about the draft guideline identified at the meeting, and hearing public comment, the BSC voted unanimously: to support the observations made by the OGW; that CDC adopt the guideline recommendations that, according to the workgroup's report, had unanimous or majority support; and that CDC further consider the guideline recommendations for which the group had mixed opinions. CDC carefully considered the OGW observations, public comments, and BSC recommendations, and revised the guideline in response.

Summary of the Clinical Evidence Review

Primary Clinical Questions

CDC conducted a clinical systematic review of the scientific evidence to identify the effectiveness, benefits, and harms of long-term opioid therapy for chronic pain, consistent with the GRADE approach (*47*,*48*). Long-term opioid therapy is defined as use of opioids on most days for >3 months. A previously published AHRQ-funded systematic review on the effectiveness and risks of long-term opioid therapy for chronic pain comprehensively addressed four clinical questions (*14*,*52*). CDC, with the assistance of a methodology expert, searched the literature to identify newly published studies on these four original questions. Because long-term opioid use might be affected by use of opioids for acute pain, CDC subsequently developed a fifth clinical question (last in the series below), and in collaboration with a methodologist conducted a systematic review of the scientific evidence to address it. In brief, five clinical questions were addressed:

- The effectiveness of long-term opioid therapy versus placebo, no opioid therapy, or nonopioid therapy for long term (≥1 year) outcomes related to pain, function, and quality of life, and how effectiveness varies according to the type/cause of pain, patient demographics, and patient comorbidities (Key Question [KQ] 1).
- The risks of opioids versus placebo or no opioids on abuse, addiction, overdose, and other harms, and how harms vary according to the type/cause of pain, patient demographics, patient comorbidities, and dose (KQ2).
- The comparative effectiveness of opioid dosing strategies (different methods for initiating and titrating opioids; immediate-release versus ER/LA opioids; different ER/LA opioids; immediate-release plus ER/LA opioids versus ER/LA opioids alone; scheduled, continuous versus as-needed dosing; dose escalation versus dose maintenance; opioid rotation versus maintenance; different strategies for treating acute exacerbations of chronic pain; decreasing opioid doses or tapering off versus continuation; and different tapering protocols and strategies) (KQ3).
- The accuracy of instruments for predicting risk for opioid overdose, addiction, abuse, or misuse; the effectiveness of risk mitigation strategies (use of risk prediction instruments); effectiveness of risk mitigation strategies including opioid management plans, patient education, urine drug testing, prescription drug monitoring program (PDMP) data, monitoring instruments, monitoring intervals, pill counts, and abuse-deterrent formulations for reducing risk for opioid overdose, addiction, abuse, or misuse; and the comparative effectiveness of treatment strategies for managing patients with addiction (KQ4).
- The effects of prescribing opioid therapy versus not prescribing opioid therapy for acute pain on long-term use (KQ5).

The review was focused on the effectiveness of long-term opioid therapy on long-term (>1 year) outcomes related to pain, function, and quality of life to ensure that findings are relevant to patients with chronic pain and long-term opioid prescribing. The effectiveness of short-term opioid therapy has already been established (*10*). However, opioids have unique effects such as tolerance and physical dependence that might influence assessments of benefit over time. These effects raise questions about whether findings on short-term effectiveness of opioid therapy can be extrapolated to estimate benefits of long-term therapy for chronic pain. Thus, it is important to consider studies that provide data on long-term benefit. For certain opioid-related harms (overdose, fractures, falls, motor vehicle crashes), observational studies were included with outcomes measured at shorter intervals because such outcomes can occur early during opioid therapy, and such harms are not captured well in short-term clinical trials. A detailed listing of the key questions is provided in the Clinical Evidence Review (http://stacks.cdc.gov/view/cdc/38026).

Clinical Evidence Systematic Review Methods

Complete methods and data for the 2014 AHRQ report, upon which this updated systematic review is based, have been published previously (*14*,*52*). Study authors developed the protocol using a standardized process (*53*) with input from experts and the public and registered the protocol in the PROSPERO database (*54*). For the 2014 AHRQ report, a research librarian searched MEDLINE, the Cochrane Central Register of Controlled Trials, the Cochrane Database of Systematic Reviews, PsycINFO, and CINAHL for English-language articles published January 2008 through August 2014, using search terms for opioid therapy, specific opioids, chronic pain, and comparative study designs. Also included were relevant studies from an earlier review (*10*) in which searches were conducted without a date restriction, reference lists were reviewed, and ClinicalTrials.gov was searched. CDC updated the AHRQ literature search using the same search strategies as in the original review including studies published before April, 2015. Seven additional studies met inclusion criteria and were added to the review. CDC used the GRADE approach outlined in the ACIP Handbook for Developing Evidence-Based Recommendations (*47*) to rate the quality of evidence for the full body of evidence (evidence from the 2014 AHRQ review plus the update) for each clinical question. Evidence was categorized into the following types: type 1 (randomized clinical trials or overwhelming evidence from observational studies), type 2 (randomized clinical trials with important limitations, or exceptionally strong evidence from observational studies), type 3 (observational studies, or randomized clinical trials with notable limitations), or type 4 (clinical experience and observations, observational studies with important limitations, or randomized clinical trials with several major limitations). When no studies were present, evidence was considered to be insufficient. Per GRADE methods, type of evidence was categorized by study design as well as a function of limitations in study design or implementation, imprecision of estimates, variability in findings, indirectness of evidence, publication bias, magnitude of treatment effects, dose-response gradient, and constellation of plausible biases that could change effects. Results were synthesized qualitatively, highlighting new evidence identified during the update process. Meta-analysis was not attempted due to the small numbers of studies, variability in study designs and clinical heterogeneity, and methodological shortcomings of the studies. More detailed information about data sources and searches, study selection, data extraction and quality assessment, data synthesis, and update search yield and new evidence for the current review is provided in the Clinical Evidence Review (http://stacks.cdc.gov/view/cdc/38026).

Summary of Findings for Clinical Questions

The main findings of this updated review are consistent with the findings of the 2014 AHRQ report (*14*). In summary, evidence on long-term opioid therapy for chronic pain outside of end-of-life care remains limited, with insufficient evidence to determine long-term benefits versus no opioid therapy, though evidence suggests risk for serious harms that appears to be dose-dependent. These findings supplement findings from a previous review of the effectiveness of opioids for adults with chronic noncancer pain. In this previous review, based on randomized trials predominantly ≤12 weeks in duration, opioids were found to be moderately effective for pain relief, with small benefits for functional outcomes; although estimates vary, based on uncontrolled studies, a high percentage of patients discontinued long-term opioid use because of lack of efficacy and because of adverse events (*10*).

The GRADE evidence summary with type of evidence ratings for the five clinical questions for the current evidence review are outlined (Table 1). This summary is based on studies included in the AHRQ 2014 review (35 studies) plus additional studies identified in the updated search (seven studies). Additional details on findings from the original review are provided in the full 2014 AHRQ report (*14*,*52*). Full details on the clinical evidence review findings supporting this guideline are provided in the Clinical Evidence Review (http://stacks.cdc.gov/view/cdc/38026).

Effectiveness

For KQ1, no study of opioid therapy versus placebo, no opioid therapy, or nonopioid therapy for chronic pain evaluated long-term (≥1 year) outcomes related to pain, function, or quality of life. Most placebo-controlled randomized clinical trials were ≤6 weeks in duration. Thus, the body of evidence for KQ1 is rated as insufficient (0 studies contributing) (*14*).

Harms

For KQ2, the body of evidence is rated as type 3 (12 studies contributing; 11 from the original review plus one new study). One fair-quality cohort study found that long-term opioid therapy is associated with increased risk for an opioid abuse or dependence diagnosis (as defined by ICD-9-CM codes) versus no opioid prescription (*22*). Rates of opioid abuse or dependence diagnosis ranged from 0.7% with lower-dose (≤36 MME) chronic therapy to 6.1% with higher-dose (≥120 MME) chronic therapy, versus 0.004% with no opioids prescribed. Ten fair-quality uncontrolled studies reported estimates of opioid abuse, addiction, and related outcomes (*55*–*65*). In primary care settings, prevalence of opioid dependence

(using DSM-IV criteria) ranged from 3% to 26% (*55*,*56*,*59*). In pain clinic settings, prevalence of addiction ranged from 2% to 14% (*57*,*58*,*60*,*61*,*63–65*).

Factors associated with increased risk for misuse included history of substance use disorder, younger age, major depression, and use of psychotropic medications (*55*,*62*). Two studies reported on the association between opioid use and risk for overdose (*66*,*67*). One large fair-quality retrospective cohort study found that recent opioid use was associated with increased risk for any overdose events and serious overdose events versus nonuse (*66*). It also found higher doses associated with increased risk. Relative to 1–19 MME/day, the adjusted hazard ratio (HR) for any overdose event (consisting of mostly nonfatal overdose) was 1.44 for 20 to 49 MME/day, 3.73 for 50–99 MME/day, and 8.87 for ≥100 MME/day. A similar pattern was observed for serious overdose. A good-quality population-based, nested case-control study also found a dose-dependent association with risk for overdose death (*67*). Relative to 1–19 MME/day, the adjusted odds ratio (OR) was 1.32 for 20–49 MME/day, 1.92 for 50–99 MME/day, 2.04 for 100–199 MME/day, and 2.88 for ≥200 MME/day.

Findings of increased fracture risk for current opioid use, versus nonuse, were mixed in two studies (*68*,*69*). Two studies found an association between opioid use and increased risk for cardiovascular events (*70*,*71*). Indirect evidence was found for endocrinologic harms (increased use of medications for erectile dysfunction or testosterone from one previously included study; laboratory-defined androgen deficiency from one newly reviewed study) (*72*,*73*). One study found that opioid dosages ≥20 MME/day were associated with increased odds of road trauma among drivers (*74*).

Opioid Dosing Strategies

For KQ3, the body of evidence is rated as type 4 (14 studies contributing; 12 from the original review plus two new studies). For initiation and titration of opioids, the 2014 AHRQ report found insufficient evidence from three fair-quality, open-label trials to determine comparative effectiveness of ER/LA versus immediate-release opioids for titrating patients to stable pain control (*75*,*76*). One new fair-quality cohort study of Veterans Affairs patients found initiation of therapy with an ER/LA opioid associated with greater risk for nonfatal overdose than initiation with an immediate-release opioid, with risk greatest in the first 2 weeks after initiation of treatment (*77*).

For comparative effectiveness and harms of ER/LA opioids, the 2014 AHRQ report included three randomized, head-to-head trials of various ER/LA opioids that found no clear differences in 1-year outcomes related to pain or function (*78–80*) but had methodological shortcomings. A fair-quality retrospective cohort study based on national Veterans Health Administration system pharmacy data found that methadone was associated with lower overall risk for all-cause mortality versus morphine (*81*), and a fair-quality retrospective cohort study based on Oregon Medicaid data found no statistically significant differences between methadone and long-acting morphine in risk for death or overdose symptoms (*82*). However, a new observational study (*83*) found methadone associated with increased risk for overdose versus sustained-release morphine among Tennessee Medicaid patients. The observed inconsistency in study findings suggests that risks of methadone might vary in different settings as a function of different monitoring and management protocols, though more research is needed to understand factors associated with safer methadone prescribing.

For dose escalation, the 2014 AHRQ report included one fair-quality randomized trial that found no differences between more liberal dose escalation and maintenance of current doses after 12 months in pain, function, all-cause withdrawals, or withdrawals due to opioid misuse (*84*). However, the difference in opioid dosages prescribed at the end of the trial was relatively small (mean 52 MME/day with more liberal dosing versus 40 MME/day). Evidence on other comparisons related to opioid dosing strategies (ER/LA versus immediate-release opioids; immediate-release plus ER/LA opioids versus ER/LA opioids alone; scheduled continuous dosing versus as-needed dosing; or opioid rotation versus maintenance of current therapy; long-term effects of strategies for treating acute exacerbations of chronic pain) was not available or too limited to determine effects on long-term clinical outcomes. For example, evidence on the comparative effectiveness of opioid tapering or discontinuation versus maintenance, and of different opioid tapering strategies, was limited to small, poor-quality studies (*85–87*).

Risk Assessment and Mitigation

For KQ4, the body of evidence is rated as type 3 for the accuracy of risk assessment tools and insufficient for the effectiveness of use of risk assessment tools and mitigation strategies in reducing harms (six studies contributing; four from the original review plus two new studies). The 2014 AHRQ report included four studies (*88–91*) on the accuracy of risk assessment instruments, administered prior to opioid therapy initiation, for predicting opioid abuse or misuse. Results for the Opioid Risk Tool (ORT) (*89–91*) were extremely inconsistent; evidence for other risk assessment instruments was very sparse, and studies had serious methodological shortcomings. One additional fair-quality (*92*) and one poor-quality (*93*) study identified for this update compared the predictive accuracy of the ORT, the Screener and Opioid Assessment for Patients with Pain-Revised (SOAPP-R), and the Brief Risk Interview.

For the ORT, sensitivity was 0.58 and 0.75 and specificity 0.54 and 0.86; for the SOAPP-R, sensitivity was 0.53 and 0.25 and specificity 0.62 and 0.73; and for the Brief Risk Interview, sensitivity was 0.73 and 0.83 and specificity 0.43 and 0.88. For the ORT, positive likelihood ratios ranged from noninformative (positive likelihood ratio close to 1) to moderately useful (positive likelihood ratio >5). The SOAPP-R was associated with noninformative likelihood ratios (estimates close to 1) in both studies.

No study evaluated the effectiveness of risk mitigation strategies (use of risk assessment instruments, opioid management plans, patient education, urine drug testing, use of PDMP data, use of monitoring instruments, more frequent monitoring intervals, pill counts, or use of abuse-deterrent formulations) for improving outcomes related to overdose, addiction, abuse, or misuse.

Effects of Opioid Therapy for Acute Pain on Long-Term Use

For KQ5, the body of evidence is rated as type 3 (two new studies contributing). Two fair-quality retrospective cohort studies found opioid therapy prescribed for acute pain associated with greater likelihood of long-term use. One study evaluated opioid-naïve patients who had undergone low-risk surgery, such as cataract surgery and varicose vein stripping (*94*). Use of opioids within 7 days of surgery was associated with increased risk for use at 1 year. The other study found that among patients with a workers' compensation claim for acute low back pain, compared to patients who did not receive opioids early after injury (defined as use within 15 days following onset of pain), patients who did receive early opioids had an increased likelihood of receiving five or more opioid prescriptions 30–730 days following onset that increased with greater early exposure. Versus no early opioid use, the adjusted OR was 2.08 (95% CI = 1.55–2.78) for 1–140 MME/day and increased to 6.14 (95% confidence interval [CI] = 4.92–7.66) for ≥450 MME/day (*95*).

Summary of the Contextual Evidence Review

Primary Areas of Focus

Contextual evidence is complementary information that assists in translating the clinical research findings into recommendations. CDC conducted contextual evidence reviews on four topics to supplement the clinical evidence review findings:

- Effectiveness of nonpharmacologic (e.g., cognitive behavioral therapy [CBT], exercise therapy, interventional treatments, and multimodal pain treatment) and nonopioid pharmacologic treatments (e.g., acetaminophen, nonsteroidal anti-inflammatory drugs [NSAIDs], antidepressants, and anticonvulsants), including studies of any duration.
- Benefits and harms of opioid therapy (including additional studies not included in the clinical evidence review, such as studies that were not restricted to patients with chronic pain, evaluated outcomes at any duration, performed ecological analyses, or used observational study designs other than cohort and case-cohort control studies) related to specific opioids, high-dose therapy, co-prescription with other controlled substances, duration of use, special populations, and potential usefulness of risk stratification/mitigation approaches, in addition to effectiveness of treatments associated with addressing potential harms of opioid therapy (opioid use disorder).
- Clinician and patient values and preferences related to opioids and medication risks, benefits, and use.
- Resource allocation including costs and economic efficiency of opioid therapy and risk mitigation strategies.

CDC also reviewed clinical guidelines that were relevant to opioid prescribing and could inform or complement the CDC recommendations under development (e.g., guidelines on nonpharmacologic and nonopioid pharmacologic treatments and guidelines with recommendations related to specific clinician actions such as urine drug testing or opioid tapering protocols).

Contextual Evidence Review Methods

CDC conducted a contextual evidence review to assist in developing the recommendations by providing an assessment of the balance of benefits and harms, values and preferences, and cost, consistent with the GRADE approach. Given the public health urgency for developing opioid prescribing recommendations, a rapid review was required for the contextual evidence review for the current guideline. Rapid reviews are used when there is a need to streamline the systematic review process to obtain evidence quickly (*96*). Methods used to streamline the process include limiting searches by databases, years, and languages considered, and truncating quality assessment and data abstraction protocols. CDC conducted "rapid reviews" of the contextual evidence on nonpharmacologic and nonopioid pharmacologic treatments, benefits and harms, values and preferences, and resource allocation.

Detailed information about contextual evidence data sources and searches, inclusion criteria, study selection, and

data extraction and synthesis are provided in the Contextual Evidence Review (http://stacks.cdc.gov/view/cdc/38027). In brief, CDC conducted systematic literature searches to identify original studies, systematic reviews, and clinical guidelines, depending on the topic being searched. CDC also solicited publication referrals from subject matter experts. Given the need for a rapid review process, grey literature (e.g., literature by academia, organizations, or government in the forms of reports, documents, or proceedings not published by commercial publishers) was not systematically searched. Database sources, including MEDLINE, PsycINFO, the Cochrane Central Register of Controlled Trials, and the Cochrane Database of Systematic Reviews, varied by topic. Multiple reviewers scanned study abstracts identified through the database searches and extracted relevant studies for review. CDC constructed narrative summaries and tables based on relevant articles that met inclusion criteria, which are provided in the Contextual Evidence Review (http://stacks.cdc.gov/view/cdc/38027).

Findings from the contextual reviews provide indirect evidence and should be interpreted accordingly. CDC did not formally rate the quality of evidence for the studies included in the contextual evidence review using the GRADE method. The studies that addressed benefits and harms, values and preferences, and resource allocation most often employed observational methods, used short follow-up periods, and evaluated selected samples. Therefore the strength of the evidence from these contextual review areas was considered to be low, comparable to type 3 or type 4 evidence. The quality of evidence for nonopioid pharmacologic and nonpharmacologic pain treatments was generally rated as moderate, comparable to type 2 evidence, in systematic reviews and clinical guidelines (e.g., for treatment of chronic neuropathic pain, low back pain, osteoarthritis, and fibromyalgia). Similarly, the quality of evidence on pharmacologic and psychosocial opioid use disorder treatment was generally rated as moderate, comparable to type 2 evidence, in systematic reviews and clinical guidelines.

Summary of Findings for Contextual Areas

Full narrative reviews and tables that summarize key findings from the contextual evidence review are provided in the Contextual Evidence Review (http://stacks.cdc.gov/view/cdc/38027).

Effectiveness of Nonpharmacologic and Nonopioid Pharmacologic Treatments

Several nonpharmacologic and nonopioid pharmacologic treatments have been shown to be effective in managing chronic pain in studies ranging in duration from 2 weeks to 6 months. For example, CBT that trains patients in behavioral techniques and helps patients modify situational factors and cognitive processes that exacerbate pain has small positive effects on disability and catastrophic thinking (*97*). Exercise therapy can help reduce pain and improve function in chronic low back pain (*98*), improve function and reduce pain in osteoarthritis of the knee (*99*) and hip (*100*), and improve well-being, fibromyalgia symptoms, and physical function in fibromyalgia (*101*). Multimodal and multidisciplinary therapies (e.g., therapies that combine exercise and related therapies with psychologically based approaches) can help reduce pain and improve function more effectively than single modalities (*102*,*103*). Nonopioid pharmacologic approaches used for pain include analgesics such as acetaminophen, NSAIDs, and cyclooxygenase 2 (COX-2) inhibitors; selected anticonvulsants; and selected antidepressants (particularly tricyclics and serotonin and norepinephrine reuptake inhibitors [SNRIs]). Multiple guidelines recommend acetaminophen as first-line pharmacotherapy for osteoarthritis (*104*–*109*) or for low back pain (*110*) but note that it should be avoided in liver failure and that dosage should be reduced in patients with hepatic insufficiency or a history of alcohol abuse (*109*). Although guidelines also recommend NSAIDs as first-line treatment for osteoarthritis or low back pain (*106*,*110*), NSAIDs and COX-2 inhibitors do have risks, including gastrointestinal bleeding or perforation as well as renal and cardiovascular risks (*111*). FDA has recently strengthened existing label warnings that NSAIDs increase risks for heart attack and stroke, including that these risks might increase with longer use or at higher doses (*112*). Several guidelines agree that first- and second-line drugs for neuropathic pain include anticonvulsants (gabapentin or pregabalin), tricyclic antidepressants, and SNRIs (*113*–*116*). Interventional approaches such as epidural injection for certain conditions (e.g., lumbar radiculopathy) can provide short-term improvement in pain (*117*–*119*). Epidural injection has been associated with rare but serious adverse events, including loss of vision, stroke, paralysis, and death (*120*).

Benefits and Harms of Opioid Therapy

Balance between benefits and harms is a critical factor influencing the strength of clinical recommendations. In particular, CDC considered what is known from the epidemiology research about benefits and harms related to specific opioids and formulations, high dose therapy, co-prescription with other controlled substances, duration of use, special populations, and risk stratification and mitigation approaches. Additional information on benefits and harms of long-term opioid therapy from studies meeting rigorous selection criteria is provided in the clinical evidence review (e.g., see KQ2). CDC also considered the number of persons experiencing chronic pain, numbers potentially benefiting

from opioids, and numbers affected by opioid-related harms. A review of these data is presented in the background section of this document, with detailed information provided in the Contextual Evidence Review (http://stacks.cdc.gov/view/cdc/38027). Finally, CDC considered the effectiveness of treatments that addressed potential harms of opioid therapy (opioid use disorder).

Regarding specific opioids and formulations, as noted by FDA, there are serious risks of ER/LA opioids, and the indication for this class of medications is for management of pain severe enough to require daily, around-the-clock, long-term opioid treatment in patients for whom other treatment options (e.g., nonopioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain (*121*). Time-scheduled opioid use was associated with substantially higher average daily opioid dosage than as-needed opioid use in one study (*122*). Methadone has been associated with disproportionate numbers of overdose deaths relative to the frequency with which it is prescribed for pain. Methadone has been found to account for as much as a third of opioid-related overdose deaths involving single or multiple drugs in states that participated in the Drug Abuse Warning Network, which was more than any opioid other than oxycodone, despite representing <2% of opioid prescriptions outside of opioid treatment programs in the United States; further, methadone was involved in twice as many single-drug deaths as any other prescription opioid (*123*).

Regarding high-dose therapy, several epidemiologic studies that were excluded from the clinical evidence review because patient samples were not restricted to patients with chronic pain also examined the association between opioid dosage and overdose risk (*23*,*24*,*124*–*126*). Consistent with the clinical evidence review, the contextual review found that opioid-related overdose risk is dose-dependent, with higher opioid dosages associated with increased overdose risk. Two of these studies (*23*,*24*), as well as the two studies in the clinical evidence review (*66*,*67*), evaluated similar MME/day dose ranges for association with overdose risk. In these four studies, compared with opioids prescribed at <20 MME/day, the odds of overdose among patients prescribed opioids for chronic nonmalignant pain were between 1.3 (*67*) and 1.9 (*24*) for dosages of 20 to <50 MME/day, between 1.9 (*67*) and 4.6 (*24*) for dosages of 50 to <100 MME/day, and between 2.0 (*67*) and 8.9 (*66*) for dosages of ≥100 MME/day. Compared with dosages of 1–<20 MME/day, absolute risk difference approximation for 50–<100 MME/day was 0.15% for fatal overdose (*24*) and 1.40% for any overdose (*66*), and for ≥100 MME/day was 0.25% for fatal overdose (*24*) and 4.04% for any overdose (*66*). A recent study of Veterans Health Administration patients with chronic pain found that patients who died of overdoses related to opioids were prescribed higher opioid dosages (mean: 98 MME/day; median: 60 MME/day) than controls (mean: 48 MME/day, median: 25 MME/day) (*127*). Finally, another recent study of overdose deaths among state residents with and without opioid prescriptions revealed that prescription opioid-related overdose mortality rates rose rapidly up to prescribed doses of 200 MME/day, after which the mortality rates continued to increase but grew more gradually (*128*). A listing of common opioid medications and their MME equivalents is provided (Table 2).

Regarding coprescription of opioids with benzodiazepines, epidemiologic studies suggest that concurrent use of benzodiazepines and opioids might put patients at greater risk for potentially fatal overdose. Three studies of fatal overdose deaths found evidence of concurrent benzodiazepine use in 31%–61% of decedents (*67*,*128*,*129*). In one of these studies (*67*), among decedents who received an opioid prescription, those whose deaths were related to opioids were more likely to have obtained opioids from multiple physicians and pharmacies than decedents whose deaths were not related to opioids.

Regarding duration of use, patients can experience tolerance and loss of effectiveness of opioids over time (*130*). Patients who do not experience clinically meaningful pain relief early in treatment (i.e., within 1 month) are unlikely to experience pain relief with longer-term use (*131*).

Regarding populations potentially at greater risk for harm, risk is greater for patients with sleep apnea or other causes of sleep-disordered breathing, patients with renal or hepatic insufficiency, older adults, pregnant women, patients with depression or other mental health conditions, and patients with alcohol or other substance use disorders. Interpretation of clinical data on the effects of opioids on sleep-disordered breathing is difficult because of the types of study designs and methods employed, and there is no clear consensus regarding association with risk for developing obstructive sleep apnea syndrome (*132*). However, opioid therapy can decrease respiratory drive, a high percentage of patients on long-term opioid therapy have been reported to have an abnormal apnea-hypopnea index (*133*), opioid therapy can worsen central sleep apnea in obstructive sleep apnea patients, and it can cause further desaturation in obstructive sleep apnea patients not on continuous positive airway pressure (CPAP) (*31*). Reduced renal or hepatic function can result in greater peak effect and longer duration of action and reduce the dose at which respiratory depression and overdose occurs (*134*). Age-related changes in patients aged ≥65 years, such as reduced renal function and medication clearance, even in the absence of renal disease (*135*), result in a smaller therapeutic window between safe dosages and dosages associated with respiratory depression and overdose. Older adults might also be at increased risk for falls and fractures related to opioids (*136*–*138*). Opioids used

in pregnancy can be associated with additional risks to both mother and fetus. Some studies have shown an association of opioid use in pregnancy with birth defects, including neural tube defects (*139*,*140*), congenital heart defects (*140*), and gastroschisis (*140*); preterm delivery (*141*), poor fetal growth (*141*), and stillbirth (*141*). Importantly, in some cases, opioid use during pregnancy leads to neonatal opioid withdrawal syndrome (*142*). Patients with mental health comorbidities and patients with histories of substance use disorders might be at higher risk than other patients for opioid use disorder (*62*,*143*,*144*). Recent analyses found that depressed patients were at higher risk for drug overdose than patients without depression, particularly at higher opioid dosages, although investigators were unable to distinguish unintentional overdose from suicide attempts (*145*). In case-control and case-cohort studies, substance abuse/dependence was more prevalent among patients experiencing overdose than among patients not experiencing overdose (12% versus 6% [*66*], 40% versus 10% [*24*], and 26% versus 9% [*23*]).

Regarding risk stratification approaches, limited evidence was found regarding benefits and harms. Potential benefits of PDMPs and urine drug testing include the ability to identify patients who might be at higher risk for opioid overdose or opioid use disorder, and help determine which patients will benefit from greater caution and increased monitoring or interventions when risk factors are present. For example, one study found that most fatal overdoses could be identified retrospectively on the basis of two pieces of information, multiple prescribers and high total daily opioid dosage, both important risk factors for overdose (*124*,*146*) that are available to prescribers in the PDMP (*124*). However, limited evaluation of PDMPs at the state level has revealed mixed effects on changes in prescribing and mortality outcomes (*28*). Potential harms of risk stratification include underestimation of risks of opioid therapy when screening tools are not adequately sensitive, as well as potential overestimation of risk, which could lead to inappropriate clinical decisions.

Regarding risk mitigation approaches, limited evidence was found regarding benefits and harms. Although no studies were found to examine prescribing of naloxone with opioid pain medication in primary care settings, naloxone distribution through community-based programs providing prevention services for substance users has been demonstrated to be associated with decreased risk for opioid overdose death at the community level (*147*).

Concerns have been raised that prescribing changes such as dose reduction might be associated with unintended negative consequences, such as patients seeking heroin or other illicitly obtained opioids (*148*) or interference with appropriate pain treatment (*149*). With the exception of a study noting an association between an abuse-deterrent formulation of OxyContin and heroin use, showing that some patients in qualitative interviews reported switching to another opioid, including heroin, for many reasons, including cost and availability as well as ease of use (*150*), CDC did not identify studies evaluating these potential outcomes.

Finally, regarding the effectiveness of opioid use disorder treatments, methadone and buprenorphine for opioid use disorder have been found to increase retention in treatment and to decrease illicit opioid use among patients with opioid use disorder involving heroin (*151*–*153*). Although findings are mixed, some studies suggest that effectiveness is enhanced when psychosocial treatments (e.g., contingency management, community reinforcement, psychotherapeutic counseling, and family therapy) are used in conjunction with medication-assisted therapy; for example, by reducing opioid misuse and increasing retention during maintenance therapy, and improving compliance after detoxification (*154*,*155*).

Clinician and Patient Values and Preferences

Clinician and patient values and preferences can inform how benefits and harms of long-term opioid therapy are weighted and estimate the effort and resources required to effectively provide implementation support. Many physicians lack confidence in their ability to prescribe opioids safely (*156*), to predict (*157*) or detect (*158*) prescription drug abuse, and to discuss abuse with their patients (*158*). Although clinicians have reported favorable beliefs and attitudes about improvements in pain and quality of life attributed to opioids (*159*), most consider prescription drug abuse to be a "moderate" or "big" problem in their community, and large proportions are "very" concerned about opioid addiction (55%) and death (48%) (*160*). Clinicians do not consistently use practices intended to decrease the risk for misuse, such as PDMPs (*161*,*162*), urine drug testing (*163*), and opioid treatment agreements (*164*). This is likely due in part to challenges related to registering for PDMP access and logging into the PDMP (which can interrupt normal clinical workflow if data are not integrated into electronic health record systems) (*165*), competing clinical demands, perceived inadequate time to discuss the rationale for urine drug testing and to order confirmatory testing, and feeling unprepared to interpret and address results (*166*).

Many patients do not have an opinion about "opioids" or know what this term means (*167*). Most are familiar with the term "narcotics." About a third associated "narcotics" with addiction or abuse, and about half feared "addiction" from long-term "narcotic" use (*168*). Most patients taking opioids experience side effects (73% of patients taking hydrocodone for noncancer pain [*11*], 96% of patients taking opioids for chronic pain [*12*]), and side effects, rather than pain relief,

have been found to explain most of the variation in patients' preferences related to taking opioids (*12*). For example, patients taking hydrocodone for noncancer pain commonly reported side effects including dizziness, headache, fatigue, drowsiness, nausea, vomiting, and constipation (*11*). Patients with chronic pain in focus groups emphasized effectiveness of goal setting for increasing motivation and functioning (*168*). Patients taking high dosages report reliance on opioids despite ambivalence about their benefits (*169*) and regardless of pain reduction, reported problems, concerns, side effects, or perceived helpfulness (*13*).

Resource Allocation

Resource allocation (cost) is an important consideration in understanding the feasibility of clinical recommendations. CDC searched for evidence on opioid therapy compared with other treatments; costs of misuse, abuse, and overdose from prescription opioids; and costs of specific risk mitigation strategies (e.g., urine drug testing). Yearly direct and indirect costs related to prescription opioids have been estimated (based on studies published since 2010) to be $53.4 billion for nonmedical use of prescription opioids (*170*); $55.7 billion for abuse, dependence (i.e., opioid use disorder), and misuse of prescription opioids (*171*); and $20.4 billion for direct and indirect costs related to opioid-related overdose alone (*172*). In 2012, total expenses for outpatient prescription opioids were estimated at $9.0 billion, an increase of 120% from 2002 (*173*). Although there are perceptions that opioid therapy for chronic pain is less expensive than more time-intensive nonpharmacologic management approaches, many pain treatments, including acetaminophen, NSAIDs, tricyclic antidepressants, and massage therapy, are associated with lower mean and median annual costs compared with opioid therapy (*174*). COX-2 inhibitors, SNRIs, anticonvulsants, topical analgesics, physical therapy, and CBT are also associated with lower median annual costs compared with opioid therapy (*174*). Limited information was found on costs of strategies to decrease risks associated with opioid therapy; however, urine drug testing, including screening and confirmatory tests, has been estimated to cost $211–$363 per test (*175*).

Recommendations

The recommendations are grouped into three areas for consideration:

- Determining when to initiate or continue opioids for chronic pain.
- Opioid selection, dosage, duration, follow-up, and discontinuation.
- Assessing risk and addressing harms of opioid use.

There are 12 recommendations (Box 1). Each recommendation is followed by a rationale for the recommendation, with considerations for implementation noted. In accordance with the ACIP GRADE process, CDC based the recommendations on consideration of the clinical evidence, contextual evidence (including benefits and harms, values and preferences, resource allocation), and expert opinion. For each recommendation statement, CDC notes the recommendation category (A or B) and the type of the evidence (1, 2, 3, or 4) supporting the statement (Box 2). Expert opinion is reflected within each of the recommendation rationales. While there was not an attempt to reach consensus among experts, experts from the Core Expert Group and from the Opioid Guideline Workgroup ("experts") expressed overall, general support for all recommendations. Where differences in expert opinion emerged for detailed actions within the clinical recommendations or for implementation considerations, CDC notes the differences of opinion in the supporting rationale statements.

Category A recommendations indicate that most patients should receive the recommended course of action; category B recommendations indicate that different choices will be appropriate for different patients, requiring clinicians to help patients arrive at a decision consistent with patient values and preferences and specific clinical situations. Consistent with the ACIP (*47*) and GRADE process (*48*), category A recommendations were made, even with type 3 and 4 evidence, when there was broad agreement that the advantages of a clinical action greatly outweighed the disadvantages based on a consideration of benefits and harms, values and preferences, and resource allocation. Category B recommendations were made when there was broad agreement that the advantages and disadvantages of a clinical action were more balanced, but advantages were significant enough to warrant a recommendation. All recommendations are category A recommendations, with the exception of recommendation 10, which is rated as category B. Recommendations were associated with a range of evidence types, from type 2 to type 4.

In summary, the categorization of recommendations was based on the following assessment:

- No evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later (with most placebo-controlled randomized trials ≤6 weeks in duration).
- Extensive evidence shows the possible harms of opioids (including opioid use disorder, overdose, and motor vehicle injury).
- Extensive evidence suggests some benefits of nonpharmacologic and nonopioid pharmacologic treatments compared with long-term opioid therapy, with less harm.

BOX 1. CDC recommendations for prescribing opioids for chronic pain outside of active cancer, palliative, and end-of-life care

Determining When to Initiate or Continue Opioids for Chronic Pain

1. Nonpharmacologic therapy and nonopioid pharmacologic therapy are preferred for chronic pain. Clinicians should consider opioid therapy only if expected benefits for both pain and function are anticipated to outweigh risks to the patient. If opioids are used, they should be combined with nonpharmacologic therapy and nonopioid pharmacologic therapy, as appropriate.
2. Before starting opioid therapy for chronic pain, clinicians should establish treatment goals with all patients, including realistic goals for pain and function, and should consider how therapy will be discontinued if benefits do not outweigh risks. Clinicians should continue opioid therapy only if there is clinically meaningful improvement in pain and function that outweighs risks to patient safety.
3. Before starting and periodically during opioid therapy, clinicians should discuss with patients known risks and realistic benefits of opioid therapy and patient and clinician responsibilities for managing therapy.

Opioid Selection, Dosage, Duration, Follow-Up, and Discontinuation

4. When starting opioid therapy for chronic pain, clinicians should prescribe immediate-release opioids instead of extended-release/long-acting (ER/LA) opioids.
5. When opioids are started, clinicians should prescribe the lowest effective dosage. Clinicians should use caution when prescribing opioids at any dosage, should carefully reassess evidence of individual benefits and risks when increasing dosage to ≥50 morphine milligram equivalents (MME)/day, and should avoid increasing dosage to ≥90 MME/day or carefully justify a decision to titrate dosage to ≥90 MME/day.
6. Long-term opioid use often begins with treatment of acute pain. When opioids are used for acute pain, clinicians should prescribe the lowest effective dose of immediate-release opioids and should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids. Three days or less will often be sufficient; more than seven days will rarely be needed.
7. Clinicians should evaluate benefits and harms with patients within 1 to 4 weeks of starting opioid therapy for chronic pain or of dose escalation. Clinicians should evaluate benefits and harms of continued therapy with patients every 3 months or more frequently. If benefits do not outweigh harms of continued opioid therapy, clinicians should optimize other therapies and work with patients to taper opioids to lower dosages or to taper and discontinue opioids.

Assessing Risk and Addressing Harms of Opioid Use

8. Before starting and periodically during continuation of opioid therapy, clinicians should evaluate risk factors for opioid-related harms. Clinicians should incorporate into the management plan strategies to mitigate risk, including considering offering naloxone when factors that increase risk for opioid overdose, such as history of overdose, history of substance use disorder, higher opioid dosages (≥50 MME/day), or concurrent benzodiazepine use, are present.
9. Clinicians should review the patient's history of controlled substance prescriptions using state prescription drug monitoring program (PDMP) data to determine whether the patient is receiving opioid dosages or dangerous combinations that put him or her at high risk for overdose. Clinicians should review PDMP data when starting opioid therapy for chronic pain and periodically during opioid therapy for chronic pain, ranging from every prescription to every 3 months.
10. When prescribing opioids for chronic pain, clinicians should use urine drug testing before starting opioid therapy and consider urine drug testing at least annually to assess for prescribed medications as well as other controlled prescription drugs and illicit drugs.
11. Clinicians should avoid prescribing opioid pain medication and benzodiazepines concurrently whenever possible.
12. Clinicians should offer or arrange evidence-based treatment (usually medication-assisted treatment with buprenorphine or methadone in combination with behavioral therapies) for patients with opioid use disorder.

* All recommendations are category A (apply to all patients outside of active cancer treatment, palliative care, and end-of-life care) except recommendation 10 (designated category B, with individual decision making required); see full guideline for evidence ratings.

BOX 2. Interpretation of recommendation categories and evidence type

Recommendation Categories

Based on evidence type, balance between desirable and undesirable effects, values and preferences, and resource allocation (cost).

Category A recommendation: Applies to all persons; most patients should receive the recommended course of action.

Category B recommendation: Individual decision making needed; different choices will be appropriate for different patients. Clinicians help patients arrive at a decision consistent with patient values and preferences and specific clinical situations.

Evidence Type

Based on study design as well as a function of limitations in study design or implementation, imprecision of estimates, variability in findings, indirectness of evidence, publication bias, magnitude of treatment effects, dose-response gradient, and constellation of plausible biases that could change effects.

Type 1 evidence: Randomized clinical trials or overwhelming evidence from observational studies.

Type 2 evidence: Randomized clinical trials with important limitations, or exceptionally strong evidence from observational studies.

Type 3 evidence: Observational studies or randomized clinical trials with notable limitations.

Type 4 evidence: Clinical experience and observations, observational studies with important limitations, or randomized clinical trials with several major limitations.

Determining When to Initiate or Continue Opioids for Chronic Pain

1. **Nonpharmacologic therapy and nonopioid pharmacologic therapy are preferred for chronic pain. Clinicians should consider opioid therapy only if expected benefits for both pain and function are anticipated to outweigh risks to the patient. If opioids are used, they should be combined with nonpharmacologic therapy and nonopioid pharmacologic therapy, as appropriate (recommendation category: A, evidence type: 3).**

Patients with pain should receive treatment that provides the greatest benefits relative to risks. The contextual evidence review found that many nonpharmacologic therapies, including physical therapy, weight loss for knee osteoarthritis, psychological therapies such as CBT, and certain interventional procedures can ameliorate chronic pain. There is high-quality evidence that exercise therapy (a prominent modality in physical therapy) for hip (*100*) or knee (*99*) osteoarthritis reduces pain and improves function immediately after treatment and that the improvements are sustained for at least 2–6 months. Previous guidelines have strongly recommended aerobic, aquatic, and/or resistance exercises for patients with osteoarthritis of the knee or hip (*176*). Exercise therapy also can help reduce pain and improve function in low back pain and can improve global well-being and physical function in fibromyalgia (*98*,*101*). Multimodal therapies and multidisciplinary biopsychosocial rehabilitation-combining approaches (e.g., psychological therapies with exercise) can reduce long-term pain and disability compared with usual care and compared with physical treatments (e.g., exercise) alone. Multimodal therapies are not always available or reimbursed by insurance and can be time-consuming and costly for patients. Interventional approaches such as arthrocentesis and intraarticular glucocorticoid injection for pain associated with rheumatoid arthritis (*117*) or osteoarthritis (*118*) and subacromial corticosteroid injection for rotator cuff disease (*119*) can provide short-term improvement in pain and function. Evidence is insufficient to determine the extent to which repeated glucocorticoid injection increases potential risks such as articular cartilage changes (in osteoarthritis) and sepsis (*118*). Serious adverse events are rare but have been reported with epidural injection (*120*).

Several nonopioid pharmacologic therapies (including acetaminophen, NSAIDs, and selected antidepressants and anticonvulsants) are effective for chronic pain. In particular, acetaminophen and NSAIDs can be useful for arthritis and low back pain. Selected anticonvulsants such as pregabalin and gabapentin can improve pain in diabetic neuropathy and post-herpetic neuralgia (contextual evidence review). Pregabalin, gabapentin, and carbamazepine are FDA-approved for treatment of certain neuropathic pain conditions, and pregabalin is FDA approved for fibromyalgia management. In patients with or without depression, tricyclic antidepressants and SNRIs provide effective analgesia for neuropathic pain conditions including diabetic neuropathy and post-herpetic neuralgia, often at lower dosages and with a shorter time to onset of effect than for treatment of depression (see contextual evidence review). Tricyclics and SNRIs can also relieve fibromyalgia symptoms. The SNRI duloxetine is FDA-approved for the treatment of diabetic neuropathy and fibromyalgia. Because patients with chronic pain often suffer from concurrent depression (*144*), and depression can exacerbate physical symptoms including pain (*177*), patients with co-occurring pain and depression are especially likely to benefit from antidepressant medication (see Recommendation 8). Nonopioid pharmacologic therapies

are not generally associated with substance use disorder, and the numbers of fatal overdoses associated with nonopioid medications are a fraction of those associated with opioid medications (contextual evidence review). For example, acetaminophen, NSAIDs, and opioid pain medication were involved in 881, 228, and 16,651 pharmaceutical overdose deaths in the United States in 2010 (*178*). However, nonopioid pharmacologic therapies are associated with certain risks, particularly in older patients, pregnant patients, and patients with certain co-morbidities such as cardiovascular, renal, gastrointestinal, and liver disease (see contextual evidence review). For example, acetaminophen can be hepatotoxic at dosages of >3–4 grams/day and at lower dosages in patients with chronic alcohol use or liver disease (*109*). NSAID use has been associated with gastritis, peptic ulcer disease, cardiovascular events (*111*,*112*), and fluid retention, and most NSAIDs (choline magnesium trilisate and selective COX-2 inhibitors are exceptions) interfere with platelet aggregation (*179*). Clinicians should review FDA-approved labeling including boxed warnings before initiating treatment with any pharmacologic therapy.

Although opioids can reduce pain during short-term use, the clinical evidence review found insufficient evidence to determine whether pain relief is sustained and whether function or quality of life improves with long-term opioid therapy (KQ1). While benefits for pain relief, function, and quality of life with long-term opioid use for chronic pain are uncertain, risks associated with long-term opioid use are clearer and significant. Based on the clinical evidence review, long-term opioid use for chronic pain is associated with serious risks including increased risk for opioid use disorder, overdose, myocardial infarction, and motor vehicle injury (KQ2). At a population level, more than 165,000 persons in the United States have died from opioid pain-medication-related overdoses since 1999 (see Contextual Evidence Review).

Integrated pain management requires coordination of medical, psychological, and social aspects of health care and includes primary care, mental health care, and specialist services when needed (*180*). Nonpharmacologic physical and psychological treatments such as exercise and CBT are approaches that encourage active patient participation in the care plan, address the effects of pain in the patient's life, and can result in sustained improvements in pain and function without apparent risks. Despite this, these therapies are not always or fully covered by insurance, and access and cost can be barriers for patients. For many patients, aspects of these approaches can be used even when there is limited access to specialty care. For example, previous guidelines have strongly recommended aerobic, aquatic, and/or resistance exercises for patients with osteoarthritis of the knee or hip (*176*) and maintenance of activity for patients with low back pain (*110*). A randomized trial found no difference in reduced chronic low back pain intensity, frequency or disability between patients assigned to relatively low-cost group aerobics and individual physiotherapy or muscle reconditioning sessions (*181*). Low-cost options to integrate exercise include brisk walking in public spaces or use of public recreation facilities for group exercise. CBT addresses psychosocial contributors to pain and improves function (*97*). Primary care clinicians can integrate elements of a cognitive behavioral approach into their practice by encouraging patients to take an active role in the care plan, by supporting patients in engaging in beneficial but potentially anxiety-provoking activities, such as exercise (*179*), or by providing education in relaxation techniques and coping strategies. In many locations, there are free or low-cost patient support, self-help, and educational community-based programs that can provide stress reduction and other mental health benefits. Patients with more entrenched anxiety or fear related to pain, or other significant psychological distress, can be referred for formal therapy with a mental health specialist (e.g., psychologist, psychiatrist, clinical social worker). Multimodal therapies should be considered for patients not responding to single-modality therapy, and combinations should be tailored depending on patient needs, cost, and convenience.

To guide patient-specific selection of therapy, clinicians should evaluate patients and establish or confirm the diagnosis. Detailed recommendations on diagnosis are provided in other guidelines (*110*,*179*), but evaluation should generally include a focused history, including history and characteristics of pain and potentially contributing factors (e.g., function, psychosocial stressors, sleep) and physical exam, with imaging or other diagnostic testing only if indicated (e.g., if severe or progressive neurologic deficits are present or if serious underlying conditions are suspected) (*110*,*179*). For complex pain syndromes, pain specialty consultation can be considered to assist with diagnosis as well as management. Diagnosis can help identify disease-specific interventions to reverse or ameliorate pain; for example, improving glucose control to prevent progression of diabetic neuropathy; immune-modulating agents for rheumatoid arthritis; physical or occupational therapy to address posture, muscle weakness, or repetitive occupational motions that contribute to musculoskeletal pain; or surgical intervention to relieve mechanical/compressive pain (*179*). The underlying mechanism for most pain syndromes can be categorized as neuropathic (e.g., diabetic neuropathy, postherpetic neuralgia, fibromyalgia), or nociceptive (e.g., osteoarthritis, muscular back pain). The diagnosis and pathophysiologic mechanism of pain have implications for symptomatic pain treatment with medication. For example, evidence is limited or insufficient

for improved pain or function with long-term use of opioids for several chronic pain conditions for which opioids are commonly prescribed, such as low back pain (*182*), headache (*183*), and fibromyalgia (*184*). Although NSAIDs can be used for exacerbations of nociceptive pain, other medications (e.g., tricyclics, selected anticonvulsants, or transdermal lidocaine) generally are recommended for neuropathic pain. In addition, improvement of neuropathic pain can begin weeks or longer after symptomatic treatment is initiated (*179*). Medications should be used only after assessment and determination that expected benefits outweigh risks given patient-specific factors. For example, clinicians should consider falls risk when selecting and dosing potentially sedating medications such as tricyclics, anticonvulsants, or opioids, and should weigh risks and benefits of use, dose, and duration of NSAIDs when treating older adults as well as patients with hypertension, renal insufficiency, or heart failure, or those with risk for peptic ulcer disease or cardiovascular disease. Some guidelines recommend topical NSAIDs for localized osteoarthritis (e.g., knee osteoarthritis) over oral NSAIDs in patients aged ≥75 years to minimize systemic effects (*176*).

Experts agreed that opioids should not be considered first-line or routine therapy for chronic pain (i.e., pain continuing or expected to continue >3 months or past the time of normal tissue healing) outside of active cancer, palliative, and end-of-life care, given small to moderate short-term benefits, uncertain long-term benefits, and potential for serious harms; although evidence on long-term benefits of nonopioid therapies is also limited, these therapies are also associated with short-term benefits, and risks are much lower. This does not mean that patients should be required to sequentially "fail" nonpharmacologic and nonopioid pharmacologic therapy before proceeding to opioid therapy. Rather, expected benefits specific to the clinical context should be weighed against risks before initiating therapy. In some clinical contexts (e.g., headache or fibromyalgia), expected benefits of initiating opioids are unlikely to outweigh risks regardless of previous nonpharmacologic and nonopioid pharmacologic therapies used. In other situations (e.g., serious illness in a patient with poor prognosis for return to previous level of function, contraindications to other therapies, and clinician and patient agreement that the overriding goal is patient comfort), opioids might be appropriate regardless of previous therapies used. In addition, when opioid pain medication is used, it is more likely to be effective if integrated with nonpharmacologic therapy. Nonpharmacologic approaches such as exercise and CBT should be used to reduce pain and improve function in patients with chronic pain. Nonopioid pharmacologic therapy should be used when benefits outweigh risks and should be combined with nonpharmacologic therapy to reduce pain and improve function. If opioids are used, they should be combined with nonpharmacologic therapy and nonopioid pharmacologic therapy, as appropriate, to provide greater benefits to patients in improving pain and function.

2. **Before starting opioid therapy for chronic pain, clinicians should establish treatment goals with all patients, including realistic goals for pain and function, and should consider how opioid therapy will be discontinued if benefits do not outweigh risks. Clinicians should continue opioid therapy only if there is clinically meaningful improvement in pain and function that outweighs risks to patient safety (recommendation category: A, evidence type: 4).**

The clinical evidence review found insufficient evidence to determine long-term benefits of opioid therapy for chronic pain and found an increased risk for serious harms related to long-term opioid therapy that appears to be dose-dependent. In addition, studies on currently available risk assessment instruments were sparse and showed inconsistent results (KQ4). The clinical evidence review for the current guideline considered studies with outcomes examined at ≥1 year that compared opioid use versus nonuse or placebo. Studies of opioid therapy for chronic pain that did not have a nonopioid control group have found that although many patients discontinue opioid therapy for chronic noncancer pain due to adverse effects or insufficient pain relief, there is weak evidence that patients who are able to continue opioid therapy for at least 6 months can experience clinically significant pain relief and insufficient evidence that function or quality of life improves (*185*). These findings suggest that it is very difficult for clinicians to predict whether benefits of opioids for chronic pain will outweigh risks of ongoing treatment for individual patients. Opioid therapy should not be initiated without consideration of an "exit strategy" to be used if the therapy is unsuccessful.

Experts agreed that before opioid therapy is initiated for chronic pain outside of active cancer, palliative, and end-of-life care, clinicians should determine how effectiveness will be evaluated and should establish treatment goals with patients. Because the line between acute pain and initial chronic pain is not always clear, it might be difficult for clinicians to determine when they are initiating opioids for chronic pain rather than treating acute pain. Pain lasting longer than 3 months or past the time of normal tissue healing (which could be substantially shorter than 3 months, depending on the condition) is generally no longer considered acute. However, establishing treatment goals with a patient who has already received opioid therapy for 3 months would defer this discussion well past the point of

initiation of opioid therapy for chronic pain. Clinicians often write prescriptions for long-term use in 30-day increments, and opioid prescriptions written for ≥30 days are likely to represent initiation or continuation of long-term opioid therapy. Before writing an opioid prescription for ≥30 days, clinicians should establish treatment goals with patients. Clinicians seeing new patients already receiving opioids should establish treatment goals for continued opioid therapy. Although the clinical evidence review did not find studies evaluating the effectiveness of written agreements or treatment plans (KQ4), clinicians and patients who set a plan in advance will clarify expectations regarding how opioids will be prescribed and monitored, as well as situations in which opioids will be discontinued or doses tapered (e.g., if treatment goals are not met, opioids are no longer needed, or adverse events put the patient at risk) to improve patient safety.

Experts thought that goals should include improvement in both pain relief and function (and therefore in quality of life). However, there are some clinical circumstances under which reductions in pain without improvement in physical function might be a more realistic goal (e.g., diseases typically associated with progressive functional impairment or catastrophic injuries such as spinal cord trauma). Experts noted that function can include emotional and social as well as physical dimensions. In addition, experts emphasized that mood has important interactions with pain and function. Experts agreed that clinicians may use validated instruments such as the three-item "Pain average, interference with Enjoyment of life, and interference with General activity" (PEG) Assessment Scale (*186*) to track patient outcomes. Clinically meaningful improvement has been defined as a 30% improvement in scores for both pain and function (*187*). Monitoring progress toward patient-centered functional goals (e.g., walking the dog or walking around the block, returning to part-time work, attending family sports or recreational activities) can also contribute to the assessment of functional improvement. Clinicians should use these goals in assessing benefits of opioid therapy for individual patients and in weighing benefits against risks of continued opioid therapy (see Recommendation 7, including recommended intervals for follow-up). Because depression, anxiety, and other psychological co-morbidities often coexist with and can interfere with resolution of pain, clinicians should use validated instruments to assess for these conditions (see Recommendation 8) and ensure that treatment for these conditions is optimized. If patients receiving opioid therapy for chronic pain do not experience meaningful improvements in both pain and function compared with prior to initiation of opioid therapy, clinicians should consider working with patients to taper and discontinue opioids (see Recommendation 7) and should use nonpharmacologic and nonopioid pharmacologic approaches to pain management (see Recommendation 1).

3. Before starting and periodically during opioid therapy, clinicians should discuss with patients known risks and realistic benefits of opioid therapy and patient and clinician responsibilities for managing therapy (recommendation category: A, evidence type: 3).

The clinical evidence review did not find studies evaluating effectiveness of patient education or opioid treatment plans as risk-mitigation strategies (KQ4). However, the contextual evidence review found that many patients lack information about opioids and identified concerns that some clinicians miss opportunities to effectively communicate about safety. Given the substantial evidence gaps on opioids, uncertain benefits of long-term use, and potential for serious harms, patient education and discussion before starting opioid therapy are critical so that patient preferences and values can be understood and used to inform clinical decisions. Experts agreed that essential elements to communicate to patients before starting and periodically during opioid therapy include realistic expected benefits, common and serious harms, and expectations for clinician and patient responsibilities to mitigate risks of opioid therapy.

Clinicians should involve patients in decisions about whether to start or continue opioid therapy. Given potentially serious risks of long-term opioid therapy, clinicians should ensure that patients are aware of potential benefits of, harms of, and alternatives to opioids before starting or continuing opioid therapy. Clinicians are encouraged to have open and honest discussions with patients to inform mutual decisions about whether to start or continue opioid therapy. Important considerations include the following:

- Be explicit and realistic about expected benefits of opioids, explaining that while opioids can reduce pain during short-term use, there is no good evidence that opioids improve pain or function with long-term use, and that complete relief of pain is unlikely (clinical evidence review, KQ1).
- Emphasize improvement in function as a primary goal and that function can improve even when pain is still present.
- Advise patients about serious adverse effects of opioids, including potentially fatal respiratory depression and development of a potentially serious lifelong opioid use disorder that can cause distress and inability to fulfill major role obligations.
- Advise patients about common effects of opioids, such as constipation, dry mouth, nausea, vomiting, drowsiness, confusion, tolerance, physical dependence, and withdrawal symptoms when stopping opioids. To prevent constipation associated with opioid use, advise patients to increase

hydration and fiber intake and to maintain or increase physical activity. Stool softeners or laxatives might be needed.
- Discuss effects that opioids might have on ability to safely operate a vehicle, particularly when opioids are initiated, when dosages are increased, or when other central nervous system depressants, such as benzodiazepines or alcohol, are used concurrently.
- Discuss increased risks for opioid use disorder, respiratory depression, and death at higher dosages, along with the importance of taking only the amount of opioids prescribed, i.e., not taking more opioids or taking them more often.
- Review increased risks for respiratory depression when opioids are taken with benzodiazepines, other sedatives, alcohol, illicit drugs such as heroin, or other opioids.
- Discuss risks to household members and other individuals if opioids are intentionally or unintentionally shared with others for whom they are not prescribed, including the possibility that others might experience overdose at the same or at lower dosage than prescribed for the patient, and that young children are susceptible to unintentional ingestion. Discuss storage of opioids in a secure, preferably locked location and options for safe disposal of unused opioids (*188*).
- Discuss the importance of periodic reassessment to ensure that opioids are helping to meet patient goals and to allow opportunities for opioid discontinuation and consideration of additional nonpharmacologic or nonopioid pharmacologic treatment options if opioids are not effective or are harmful.
- Discuss planned use of precautions to reduce risks, including use of prescription drug monitoring program information (see Recommendation 9) and urine drug testing (see Recommendation 10). Consider including discussion of naloxone use for overdose reversal (see Recommendation 8).
- Consider whether cognitive limitations might interfere with management of opioid therapy (for older adults in particular) and, if so, determine whether a caregiver can responsibly co-manage medication therapy. Discuss the importance of reassessing safer medication use with both the patient and caregiver.

Given the possibility that benefits of opioid therapy might diminish or that risks might become more prominent over time, it is important that clinicians review expected benefits and risks of continued opioid therapy with patients periodically, at least every 3 months (see Recommendation 7).

Opioid Selection, Dosage, Duration, Follow-Up, and Discontinuation

4. When starting opioid therapy for chronic pain, clinicians should prescribe immediate-release opioids instead of extended-release/long-acting (ER/LA) opioids (recommendation category: A, evidence type: 4).

ER/LA opioids include methadone, transdermal fentanyl, and extended-release versions of opioids such as oxycodone, oxymorphone, hydrocodone, and morphine. The clinical evidence review found a fair-quality study showing a higher risk for overdose among patients initiating treatment with ER/LA opioids than among those initiating treatment with immediate-release opioids (*77*). The clinical evidence review did not find evidence that continuous, time-scheduled use of ER/LA opioids is more effective or safer than intermittent use of immediate-release opioids or that time-scheduled use of ER/LA opioids reduces risks for opioid misuse or addiction (KQ3).

In 2014, the FDA modified the labeling for ER/LA opioid pain medications, noting serious risks and recommending that ER/LA opioids be reserved for "management of pain severe enough to require daily, around-the-clock, long-term opioid treatment" when "alternative treatment options (e.g., nonopioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain" and not used as "as needed" pain relievers (*121*). FDA has also noted that some ER/LA opioids are only appropriate for opioid-tolerant patients, defined as patients who have received certain dosages of opioids (e.g., 60 mg daily of oral morphine, 30 mg daily of oral oxycodone, or equianalgesic dosages of other opioids) for at least 1 week (*189*). Time-scheduled opioid use can be associated with greater total average daily opioid dosage compared with intermittent, as-needed opioid use (contextual evidence review). In addition, experts indicated that there was not enough evidence to determine the safety of using immediate-release opioids for breakthrough pain when ER/LA opioids are used for chronic pain outside of active cancer pain, palliative care, or end-of-life care, and that this practice might be associated with dose escalation.

Abuse-deterrent technologies have been employed to prevent manipulation intended to defeat extended-release properties of ER/LA opioids and to prevent opioid use by unintended routes of administration, such as injection of oral opioids. As indicated in FDA guidance for industry on evaluation and labeling of abuse-deterrent opioids (*190*), although abuse-deterrent technologies are expected to make manipulation of opioids more difficult or less rewarding, they do not prevent

opioid abuse through oral intake, the most common route of opioid abuse, and can still be abused by nonoral routes. The "abuse-deterrent" label does not indicate that there is no risk for abuse. No studies were found in the clinical evidence review assessing the effectiveness of abuse-deterrent technologies as a risk mitigation strategy for deterring or preventing abuse. In addition, abuse-deterrent technologies do not prevent unintentional overdose through oral intake. Experts agreed that recommendations could not be offered at this time related to use of abuse-deterrent formulations.

In comparing different ER/LA formulations, the clinical evidence review found inconsistent results for overdose risk with methadone versus other ER/LA opioids used for chronic pain (KQ3). The contextual evidence review found that methadone has been associated with disproportionate numbers of overdose deaths relative to the frequency with which it is prescribed for chronic pain. In addition, methadone is associated with cardiac arrhythmias along with QT prolongation on the electrocardiogram, and it has complicated pharmacokinetics and pharmacodynamics, including a long and variable half-life and peak respiratory depressant effect occurring later and lasting longer than peak analgesic effect. Experts noted that the pharmacodynamics of methadone are subject to more inter-individual variability than other opioids. In regard to other ER/LA opioid formulations, experts noted that the absorption and pharmacodynamics of transdermal fentanyl are complex, with gradually increasing serum concentration during the first part of the 72-hour dosing interval, as well as variable absorption based on factors such as external heat. In addition, the dosing of transdermal fentanyl in mcg/hour, which is not typical for a drug used by outpatients, can be confusing. Experts thought that these complexities might increase the risk for fatal overdose when methadone or transdermal fentanyl is prescribed to a patient who has not used it previously or by clinicians who are not familiar with its effects.

Experts agreed that for patients not already receiving opioids, clinicians should not initiate opioid treatment with ER/LA opioids and should not prescribe ER/LA opioids for intermittent use. 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. When changing to an ER/LA opioid for a patient previously receiving a different immediate-release opioid, clinicians should consult product labeling and reduce total daily dosage to account for incomplete opioid cross-tolerance. Clinicians should use additional caution with ER/LA opioids and consider a longer dosing interval when prescribing to 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. Although there might be situations in which clinicians need to prescribe immediate-release and ER/LA opioids together (e.g., transitioning patients from ER/LA opioids to immediate-release opioids by temporarily using lower dosages of both), in general, avoiding the use of immediate-release opioids in combination with ER/LA opioids is preferable, given potentially increased risk and diminishing returns of such an approach for chronic pain.

When an ER/LA opioid is prescribed, using one with predictable pharmacokinetics and pharmacodynamics is preferred to minimize unintentional overdose risk. In particular, unusual characteristics of methadone and of transdermal fentanyl make safe prescribing of these medications for pain especially challenging.

- Methadone should not be the first choice for an ER/LA opioid. Only clinicians who are familiar with methadone's unique risk profile and who are prepared to educate and closely monitor their patients, including risk assessment for QT prolongation and consideration of electrocardiographic monitoring, should consider prescribing methadone for pain. A clinical practice guideline that contains further guidance regarding methadone prescribing for pain has been published previously (*191*).
- Because dosing effects of transdermal fentanyl are often misunderstood by both clinicians and patients, only clinicians who are familiar with the dosing and absorption properties of transdermal fentanyl and are prepared to educate their patients about its use should consider prescribing it.

5. When opioids are started, clinicians should prescribe the lowest effective dosage. Clinicians should use caution when prescribing opioids at any dosage, should carefully reassess evidence of individual benefits and risks when considering increasing dosage to ≥50 morphine milligram equivalents (MME)/day, and should avoid increasing dosage to ≥90 MME/day or carefully justify a decision to titrate dosage to ≥90 MME/day (recommendation category: A, evidence type: 3).

Benefits of high-dose opioids for chronic pain are not established. The clinical evidence review found only one study (*84*) addressing effectiveness of dose titration for outcomes related to pain control, function, and quality of life (KQ3). This randomized trial found no difference in pain or function between a more liberal opioid dose escalation strategy and maintenance of current dosage. (These groups were prescribed average dosages of 52 and 40 MME/day, respectively, at the end of the trial.) At the same time, risks for serious harms

related to opioid therapy increase at higher opioid dosage. The clinical evidence review found that higher opioid dosages are associated with increased risks for motor vehicle injury, opioid use disorder, and overdose (KQ2). The clinical and contextual evidence reviews found that opioid overdose risk increases in a dose-response manner, that dosages of 50–<100 MME/day have been found to increase risks for opioid overdose by factors of 1.9 to 4.6 compared with dosages of 1–<20 MME/day, and that dosages ≥100 MME/day are associated with increased risks of overdose 2.0–8.9 times the risk at 1–<20 MME/day. In a national sample of Veterans Health Administration patients with chronic pain who were prescribed opioids, mean prescribed opioid dosage among patients who died from opioid overdose was 98 MME (median 60 MME) compared with mean prescribed opioid dosage of 48 MME (median 25 MME) among patients not experiencing fatal overdose (*127*).

The contextual evidence review found that although there is not a single dosage threshold below which overdose risk is eliminated, holding dosages <50 MME/day would likely reduce risk among a large proportion of patients who would experience fatal overdose at higher prescribed dosages. Experts agreed that lower dosages of opioids reduce the risk for overdose, but that a single dosage threshold for safe opioid use could not be identified. Experts noted that daily opioid dosages close to or greater than 100 MME/day are associated with significant risks, that dosages <50 MME/day are safer than dosages of 50–100 MME/day, and that dosages <20 MME/day are safer than dosages of 20–50 MME/day. One expert thought that a specific dosage at which the benefit/risk ratio of opioid therapy decreases could not be identified. Most experts agreed that, in general, increasing dosages to 50 or more MME/day increases overdose risk without necessarily adding benefits for pain control or function and that clinicians should carefully reassess evidence of individual benefits and risks when considering increasing opioid dosages to ≥50 MME/day. Most experts also agreed that opioid dosages should not be increased to ≥90 MME/day without careful justification based on diagnosis and on individualized assessment of benefits and risks.

When opioids are used for chronic pain outside of active cancer, palliative, and end-of-life care, clinicians should start opioids at the lowest possible effective dosage (the lowest starting dosage on product labeling for patients not already taking opioids and according to product labeling guidance regarding tolerance for patients already taking opioids). Clinicians should use additional caution when initiating opioids for patients aged ≥65 years and for patients with renal or hepatic insufficiency because decreased clearance of drugs in these patients can result in accumulation of drugs to toxic levels. Clinicians should use caution when increasing opioid dosages and increase dosage by the smallest practical amount because overdose risk increases with increases in opioid dosage. Although there is limited evidence to recommend specific intervals for dosage titration, a previous guideline recommended waiting at least five half-lives before increasing dosage and waiting at least a week before increasing dosage of methadone to make sure that full effects of the previous dosage are evident (*31*). Clinicians should re-evaluate patients after increasing dosage for changes in pain, function, and risk for harm (see Recommendation 7). Before increasing total opioid dosage to ≥50 MME/day, clinicians should reassess whether opioid treatment is meeting the patient's treatment goals (see Recommendation 2). If a patient's opioid dosage for all sources of opioids combined reaches or exceeds 50 MME/day, clinicians should implement additional precautions, including increased frequency of follow-up (see Recommendation 7) and considering offering naloxone and overdose prevention education to both patients and the patients' household members (see Recommendation 8). Clinicians should avoid increasing opioid dosages to ≥90 MME/day or should carefully justify a decision to increase dosage to ≥90 MME/day based on individualized assessment of benefits and risks and weighing factors such as diagnosis, incremental benefits for pain and function relative to harms as dosages approach 90 MME/day, other treatments and effectiveness, and recommendations based on consultation with pain specialists. If patients do not experience improvement in pain and function at ≥90 MME/day, or if there are escalating dosage requirements, clinicians should discuss other approaches to pain management with the patient, consider working with patients to taper opioids to a lower dosage or to taper and discontinue opioids (see Recommendation 7), and consider consulting a pain specialist. Some states require clinicians to implement clinical protocols at specific dosage levels. For example, before increasing long-term opioid therapy dosage to >120 MME/day, clinicians in Washington state must obtain consultation from a pain specialist who agrees that this is indicated and appropriate (*30*). Clinicians should be aware of rules related to MME thresholds and associated clinical protocols established by their states.

Established patients already taking high dosages of opioids, as well as patients transferring from other clinicians, might consider the possibility of opioid dosage reduction to be anxiety-provoking, and tapering opioids can be especially challenging after years on high dosages because of physical and psychological dependence. However, these patients should be offered the opportunity to re-evaluate their continued use of opioids at high dosages in light of recent evidence regarding the association of opioid dosage and overdose risk. Clinicians should explain in a nonjudgmental manner to patients already taking high opioid dosages (≥90 MME/day) that there is

now an established body of scientific evidence showing that overdose risk is increased at higher opioid dosages. Clinicians should empathically review benefits and risks of continued high-dosage opioid therapy and should offer to work with the patient to taper opioids to safer dosages. For patients who agree to taper opioids to lower dosages, clinicians should collaborate with the patient on a tapering plan (see Recommendation 7). Experts noted that patients tapering opioids after taking them for years might require very slow opioid tapers as well as pauses in the taper to allow gradual accommodation to lower opioid dosages. Clinicians should remain alert to signs of anxiety, depression, and opioid use disorder (see Recommendations 8 and 12) that might be unmasked by an opioid taper and arrange for management of these co-morbidities. For patients agreeing to taper to lower opioid dosages as well as for those remaining on high opioid dosages, clinicians should establish goals with the patient for continued opioid therapy (see Recommendation 2), maximize pain treatment with nonpharmacologic and nonopioid pharmacologic treatments as appropriate (see Recommendation 1), and consider consulting a pain specialist as needed to assist with pain management.

6. **Long-term opioid use often begins with treatment of acute pain. When opioids are used for acute pain, clinicians should prescribe the lowest effective dose of immediate-release opioids and should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids. Three days or less will often be sufficient; more than seven days will rarely be needed (recommendation category: A, evidence type: 4).**

The clinical evidence review found that opioid use for acute pain (i.e., pain with abrupt onset and caused by an injury or other process that is not ongoing) is associated with long-term opioid use, and that a greater amount of early opioid exposure is associated with greater risk for long-term use (KQ5). Several guidelines on opioid prescribing for acute pain from emergency departments (*192*–*194*) and other settings (*195*,*196*) have recommended prescribing ≤3 days of opioids in most cases, whereas others have recommended ≤7 days (*197*) or <14 days (*30*). Because physical dependence on opioids is an expected physiologic response in patients exposed to opioids for more than a few days (contextual evidence review), limiting days of opioids prescribed also should minimize the need to taper opioids to prevent distressing or unpleasant withdrawal symptoms. Experts noted that more than a few days of exposure to opioids significantly increases hazards, that each day of unnecessary opioid use increases likelihood of physical dependence without adding benefit, and that prescriptions with fewer days' supply will minimize the number of pills available for unintentional or intentional diversion.

Experts agreed that when opioids are needed for acute pain, clinicians should prescribe opioids at the lowest effective dose and for no longer than the expected duration of pain severe enough to require opioids to minimize unintentional initiation of long-term opioid use. The lowest effective dose can be determined using product labeling as a starting point with calibration as needed based on the severity of pain and on other clinical factors such as renal or hepatic insufficiency (see Recommendation 8). Experts thought, based on clinical experience regarding anticipated duration of pain severe enough to require an opioid, that in most cases of acute pain not related to surgery or trauma, a ≤3 days' supply of opioids will be sufficient. For example, in one study of the course of acute low back pain (not associated with malignancies, infections, spondylarthropathies, fractures, or neurological signs) in a primary care setting, there was a large decrease in pain until the fourth day after treatment with paracetamol, with smaller decreases thereafter (*198*). Some experts thought that because some types of acute pain might require more than 3 days of opioid treatment, it would be appropriate to recommend a range of ≤3–5 days or ≤3–7 days when opioids are needed. Some experts thought that a range including 7 days was too long given the expected course of severe acute pain for most acute pain syndromes seen in primary care.

Acute pain can often be managed without opioids. It is important to evaluate the patient for reversible causes of pain, for underlying etiologies with potentially serious sequelae, and to determine appropriate treatment. When the diagnosis and severity of nontraumatic, nonsurgical acute pain are reasonably assumed to warrant the use of opioids, clinicians should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids, often 3 days or less, unless circumstances clearly warrant additional opioid therapy. More than 7 days will rarely be needed. Opioid treatment for post-surgical pain is outside the scope of this guideline but has been addressed elsewhere (*30*). Clinicians should not prescribe additional opioids to patients "just in case" pain continues longer than expected. Clinicians should re-evaluate the subset of patients who experience severe acute pain that continues longer than the expected duration to confirm or revise the initial diagnosis and to adjust management accordingly. Given longer half-lives and longer duration of effects (e.g., respiratory depression) with ER/LA opioids such as methadone, fentanyl patches, or extended release versions of opioids such as oxycodone, oxymorphone, or morphine, clinicians should not prescribe ER/LA opioids for the treatment of acute pain.

7. **Clinicians should evaluate benefits and harms with patients within 1 to 4 weeks of starting opioid therapy for chronic pain or of dose escalation. Clinicians should evaluate benefits and harms of continued therapy with patients every 3 months or more frequently. If benefits do not outweigh harms of continued opioid therapy, clinicians should optimize other therapies and work with patients to taper opioids to lower dosages or to taper and discontinue opioids (recommendation category: A, evidence type: 4).**

Although the clinical evidence review did not find studies evaluating the effectiveness of more frequent monitoring intervals (KQ4), it did find that continuing opioid therapy for 3 months substantially increases risk for opioid use disorder (KQ2); therefore, follow-up earlier than 3 months might be necessary to provide the greatest opportunity to prevent the development of opioid use disorder. In addition, risk for overdose associated with ER/LA opioids might be particularly high during the first 2 weeks of treatment (KQ3). The contextual evidence review found that patients who do not have pain relief with opioids at 1 month are unlikely to experience pain relief with opioids at 6 months. Although evidence is insufficient to determine at what point within the first 3 months of opioid therapy the risks for opioid use disorder increase, reassessment of pain and function within 1 month of initiating opioids provides an opportunity to minimize risks of long-term opioid use by discontinuing opioids among patients not receiving a clear benefit from these medications. Experts noted that risks for opioid overdose are greatest during the first 3–7 days after opioid initiation or increase in dosage, particularly when methadone or transdermal fentanyl are prescribed; that follow-up within 3 days is appropriate when initiating or increasing the dosage of methadone; and that follow-up within 1 week might be appropriate when initiating or increasing the dosage of other ER/LA opioids.

Clinicians should evaluate patients to assess benefits and harms of opioids within 1 to 4 weeks of starting long-term opioid therapy or of dose escalation. Clinicians should consider follow-up intervals within the lower end of this range when ER/LA opioids are started or increased or when total daily opioid dosage is ≥50 MME/day. Shorter follow-up intervals (within 3 days) should be strongly considered when starting or increasing the dosage of methadone. At follow up, clinicians should assess benefits in function, pain control, and quality of life using tools such as the three-item "Pain average, interference with Enjoyment of life, and interference with General activity" (PEG) Assessment Scale (*186*) and/or asking patients about progress toward functional goals that have meaning for them (see Recommendation 2). Clinicians should also ask patients about common adverse effects such as constipation and drowsiness (see Recommendation 3), as well as asking about and assessing for effects that might be early warning signs for more serious problems such as overdose (e.g., sedation or slurred speech) or opioid use disorder (e.g., craving, wanting to take opioids in greater quantities or more frequently than prescribed, or difficulty controlling use). Clinicians should ask patients about their preferences for continuing opioids, given their effects on pain and function relative to any adverse effects experienced.

Because of potential changes in the balance of benefits and risks of opioid therapy over time, clinicians should regularly reassess all patients receiving long-term opioid therapy, including patients who are new to the clinician but on long-term opioid therapy, at least every 3 months. At reassessment, clinicians should determine whether opioids continue to meet treatment goals, including sustained improvement in pain and function, whether the patient has experienced common or serious adverse events or early warning signs of serious adverse events, signs of opioid use disorder (e.g., difficulty controlling use, work or family problems related to opioid use), whether benefits of opioids continue to outweigh risks, and whether opioid dosage can be reduced or opioids can be discontinued. Ideally, these reassessments would take place in person and be conducted by the prescribing clinician. In practice contexts where virtual visits are part of standard care (e.g., in remote areas where distance or other issues make follow-up visits challenging), follow-up assessments that allow the clinician to communicate with and observe the patient through video and audio could be conducted, with in-person visits occurring at least once per year. Clinicians should re-evaluate patients who are exposed to greater risk of opioid use disorder or overdose (e.g., patients with depression or other mental health conditions, a history of substance use disorder, a history of overdose, taking ≥50 MME/day, or taking other central nervous system depressants with opioids) more frequently than every 3 months. If clinically meaningful improvements in pain and function are not sustained, if patients are taking high-risk regimens (e.g., dosages ≥50 MME/day or opioids combined with benzodiazepines) without evidence of benefit, if patients believe benefits no longer outweigh risks or if they request dosage reduction or discontinuation, or if patients experience overdose or other serious adverse events (e.g., an event leading to hospitalization or disability) or warning signs of serious adverse events, clinicians should work with patients to reduce opioid dosage or to discontinue opioids when possible. Clinicians should maximize pain treatment with nonpharmacologic and nonopioid pharmacologic treatments as appropriate (see Recommendation 1) and consider consulting a pain specialist as needed to assist with pain management.

Considerations for Tapering Opioids

Although the clinical evidence review did not find high-quality studies comparing the effectiveness of different tapering protocols for use when opioid dosage is reduced or opioids are discontinued (KQ3), tapers reducing weekly dosage by 10%–50% of the original dosage have been recommended by other clinical guidelines (*199*), and a rapid taper over 2–3 weeks has been recommended in the case of a severe adverse event such as overdose (*30*). Experts noted that tapers slower than 10% per week (e.g., 10% per month) also might be appropriate and better tolerated than more rapid tapers, particularly when patients have been taking opioids for longer durations (e.g., for years). Opioid withdrawal during pregnancy has been associated with spontaneous abortion and premature labor.

When opioids are reduced or discontinued, a taper slow enough to minimize symptoms and signs of opioid withdrawal (e.g., drug craving, anxiety, insomnia, abdominal pain, vomiting, diarrhea, diaphoresis, mydriasis, tremor, tachycardia, or piloerection) should be used. A decrease of 10% of the original dose per week is a reasonable starting point; experts agreed that tapering plans may be individualized based on patient goals and concerns. Experts noted that at times, tapers might have to be paused and restarted again when the patient is ready and might have to be slowed once patients reach low dosages. Tapers may be considered successful as long as the patient is making progress. Once the smallest available dose is reached, the interval between doses can be extended. Opioids may be stopped when taken less frequently than once a day. More rapid tapers might be needed for patient safety under certain circumstances (e.g., for patients who have experienced overdose on their current dosage). Ultrarapid detoxification under anesthesia is associated with substantial risks, including death, and should not be used (*200*). Clinicians should access appropriate expertise if considering tapering opioids during pregnancy because of possible risk to the pregnant patient and to the fetus if the patient goes into withdrawal. Patients who are not taking opioids (including patients who are diverting all opioids they obtain) do not require tapers. Clinicians should discuss with patients undergoing tapering the increased risk for overdose on abrupt return to a previously prescribed higher dose. Primary care clinicians should collaborate with mental health providers and with other specialists as needed to optimize nonopioid pain management (see Recommendation 1), as well as psychosocial support for anxiety related to the taper. More detailed guidance on tapering, including management of withdrawal symptoms has been published previously (*30*,*201*). If a patient exhibits signs of opioid use disorder, clinicians should offer or arrange for treatment of opioid use disorder (see Recommendation 12) and consider offering naloxone for overdose prevention (see Recommendation 8).

Assessing Risk and Addressing Harms of Opioid Use

8. Before starting and periodically during continuation of opioid therapy, clinicians should evaluate risk factors for opioid-related harms. Clinicians should incorporate into the management plan strategies to mitigate risk, including considering offering naloxone when factors that increase risk for opioid overdose, such as history of overdose, history of substance use disorder, higher opioid dosages (≥50 MME/day), or concurrent benzodiazepine use, are present (recommendation category: A, evidence type: 4).

The clinical evidence review found insufficient evidence to determine how harms of opioids differ depending on patient demographics or patient comorbidities (KQ2). However, based on the contextual evidence review and expert opinion, certain risk factors are likely to increase susceptibility to opioid-associated harms and warrant incorporation of additional strategies into the management plan to mitigate risk. Clinicians should assess these risk factors periodically, with frequency varying by risk factor and patient characteristics. For example, factors that vary more frequently over time, such as alcohol use, require more frequent follow up. In addition, clinicians should consider offering naloxone, re-evaluating patients more frequently (see Recommendation 7), and referring to pain and/or behavioral health specialists when factors that increase risk for harm, such as history of overdose, history of substance use disorder, higher dosages of opioids (≥50 MME/day), and concurrent use of benzodiazepines with opioids, are present.

Patients with Sleep-Disordered Breathing, Including Sleep Apnea

Risk factors for sleep-disordered breathing include congestive heart failure, and obesity. Experts noted that careful monitoring and cautious dose titration should be used if opioids are prescribed for patients with mild sleep-disordered breathing. Clinicians should avoid prescribing opioids to patients with moderate or severe sleep-disordered breathing whenever possible to minimize risks for opioid overdose (contextual evidence review).

Pregnant Women

Opioids used in pregnancy might be associated with additional risks to both mother and fetus. Some studies have shown an association of opioid use in pregnancy with stillbirth, poor fetal growth, pre-term delivery, and birth defects (contextual evidence review). Importantly, in some cases, opioid use during pregnancy leads to neonatal opioid withdrawal syndrome. Clinicians and patients together should carefully weigh risks and benefits when making decisions

about whether to initiate opioid therapy for chronic pain during pregnancy. In addition, before initiating opioid therapy for chronic pain for reproductive-age women, clinicians should discuss family planning and how long-term opioid use might affect any future pregnancy. For pregnant women already receiving opioids, clinicians should access appropriate expertise if considering tapering opioids because of possible risk to the pregnant patient and to the fetus if the patient goes into withdrawal (see Recommendation 7). For pregnant women with opioid use disorder, medication-assisted therapy with buprenorphine or methadone has been associated with improved maternal outcomes and should be offered (*202*) (see Recommendation 12). Clinicians caring for pregnant women receiving opioids for pain or receiving buprenorphine or methadone for opioid use disorder should arrange for delivery at a facility prepared to monitor, evaluate for, and treat neonatal opioid withdrawal syndrome. In instances when travel to such a facility would present an undue burden on the pregnant woman, it is appropriate to deliver locally, monitor and evaluate the newborn for neonatal opioid withdrawal syndrome, and transfer the newborn for additional treatment if needed. Neonatal toxicity and death have been reported in breast-feeding infants whose mothers are taking codeine (contextual evidence review); previous guidelines have recommended that codeine be avoided whenever possible among mothers who are breast feeding and, if used, should be limited to the lowest possible dose and to a 4-day supply (*203*).

Patients with Renal or Hepatic Insufficiency

Clinicians should use additional caution and increased monitoring (see Recommendation 7) to minimize risks of opioids prescribed for patients with renal or hepatic insufficiency, given their decreased ability to process and excrete drugs, susceptibility to accumulation of opioids, and reduced therapeutic window between safe dosages and dosages associated with respiratory depression and overdose (contextual evidence review; see Recommendations 4, 5, and 7).

Patients Aged ≥65 Years

Inadequate pain treatment among persons aged ≥65 years has been documented (*204*). Pain management for older patients can be challenging given increased risks of both nonopioid pharmacologic therapies (see Recommendation 1) and opioid therapy in this population. Given reduced renal function and medication clearance even in the absence of renal disease, patients aged ≥65 years might have increased susceptibility to accumulation of opioids and a smaller therapeutic window between safe dosages and dosages associated with respiratory depression and overdose (contextual evidence review). Some older adults suffer from cognitive impairment, which can increase risk for medication errors and make opioid-related confusion more dangerous. In addition, older adults are more likely than younger adults to experience co-morbid medical conditions and more likely to receive multiple medications, some of which might interact with opioids (such as benzodiazepines). Clinicians should use additional caution and increased monitoring (see Recommendations 4, 5, and 7) to minimize risks of opioids prescribed for patients aged ≥65 years. Experts suggested that clinicians educate older adults receiving opioids to avoid risky medication-related behaviors such as obtaining controlled medications from multiple prescribers and saving unused medications. Clinicians should also implement interventions to mitigate common risks of opioid therapy among older adults, such as exercise or bowel regimens to prevent constipation, risk assessment for falls, and patient monitoring for cognitive impairment.

Patients with Mental Health Conditions

Because psychological distress frequently interferes with improvement of pain and function in patients with chronic pain, using validated instruments such as the Generalized Anxiety Disorder (GAD)-7 and the Patient Health Questionnaire (PHQ)-9 or the PHQ-4 to assess for anxiety, post-traumatic stress disorder, and/or depression (*205*), might help clinicians improve overall pain treatment outcomes. Experts noted that clinicians should use additional caution and increased monitoring (see Recommendation 7) to lessen the increased risk for opioid use disorder among patients with mental health conditions (including depression, anxiety disorders, and PTSD), as well as increased risk for drug overdose among patients with depression. Previous guidelines have noted that opioid therapy should not be initiated during acute psychiatric instability or uncontrolled suicide risk, and that clinicians should consider behavioral health specialist consultation for any patient with a history of suicide attempt or psychiatric disorder (*31*). In addition, patients with anxiety disorders and other mental health conditions are more likely to receive benzodiazepines, which can exacerbate opioid-induced respiratory depression and increase risk for overdose (see Recommendation 11). Clinicians should ensure that treatment for depression and other mental health conditions is optimized, consulting with behavioral health specialists when needed. Treatment for depression can improve pain symptoms as well as depression and might decrease overdose risk (contextual evidence review). For treatment of chronic pain in patients with depression, clinicians should strongly consider using tricyclic or SNRI antidepressants for analgesic as well as antidepressant effects if these medications are not otherwise contraindicated (see Recommendation 1).

Patients with Substance Use Disorder

Illicit drugs and alcohol are listed as contributory factors on a substantial proportion of death certificates for opioid-related overdose deaths (contextual evidence review). Previous guidelines have recommended screening or risk assessment tools to identify patients at higher risk for misuse or abuse of opioids. However, the clinical evidence review found that currently available risk-stratification tools (e.g., Opioid Risk Tool, Screener and Opioid Assessment for Patients with Pain Version 1, SOAPP-R, and Brief Risk Interview) show insufficient accuracy for classification of patients as at low or high risk for abuse or misuse (KQ4). Clinicians should always exercise caution when considering or prescribing opioids for any patient with chronic pain outside of active cancer, palliative, and end-of-life care and should not overestimate the ability of these tools to rule out risks from long-term opioid therapy.

Clinicians should ask patients about their drug and alcohol use. Single screening questions can be used (*206*). For example, the question "How many times in the past year have you used an illegal drug or used a prescription medication for nonmedical reasons?" (with an answer of one or more considered positive) was found in a primary care setting to be 100% sensitive and 73.5% specific for the detection of a drug use disorder compared with a standardized diagnostic interview (*207*). Validated screening tools such as the Drug Abuse Screening Test (DAST) (*208*) and the Alcohol Use Disorders Identification Test (AUDIT) (*209*) can also be used. Clinicians should use PDMP data (see Recommendation 9) and drug testing (see Recommendation 10) as appropriate to assess for concurrent substance use that might place patients at higher risk for opioid use disorder and overdose. Clinicians should also provide specific counseling on increased risks for overdose when opioids are combined with other drugs or alcohol (see Recommendation 3) and ensure that patients receive effective treatment for substance use disorders when needed (see Recommendation 12).

The clinical evidence review found insufficient evidence to determine how harms of opioids differ depending on past or current substance use disorder (KQ2), although a history of substance use disorder was associated with misuse. Similarly, based on contextual evidence, patients with drug or alcohol use disorders are likely to experience greater risks for opioid use disorder and overdose than persons without these conditions. If clinicians consider opioid therapy for chronic pain outside of active cancer, palliative, and end-of-life care for patients with drug or alcohol use disorders, they should discuss increased risks for opioid use disorder and overdose with patients, carefully consider whether benefits of opioids outweigh increased risks, and incorporate strategies to mitigate risk into the management plan, such as considering offering naloxone (see Offering Naloxone to Patients When Factors That Increase Risk for Opioid-Related Harms Are Present) and increasing frequency of monitoring (see Recommendation 7) when opioids are prescribed. Because pain management in patients with substance use disorder can be complex, clinicians should consider consulting substance use disorder specialists and pain specialists regarding pain management for persons with active or recent past history of substance abuse. Experts also noted that clinicians should communicate with patients' substance use disorder treatment providers if opioids are prescribed.

Patients with Prior Nonfatal Overdose

Although studies were not identified that directly addressed the risk for overdose among patients with prior nonfatal overdose who are prescribed opioids, based on clinical experience, experts thought that prior nonfatal overdose would substantially increase risk for future nonfatal or fatal opioid overdose. If patients experience nonfatal opioid overdose, clinicians should work with them to reduce opioid dosage and to discontinue opioids when possible (see Recommendation 7). If clinicians continue opioid therapy for chronic pain outside of active cancer, palliative, and end-of-life care in patients with prior opioid overdose, they should discuss increased risks for overdose with patients, carefully consider whether benefits of opioids outweigh substantial risks, and incorporate strategies to mitigate risk into the management plan, such as considering offering naloxone (see Offering Naloxone to Patients When Factors That Increase Risk for Opioid-Related Harms Are Present) and increasing frequency of monitoring (see Recommendation 7) when opioids are prescribed.

Offering Naloxone to Patients When Factors That Increase Risk for Opioid-Related Harms Are Present

Naloxone is an opioid antagonist that can reverse severe respiratory depression; its administration by lay persons, such as friends and family of persons who experience opioid overdose, can save lives. Naloxone precipitates acute withdrawal among patients physically dependent on opioids. Serious adverse effects, such as pulmonary edema, cardiovascular instability, and seizures, have been reported but are rare at doses consistent with labeled use for opioid overdose (*210*). The contextual evidence review did not find any studies on effectiveness of prescribing naloxone for overdose prevention among patients prescribed opioids for chronic pain. However, there is evidence for effectiveness of naloxone provision in preventing opioid-related overdose death at the community level through community-based distribution (e.g., through overdose education and naloxone distribution programs in community service agencies) to persons at risk for overdose

(mostly due to illicit opiate use), and it is plausible that effectiveness would be observed when naloxone is provided in the clinical setting as well. Experts agreed that it is preferable not to initiate opioid treatment when factors that increase risk for opioid-related harms are present. Opinions diverged about the likelihood of naloxone being useful to patients and the circumstances under which it should be offered. However, most experts agreed that clinicians should consider offering naloxone when prescribing opioids to patients at increased risk for overdose, including patients with a history of overdose, patients with a history of substance use disorder, patients taking benzodiazepines with opioids (see Recommendation 11), patients at risk for returning to a high dose to which they are no longer tolerant (e.g., patients recently released from prison), and patients taking higher dosages of opioids (≥50 MME/day). Practices should provide education on overdose prevention and naloxone use to patients receiving naloxone prescriptions and to members of their households. Experts noted that naloxone co-prescribing can be facilitated by clinics or practices with resources to provide naloxone training and by collaborative practice models with pharmacists. Resources for prescribing naloxone in primary care settings can be found through Prescribe to Prevent at http://prescribetoprevent.org.

9. Clinicians should review the patient's history of controlled substance prescriptions using state prescription drug monitoring program (PDMP) data to determine whether the patient is receiving opioid dosages or dangerous combinations that put him or her at high risk for overdose. Clinicians should review PDMP data when starting opioid therapy for chronic pain and periodically during opioid therapy for chronic pain, ranging from every prescription to every 3 months (recommendation category: A, evidence type: 4).

PDMPs are state-based databases that collect information on controlled prescription drugs dispensed by pharmacies in most states and, in select states, by dispensing physicians as well. In addition, some clinicians employed by the federal government, including some clinicians in the Indian Health Care Delivery System, are not licensed in the states where they practice, and do not have access to PDMP data. Certain states require clinicians to review PDMP data prior to writing each opioid prescription (see state-level PDMP-related policies on the National Alliance for Model State Drug Laws website at http://www.namsdl.org/prescription-monitoring-programs.cfm). The clinical evidence review did not find studies evaluating the effectiveness of PDMPs on outcomes related to overdose, addiction, abuse, or misuse (KQ4). However, even though evidence is limited on the effectiveness of PDMP implementation at the state level on prescribing and mortality outcomes (*28*), the contextual evidence review found that most fatal overdoses were associated with patients receiving opioids from multiple prescribers and/or with patients receiving high total daily opioid dosages; information on both of these risk factors for overdose are available to prescribers in the PDMP. PDMP data also can be helpful when patient medication history is not otherwise available (e.g., for patients from other locales) and when patients transition care to a new clinician. The contextual evidence review also found that PDMP information could be used in a way that is harmful to patients. For example, it has been used to dismiss patients from clinician practices (*211*), which might adversely affect patient safety.

The contextual review found variation in state policies that affect timeliness of PDMP data (and therefore benefits of reviewing PDMP data) as well as time and workload for clinicians in accessing PDMP data. In states that permit delegating access to other members of the health care team, workload for prescribers can be reduced. These differences might result in a different balance of benefits to clinician workload in different states. Experts agreed that PDMPs are useful tools that should be consulted when starting a patient on opioid therapy and periodically during long-term opioid therapy. However, experts disagreed on how frequently clinicians should check the PDMP during long-term opioid therapy, given PDMP access issues and the lag time in reporting in some states. Most experts agreed that PDMP data should be reviewed every 3 months or more frequently during long-term opioid therapy. A minority of experts noted that, given the current burden of accessing PDMP data in some states and the lack of evidence surrounding the most effective interval for PDMP review to improve patient outcomes, annual review of PDMP data during long-term opioid therapy would be reasonable when factors that increase risk for opioid-related harms are not present.

Clinicians should review PDMP data for opioids and other controlled medications patients might have received from additional prescribers to determine whether a patient is receiving high total opioid dosages or dangerous combinations (e.g., opioids combined with benzodiazepines) that put him or her at high risk for overdose. Ideally, PDMP data should be reviewed before every opioid prescription. This is recommended in all states with well-functioning PDMPs and where PDMP access policies make this practicable (e.g., clinician and delegate access permitted), but it is not currently possible in states without functional PDMPs or in those that do not permit certain prescribers to access them. As vendors and practices facilitate integration of PDMP information into regular clinical workflow (e.g., data made available in electronic health records), clinicians' ease of access in reviewing PDMP data is expected to improve.

In addition, improved timeliness of PDMP data will improve their value in identifying patient risks.

If patients are found to have high opioid dosages, dangerous combinations of medications, or multiple controlled substance prescriptions written by different clinicians, several actions can be taken to augment clinicians' abilities to improve patient safety:

- Clinicians should discuss information from the PDMP with their patient and confirm that the patient is aware of the additional prescriptions. Occasionally, PDMP information can be incorrect (e.g., if the wrong name or birthdate has been entered, the patient uses a nickname or maiden name, or another person has used the patient's identity to obtain prescriptions).
- Clinicians should discuss safety concerns, including increased risk for respiratory depression and overdose, with patients found to be receiving opioids from more than one prescriber or receiving medications that increase risk when combined with opioids (e.g., benzodiazepines) and consider offering naloxone (see Recommendation 8).
- Clinicians should avoid prescribing opioids and benzodiazepines concurrently whenever possible. Clinicians should communicate with others managing the patient to discuss the patient's needs, prioritize patient goals, weigh risks of concurrent benzodiazepine and opioid exposure, and coordinate care (see Recommendation 11).
- Clinicians should calculate the total MME/day for concurrent opioid prescriptions to help assess the patient's overdose risk (see Recommendation 5). If patients are found to be receiving high total daily dosages of opioids, clinicians should discuss their safety concerns with the patient, consider tapering to a safer dosage (see Recommendations 5 and 7), and consider offering naloxone (see Recommendation 8).
- Clinicians should discuss safety concerns with other clinicians who are prescribing controlled substances for their patient. Ideally clinicians should first discuss concerns with their patient and inform him or her that they plan to coordinate care with the patient's other prescribers to improve the patient's safety.
- Clinicians should consider the possibility of a substance use disorder and discuss concerns with their patient (see Recommendation 12).
- If clinicians suspect their patient might be sharing or selling opioids and not taking them, clinicians should consider urine drug testing to assist in determining whether opioids can be discontinued without causing withdrawal (see Recommendations 7 and 10). A negative drug test for prescribed opioids might indicate the patient is not taking prescribed opioids, although clinicians should consider other possible reasons for this test result (see Recommendation 10).

Experts agreed that clinicians should not dismiss patients from their practice on the basis of PDMP information. Doing so can adversely affect patient safety, could represent patient abandonment, and could result in missed opportunities to provide potentially lifesaving information (e.g., about risks of opioids and overdose prevention) and interventions (e.g., safer prescriptions, nonopioid pain treatment [see Recommendation 1], naloxone [see Recommendation 8], and effective treatment for substance use disorder [see Recommendation 12]).

10. When prescribing opioids for chronic pain, clinicians should use urine drug testing before starting opioid therapy and consider urine drug testing at least annually to assess for prescribed medications as well as other controlled prescription drugs and illicit drugs (recommendation category: B, evidence type: 4).

Concurrent use of opioid pain medications with other opioid pain medications, benzodiazepines, or heroin can increase patients' risk for overdose. Urine drug tests can provide information about drug use that is not reported by the patient. In addition, urine drug tests can assist clinicians in identifying when patients are not taking opioids prescribed for them, which might in some cases indicate diversion or other clinically important issues such as difficulties with adverse effects. Urine drug tests do not provide accurate information about how much or what dose of opioids or other drugs a patient took. The clinical evidence review did not find studies evaluating the effectiveness of urine drug screening for risk mitigation during opioid prescribing for pain (KQ4). The contextual evidence review found that urine drug testing can provide useful information about patients assumed not to be using unreported drugs. Urine drug testing results can be subject to misinterpretation and might sometimes be associated with practices that might harm patients (e.g., stigmatization, inappropriate termination from care). Routine use of urine drug tests with standardized policies at the practice or clinic level might destigmatize their use. Although random drug testing also might destigmatize urine drug testing, experts thought that truly random testing was not feasible in clinical practice. Some clinics obtain a urine specimen at every visit, but only send it for testing on a random schedule. Experts noted that in addition to direct costs of urine drug testing, which often are not covered fully by insurance and can be a burden for patients, clinician time is needed to interpret, confirm, and communicate results.

Experts agreed that prior to starting opioids for chronic pain and periodically during opioid therapy, clinicians should

use urine drug testing to assess for prescribed opioids as well as other controlled substances and illicit drugs that increase risk for overdose when combined with opioids, including nonprescribed opioids, benzodiazepines, and heroin. There was some difference of opinion among experts as to whether this recommendation should apply to all patients, or whether this recommendation should entail individual decision making with different choices for different patients based on values, preferences, and clinical situations. While experts agreed that clinicians should use urine drug testing before initiating opioid therapy for chronic pain, they disagreed on how frequently urine drug testing should be conducted during long-term opioid therapy. Most experts agreed that urine drug testing at least annually for all patients was reasonable. Some experts noted that this interval might be too long in some cases and too short in others, and that the follow-up interval should be left to the discretion of the clinician. Previous guidelines have recommended more frequent urine drug testing in patients thought to be at higher risk for substance use disorder (*30*). However, experts thought that predicting risk prior to urine drug testing is challenging and that currently available tools do not allow clinicians to reliably identify patients who are at low risk for substance use disorder.

In most situations, initial urine drug testing can be performed with a relatively inexpensive immunoassay panel for commonly prescribed opioids and illicit drugs. Patients prescribed less commonly used opioids might require specific testing for those agents. The use of confirmatory testing adds substantial costs and should be based on the need to detect specific opioids that cannot be identified on standard immunoassays or on the presence of unexpected urine drug test results. Clinicians should be familiar with the drugs included in urine drug testing panels used in their practice and should understand how to interpret results for these drugs. For example, a positive "opiates" immunoassay detects morphine, which might reflect patient use of morphine, codeine, or heroin, but this immunoassay does not detect synthetic opioids (e.g., fentanyl or methadone) and might not detect semisynthetic opioids (e.g., oxycodone). However, many laboratories use an oxycodone immunoassay that detects oxycodone and oxymorphone. In some cases, positive results for specific opioids might reflect metabolites from opioids the patient is taking and might not mean the patient is taking the specific opioid for which the test was positive. For example, hydromorphone is a metabolite of hydrocodone, and oxymorphone is a metabolite of oxycodone. Detailed guidance on interpretation of urine drug test results, including which tests to order and expected results, drug detection time in urine, drug metabolism, and other considerations has been published previously (*30*). Clinicians should not test for substances for which results would not affect patient management or for which implications for patient management are unclear. For example, experts noted that there might be uncertainty about the clinical implications of a positive urine drug test for tetrahyrdocannabinol (THC). In addition, restricting confirmatory testing to situations and substances for which results can reasonably be expected to affect patient management can reduce costs of urine drug testing, given the substantial costs associated with confirmatory testing methods. Before ordering urine drug testing, clinicians should have a plan for responding to unexpected results. Clinicians should explain to patients that urine drug testing is intended to improve their safety and should also explain expected results (e.g., presence of prescribed medication and absence of drugs, including illicit drugs, not reported by the patient). Clinicians should ask patients about use of prescribed and other drugs and ask whether there might be unexpected results. This will provide an opportunity for patients to provide information about changes in their use of prescribed opioids or other drugs. Clinicians should discuss unexpected results with the local laboratory or toxicologist and with the patient. Discussion with patients prior to specific confirmatory testing can sometimes yield a candid explanation of why a particular substance is present or absent and obviate the need for expensive confirmatory testing on that visit. For example, a patient might explain that the test is negative for prescribed opioids because she felt opioids were no longer helping and discontinued them. If unexpected results are not explained, a confirmatory test using a method selective enough to differentiate specific opioids and metabolites (e.g., gas or liquid chromatography/mass spectrometry) might be warranted to clarify the situation.

Clinicians should use unexpected results to improve patient safety (e.g., change in pain management strategy [see Recommendation 1], tapering or discontinuation of opioids [see Recommendation 7], more frequent re-evaluation [see Recommendation 7], offering naloxone [see Recommendation 8], or referral for treatment for substance use disorder [see Recommendation 12], all as appropriate). If tests for prescribed opioids are repeatedly negative, confirming that the patient is not taking the prescribed opioid, clinicians can discontinue the prescription without a taper. Clinicians should not dismiss patients from care based on a urine drug test result because this could constitute patient abandonment and could have adverse consequences for patient safety, potentially including the patient obtaining opioids from alternative sources and the clinician missing opportunities to facilitate treatment for substance use disorder.

11. Clinicians should avoid prescribing opioid pain medication and benzodiazepines concurrently

whenever possible (recommendation category: A, evidence type: 3).

Benzodiazepines and opioids both cause central nervous system depression and can decrease respiratory drive. Concurrent use is likely to put patients at greater risk for potentially fatal overdose. The clinical evidence review did not address risks of benzodiazepine co-prescription among patients prescribed opioids. However, the contextual evidence review found evidence in epidemiologic series of concurrent benzodiazepine use in large proportions of opioid-related overdose deaths, and a case-cohort study found concurrent benzodiazepine prescription with opioid prescription to be associated with a near quadrupling of risk for overdose death compared with opioid prescription alone (*212*). Experts agreed that although there are circumstances when it might be appropriate to prescribe opioids to a patient receiving benzodiazepines (e.g., severe acute pain in a patient taking long-term, stable low-dose benzodiazepine therapy), clinicians should avoid prescribing opioids and benzodiazepines concurrently whenever possible. In addition, given that other central nervous system depressants (e.g., muscle relaxants, hypnotics) can potentiate central nervous system depression associated with opioids, clinicians should consider whether benefits outweigh risks of concurrent use of these drugs. Clinicians should check the PDMP for concurrent controlled medications prescribed by other clinicians (see Recommendation 9) and should consider involving pharmacists and pain specialists as part of the management team when opioids are co-prescribed with other central nervous system depressants. Because of greater risks of benzodiazepine withdrawal relative to opioid withdrawal, and because tapering opioids can be associated with anxiety, when patients receiving both benzodiazepines and opioids require tapering to reduce risk for fatal respiratory depression, it might be safer and more practical to taper opioids first (see Recommendation 7). Clinicians should taper benzodiazepines gradually if discontinued because abrupt withdrawal can be associated with rebound anxiety, hallucinations, seizures, delirium tremens, and, in rare cases, death (contextual evidence review). A commonly used tapering schedule that has been used safely and with moderate success is a reduction of the benzodiazepine dose by 25% every 1–2 weeks (*213*,*214*). CBT increases tapering success rates and might be particularly helpful for patients struggling with a benzodiazepine taper (*213*). If benzodiazepines prescribed for anxiety are tapered or discontinued, or if patients receiving opioids require treatment for anxiety, evidence-based psychotherapies (e.g., CBT) and/or specific anti-depressants or other nonbenzodiazepine medications approved for anxiety should be offered. Experts emphasized that clinicians should communicate with mental health professionals managing the patient to discuss the patient's needs, prioritize patient goals, weigh risks of concurrent benzodiazepine and opioid exposure, and coordinate care.

12. Clinicians should offer or arrange evidence-based treatment (usually medication-assisted treatment with buprenorphine or methadone in combination with behavioral therapies) for patients with opioid use disorder (recommendation category: A, evidence type: 2).

Opioid use disorder (previously classified as opioid abuse or opioid dependence) is defined in the *Diagnostic and Statistical Manual of Mental Disorders*, 5th edition (DSM-5) as a problematic pattern of opioid use leading to clinically significant impairment or distress, manifested by at least two defined criteria occurring within a year (http://pcssmat.org/wp-content/uploads/2014/02/5B-DSM-5-Opioid-Use-Disorder-Diagnostic-Criteria.pdf) (*20*).

The clinical evidence review found prevalence of opioid dependence (using DSM-IV diagnosis criteria) in primary care settings among patients with chronic pain on opioid therapy to be 3%–26% (KQ2). As found in the contextual evidence review and supported by moderate quality evidence, opioid agonist or partial agonist treatment with methadone maintenance therapy or buprenorphine has been shown to be more effective in preventing relapse among patients with opioid use disorder (*151–153*). Some studies suggest that using behavioral therapies in combination with these treatments can reduce opioid misuse and increase retention during maintenance therapy and improve compliance after detoxification (*154*,*155*); behavioral therapies are also recommended by clinical practice guidelines (*215*). The cited studies primarily evaluated patients with a history of illicit opioid use, rather than prescription opioid use for chronic pain. Recent studies among patients with prescription opioid dependence (based on DSM-IV criteria) have found maintenance therapy with buprenorphine and buprenorphine-naloxone effective in preventing relapse (*216*,*217*). Treatment need in a community is often not met by capacity to provide buprenorphine or methadone maintenance therapy (*218*), and patient cost can be a barrier to buprenorphine treatment because insurance coverage of buprenorphine for opioid use disorder is often limited (*219*). Oral or long-acting injectable formulations of naltrexone can also be used as medication-assisted treatment for opioid use disorder in nonpregnant adults, particularly for highly motivated persons (*220*,*221*). Experts agreed that clinicians prescribing opioids should identify treatment resources for opioid use disorder in the community and should work together to ensure sufficient treatment capacity for opioid use disorder at the practice level.

If clinicians suspect opioid use disorder based on patient concerns or behaviors or on findings in prescription drug monitoring program data (see Recommendation 9) or from urine drug testing (see Recommendation 10), they should discuss their concern with their patient and provide an opportunity for the patient to disclose related concerns or problems. Clinicians should assess for the presence of opioid use disorder using DSM-5 criteria (*20*). Alternatively, clinicians can arrange for a substance use disorder treatment specialist to assess for the presence of opioid use disorder. For patients meeting criteria for opioid use disorder, clinicians should offer or arrange for patients to receive evidence-based treatment, usually medication-assisted treatment with buprenorphine or methadone maintenance therapy in combination with behavioral therapies. Oral or long-acting injectable naltrexone, a long-acting opioid antagonist, can also be used in nonpregnant adults. Naltrexone blocks the effects of opioids if they are used but requires adherence to daily oral therapy or monthly injections. For pregnant women with opioid use disorder, medication-assisted therapy with buprenorphine (without naloxone) or methadone has been associated with improved maternal outcomes and should be offered (see Recommendation 8). Clinicians should also consider offering naloxone for overdose prevention to patients with opioid use disorder (see Recommendation 8). For patients with problematic opioid use that does not meet criteria for opioid use disorder, experts noted that clinicians can offer to taper and discontinue opioids (see Recommendation 7). For patients who choose to but are unable to taper, clinicians may reassess for opioid use disorder and offer opioid agonist therapy if criteria are met.

Physicians not already certified to provide buprenorphine in an office-based setting can undergo training to receive a waiver from the Substance Abuse and Mental Health Services Administration (SAMHSA) that allows them to prescribe buprenorphine to treat patients with opioid use disorder. Physicians prescribing opioids in communities without sufficient treatment capacity for opioid use disorder should strongly consider obtaining this waiver. Information about qualifications and the process to obtain a waiver are available from SAMHSA (*222*). Clinicians do not need a waiver to offer naltrexone for opioid use disorder as part of their practice.

Additional guidance has been published previously (*215*) on induction, use, and monitoring of buprenorphine treatment (see Part 5) and naltrexone treatment (see Part 6) for opioid use disorder and on goals, components of, and types of effective psychosocial treatment that are recommended in conjunction with pharmacological treatment of opioid use disorder (see Part 7). Clinicians unable to provide treatment themselves should arrange for patients with opioid use disorder to receive care from a substance use disorder treatment specialist, such as an office-based buprenorphine or naltrexone treatment provider, or from an opioid treatment program certified by SAMHSA to provide supervised medication-assisted treatment for patients with opioid use disorder. Clinicians should assist patients in finding qualified treatment providers and should arrange for patients to follow up with these providers, as well as arranging for ongoing coordination of care. Clinicians should not dismiss patients from their practice because of a substance use disorder because this can adversely affect patient safety and could represent patient abandonment. Identification of substance use disorder represents an opportunity for a clinician to initiate potentially life-saving interventions, and it is important for the clinician to collaborate with the patient regarding their safety to increase the likelihood of successful treatment. In addition, although identification of an opioid use disorder can alter the expected benefits and risks of opioid therapy for pain, patients with co-occurring pain and substance use disorder require ongoing pain management that maximizes benefits relative to risks. Clinicians should continue to use nonpharmacologic and nonopioid pharmacologic pain treatments as appropriate (see Recommendation 1) and consider consulting a pain specialist as needed to provide optimal pain management.

Resources to help with arranging for treatment include SAMHSA's buprenorphine physician locator (http://buprenorphine.samhsa.gov/bwns_locator); SAMHSA's Opioid Treatment Program Directory (http://dpt2.samhsa.gov/treatment/directory.aspx); SAMHSA's Provider Clinical Support System for Opioid Therapies (http://pcss-o.org), which offers extensive experience in the treatment of substance use disorders and specifically of opioid use disorder, as well as expertise on the interface of pain and opioid misuse; and SAMHSA's Provider's Clinical Support System for Medication-Assisted Treatment (http://pcssmat.org), which offers expert physician mentors to answer questions about assessment for and treatment of substance use disorders.

Conclusions and Future Directions

Clinical guidelines represent one strategy for improving prescribing practices and health outcomes. Efforts are required to disseminate the guideline and achieve widespread adoption and implementation of the recommendations in clinical settings. CDC will translate this guideline into user-friendly materials for distribution and use by health systems, medical professional societies, insurers, public health departments, health information technology developers, and clinicians and engage in dissemination efforts. CDC has provided a

checklist for prescribing opioids for chronic pain (http://stacks.cdc.gov/view/cdc/38025), additional resources such as fact sheets (http://www.cdc.gov/drugoverdose/prescribing/resources.html), and will provide a mobile application to guide clinicians in implementing the recommendations. CDC will also work with partners to support clinician education on pain management options, opioid therapy, and risk mitigation strategies (e.g., urine drug testing). Activities such as development of clinical decision support in electronic health records to assist clinicians' treatment decisions at the point of care; identification of mechanisms that insurers and pharmacy benefit plan managers can use to promote safer prescribing within plans; and development of clinical quality improvement measures and initiatives to improve prescribing and patient care within health systems have promise for increasing guideline adoption and improving practice. In addition, policy initiatives that address barriers to implementation of the guidelines, such as increasing accessibility of PDMP data within and across states, e-prescribing, and availability of clinicians who can offer medication-assisted treatment for opioid use disorder, are strategies to consider to enhance implementation of the recommended practices. CDC will work with federal partners and payers to evaluate strategies such as payment reform and health care delivery models that could improve patient health and safety. For example, strategies might include strengthened coverage for nonpharmacologic treatments, appropriate urine drug testing, and medication-assisted treatment; reimbursable time for patient counseling; and payment models that improve access to interdisciplinary, coordinated care.

As highlighted in the forthcoming report on the National Pain Strategy, an overarching federal effort that outlines a comprehensive population-level health strategy for addressing pain as a public health problem, clinical guidelines complement other strategies aimed at preventing illnesses and injuries that lead to pain. A draft of the National Pain Strategy has been published previously (*180*). These strategies include strengthening the evidence base for pain prevention and treatment strategies, reducing disparities in pain treatment, improving service delivery and reimbursement, supporting professional education and training, and providing public education. It is important that overall improvements be made in developing the workforce to address pain management in general, in addition to opioid prescribing specifically. This guideline also complements other federal efforts focused on addressing the opioid overdose epidemic including prescriber training and education, improving access to treatment for opioid use disorder, safe storage and disposal programs, utilization management mechanisms, naloxone distribution programs, law enforcement and supply reduction efforts, prescription drug monitoring program improvements, and support for community coalitions and state prevention programs.

This guideline provides recommendations that are based on the best available evidence that was interpreted and informed by expert opinion. The clinical scientific evidence informing the recommendations is low in quality. To inform future guideline development, more research is necessary to fill in critical evidence gaps. The evidence reviews forming the basis of this guideline clearly illustrate that there is much yet to be learned about the effectiveness, safety, and economic efficiency of long-term opioid therapy. As highlighted by an expert panel in a recent workshop sponsored by the National Institutes of Health on the role of opioid pain medications in the treatment of chronic pain, "evidence is insufficient for every clinical decision that a provider needs to make about the use of opioids for chronic pain" (*223*). The National Institutes of Health panel recommended that research is needed to improve our understanding of which types of pain, specific diseases, and patients are most likely to be associated with benefit and harm from opioid pain medications; evaluate multidisciplinary pain interventions; estimate cost-benefit; develop and validate tools for identification of patient risk and outcomes; assess the effectiveness and harms of opioid pain medications with alternative study designs; and investigate risk identification and mitigation strategies and their effects on patient and public health outcomes. It is also important to obtain data to inform the cost feasibility and cost-effectiveness of recommended actions, such as use of nonpharmacologic therapy and urine drug testing. Research that contributes to safer and more effective pain treatment can be implemented across public health entities and federal agencies (*4*). Additional research can inform the development of future guidelines for special populations that could not be adequately addressed in this guideline, such as children and adolescents, where evidence and guidance is needed but currently lacking. CDC is committed to working with partners to identify the highest priority research areas to build the evidence base. Yet, given that chronic pain is recognized as a significant public health problem, the risks associated with long-term opioid therapy, the availability of effective nonpharmacological and nonopioid pharmacologic treatment options for pain, and the potential for improvement in the quality of health care with the implementation of recommended practices, a guideline for prescribing is warranted with the evidence that is currently available. The balance between the benefits and the risks of long-term opioid therapy for chronic pain based on both clinical and contextual evidence is strong enough to support the issuance of category A recommendations in most cases.

CDC will revisit this guideline as new evidence becomes available to determine when evidence gaps have been sufficiently closed to warrant an update of the guideline. Until this research is conducted, clinical practice guidelines will have to be based on the best available evidence and expert opinion. This guideline is intended to improve communication between clinicians and patients about the risks and benefits of opioid therapy for chronic pain, improve the safety and effectiveness of pain treatment, and reduce the risks associated with long-term opioid therapy, including opioid use disorder, overdose, and death. CDC is committed to evaluating the guideline to identify the impact of the recommendations on clinician and patient outcomes, both intended and unintended, and revising the recommendations in future updates when warranted.

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TABLE 1. Grading of Recommendations Assessment, Development and Evaluation (GRADE) clinical evidence review ratings of the evidence for the key clinical questions regarding effectiveness and risks of long-term opioid therapy for chronic pain

Outcome	Studies	Limitations	Inconsistency	Imprecision	Type of evidence	Other factors	Estimates of effect/findings
Effectiveness and comparative effectiveness (KQ1)							
Effectiveness of long-term opioid therapy versus placebo or no opioid therapy for long-term (≥1 year) outcomes							
Pain, function, and quality of life	None	—[†]	—	—	Insufficient	—	No evidence
Harms and adverse events (KQ2)							
Risks of opioids versus placebo or no opioids on opioid abuse, addiction, and related outcomes; overdose; and other harms							
Abuse or addiction	1 cohort study (n = 568,640)	Serious limitations	Unknown (1 study)	No imprecision	3	None identified	One retrospective cohort study found long-term use of prescribed opioids associated with an increased risk of abuse or dependence diagnosis versus no opioid use (adjusted OR ranged from 14.9 to 122.5, depending on dose).
Abuse or addiction	10 uncontrolled studies (n = 3,780)	Very serious limitations	Very serious inconsistency	No imprecision	4	None identified	In primary care settings, prevalence of opioid abuse ranged from 0.6% to 8% and prevalence of dependence from 3% to 26%. In pain clinic settings, prevalence of misuse ranged from 8% to 16% and addiction from 2% to 14%. Prevalence of aberrant drug-related behaviors ranged from 6% to 37%.
Overdose	1 cohort study (n = 9,940)	Serious limitations	Unknown (1 study)	Serious imprecision	3	None identified	Current opioid use associated with increased risk of any overdose events (adjusted HR 5.2, 95% CI = 2.1–12) and serious overdose events (adjusted HR 8.4, 95% CI = 2.5–28) versus current nonuse.
Fractures	1 cohort study (n = 2,341) and 1 case–control study (n = 21,739 case patients)	Serious limitations	No inconsistency	No imprecision	3	None identified	Opioid use associated with increased risk of fracture in 1 cohort study (adjusted HR 1.28, 95% CI = 0.99–1.64) and 1 case-control study (adjusted OR 1.27, 95% CI = 1.21–1.33).
Myocardial infarction	1 cohort study (n = 426,124) and 1 case–control study (n = 11,693 case patients)	No limitations	No inconsistency	No imprecision	3	None identified	Current opioid use associated with increased risk of myocardial infarction versus nonuse (adjusted OR 1.28, 95% CI = 1.19–1.37 and incidence rate ratio 2.66, 95% CI = 2.30–3.08).
Endocrinologic harms	1 cross-sectional study (n = 11,327)	Serious limitations	Unknown (1 study)	No imprecision	3	None identified	Long-term opioid use associated with increased risk for use of medications for erectile dysfunction or testosterone replacement versus nonuse (adjusted OR 1.5, 95% CI = 1.1–1.9).
How do harms vary depending on the opioid dose used?							
Abuse or addiction	1 cohort study (n = 568,640)	Serious limitations	Unknown (1 study)	No imprecision	3	None identified	One retrospective cohort study found higher doses of long-term opioid therapy associated with increased risk of opioid abuse or dependence than lower doses. Compared to no opioid prescription, the adjusted odds ratios were 15 (95% CI = 10–21) for 1 to 36 MME/day, 29 (95 % CI = 20–41) for 36 to120 MME/day, and 122 (95 % CI = 73–205) for ≥120 MME/day.
Overdose	1 cohort study (n = 9,940) and 1 case–control study (n = 593 case patients in primary analysis)	Serious limitations	No inconsistency	No imprecision	3	Magnitude of effect, dose response relationship	Versus 1 to <20 MME/day, one cohort study found an adjusted HR for an overdose event of 1.44 (95% CI = 0.57–3.62) for 20 to <50 MME/day that increased to 8.87 (95% CI = 3.99–19.72) at ≥100 MME/day; one case-control study found an adjusted OR for an opioid-related death of 1.32 (95% CI = 0.94–1.84) for 20 to 49 MME/day that increased to 2.88 (95% CI = 1.79–4.63) at ≥200 MME/day.
Fractures	1 cohort study (n = 2,341)	Serious limitations	Unknown (1 study)	Serious imprecision	3	None identified	Risk of fracture increased from an adjusted HR of 1.20 (95% CI = 0.92–1.56) at 1 to <20 MME/day to 2.00 (95% CI = 1.24–3.24) at ≥50 MME/day; the trend was of borderline statistical significance.

See table footnotes on page 47.

TABLE 1. (*Continued*) Grading of Recommendations Assessment, Development and Evaluation (GRADE) clinical evidence review ratings of the evidence for the key clinical questions regarding effectiveness and risks of long-term opioid therapy for chronic pain

Outcome	Studies	Limitations	Inconsistency	Imprecision	Type of evidence	Other factors	Estimates of effect/findings
Myocardial infarction	1 cohort study (n = 426,124)	Serious limitations	Unknown (1 study)	No imprecision	3	None identified	Relative to a cumulative dose of 0 to 1,350 MME during a 90-day period, the incidence rate ratio for myocardial infarction for 1350 to <2700 MME was 1.21 (95% CI = 1.02–1.45), for 2,700 to <8,100 MME was 1.42 (95% CI = 1.21–1.67), for 8,100 to <18,000 MME was 1.89 (95% CI = 1.54–2.33), and for ≥18,000 MME was 1.73 (95% CI = 1.32–2.26).
Motor vehicle crash injuries	1 case–control study (n = 5,300 case patients)	No limitations	Unknown (1 study)	No imprecision	3	None identified	No association between opioid dose and risk of motor vehicle crash injuries even though opioid doses >20 MME/day were associated with increased odds of road trauma among drivers.
Endocrinologic harms	1 cross-sectional study (n = 11,327) New for update: 1 additional cross-sectional study (n=1,585)	Serious limitations	Consistent	No imprecision	3	None identified	Relative to 0 to <20 MME/day, the adjusted OR for ≥120 MME/day for use of medications for erectile dysfunction or testosterone replacement was 1.6 (95% CI = 1.0–2.4). One new cross-sectional study found higher-dose long-term opioid therapy associated with increased risk of androgen deficiency among men receiving immediate-release opioids (adjusted OR per 10 MME/day 1.16, 95% CI = 1.09–1.23), but the dose response was very weak among men receiving ER/LA opioids.
Dosing strategies (KQ3)							
Comparative effectiveness of different methods for initiating opioid therapy and titrating doses							
Pain	3 randomized trials (n = 93)	Serious limitations	Serious inconsistency	Very serious imprecision	4	None identified	Trials on effects of titration with immediate-release versus ER/LA opioids reported inconsistent results and had additional differences between treatment arms in dosing protocols (titrated versus fixed dosing) and doses of opioids used.
Overdose	New for update: 1 cohort study (n = 840,606)	Serious limitations	Unknown (1 study)	No imprecision	4	None identified	One new cross-sectional study found initiation of therapy with an ER/LA opioid associated with increased risk of overdose versus initiation with an immediate-release opioid (adjusted HR 2.33, 95% CI = 1.26–4.32).
Comparative effectiveness of different ER/LA opioids							
Pain and function	3 randomized trials (n = 1,850)	Serious limitations	No inconsistency	No imprecision	3	None identified	No differences
All-cause mortality	1 cohort study (n = 108,492) New for update: 1 cohort study (n = 38,756)	Serious limitations	Serious inconsistency	No imprecision	4	None identified	One cohort study found methadone to be associated with lower all-cause mortality risk than sustained-release morphine in a propensity-adjusted analysis (adjusted HR 0.56, 95% CI = 0.51–0.62) and one cohort study among Tennessee Medicaid patients found methadone to be associated with higher risk of all-cause mortality than sustained-release morphine (adjusted HR 1.46, 95% CI = 1.17–1.73).
Abuse and related outcomes	1 cohort study (n = 5,684)	Serious limitations	Unknown (1 study)	Serious imprecision	4	None identified	One cohort study found some differences between ER/LA opioids in rates of adverse outcomes related to abuse, but outcomes were nonspecific for opioid-related adverse events, precluding reliable conclusions.
ER/LA versus immediate-release opioids							
Endocrinologic harms	New for update: 1 cross-sectional study (n = 1,585)	Serious limitations	Unknown (1 study)	No imprecision	4	None identified	One cross-sectional study found ER/LA opioids associated with increased risk of androgen deficiency versus immediate-release opioids (adjusted OR 3.39, 95% CI = 2.39–4.77).

See table footnotes on page 47.

TABLE 1. (*Continued*) Grading of Recommendations Assessment, Development and Evaluation (GRADE) clinical evidence review ratings of the evidence for the key clinical questions regarding effectiveness and risks of long-term opioid therapy for chronic pain

Outcome	Studies	Limitations	Inconsistency	Imprecision	Type of evidence	Other factors	Estimates of effect/findings
Dose escalation versus dose maintenance or use of dose thresholds							
Pain, function, or withdrawal due to opioid misuse	1 randomized trial (n = 140)	Serious limitations	Unknown (1 study)	Very serious imprecision	3	None identified	No difference between more liberal dose escalation versus maintenance of current doses in pain, function, or risk of withdrawal due to opioid misuse, but there was limited separation in opioid doses between groups (52 versus 40 MME/day at the end of the trial).
Immediate-release versus ER/LA opioids; immediate-release plus ER/LA opioids versus ER/LA opioids alone; scheduled and continuous versus as-needed dosing of opioids; or opioid rotation versus maintenance of current therapy							
Pain, function, quality of life, and outcomes related to abuse	None	—	—	—	Insufficient	—	No evidence
Effects of decreasing or tapering opioid doses versus continuation of opioid therapy							
Pain and function	1 randomized trial (n = 10)	Very serious limitations	Unknown (1 study)	Very serious imprecision	4	None identified	Abrupt cessation of morphine was associated with increased pain and decreased function compared with continuation of morphine.
Comparative effectiveness of different tapering protocols and strategies							
Opioid abstinence	2 nonrandomized trials (n = 150)	Very serious limitations	No inconsistency	Very serious imprecision	4	None identified	No clear differences between different methods for opioid discontinuation or tapering in likelihood of opioid abstinence after 3–6 months
Risk assessment and risk mitigation strategies (KQ4)							
Diagnostic accuracy of instruments for predicting risk for opioid overdose, addiction, abuse, or misuse among patients with chronic pain being considered for long-term opioid therapy							
Opioid risk tool	3 studies of diagnostic accuracy (n = 496) New for update: 2 studies of diagnostic accuracy (n = 320)	Serious limitations	Very serious inconsistency	Serious imprecision	4	None identified	Based on a cutoff score of >4 (or unspecified), five studies (two fair-quality, three poor-quality) reported sensitivity that ranged from 0.20 to 0.99 and specificity that ranged from 0.16 to 0.88.
Screener and Opioid Assessment for Patients with Pain, Version 1	2 studies of diagnostic accuracy (n = 203)	Very serious limitations	No inconsistency	Serious imprecision	3	None identified	Based on a cutoff score of ≥8, sensitivity was 0.68 and specificity was 0.38 in one study, for a positive likelihood ratio of 1.11 and a negative likelihood ratio of 0.83. Based on a cutoff score of >6, sensitivity was 0.73 in one study.
Screener and Opioid Assessment for Patients with Pain-Revised	New for update: 2 studies of diagnostic accuracy (n = 320)	Very serious limitations	No inconsistency	Serious imprecision	3	None identified	Based on a cutoff score of >3 or unspecified, sensitivity was 0.25 and 0.53 and specificity was 0.62 and 0.73 in two studies, for likelihood ratios close to 1.
Brief Risk Interview	New for update: 2 studies of diagnostic accuracy (n = 320)	Very serious limitations	No inconsistency	Serious imprecision	3	None identified	Based on a "high risk" assessment, sensitivity was 0.73 and 0.83 and specificity was 0.43 and 0.88 in two studies, for positive likelihood ratios of 1.28 and 7.18 and negative likelihood ratios of 0.63 and 0.19.

See table footnotes on page 47.

TABLE 1. (*Continued*) Grading of Recommendations Assessment, Development and Evaluation (GRADE) clinical evidence review ratings of the evidence for the key clinical questions regarding effectiveness and risks of long-term opioid therapy for chronic pain

Outcome	Studies	Limitations	Inconsistency	Imprecision	Type of evidence	Other factors	Estimates of effect/findings
Effectiveness of risk prediction instruments on outcomes related to overdose, addiction, abuse, or misuse in patients with chronic pain							
Outcomes related to abuse	None	—	—	—	Insufficient	—	No evidence
Effectiveness of risk mitigation strategies, including opioid management plans, patient education, urine drug screening, use of prescription drug monitoring program data, use of monitoring instruments, more frequent monitoring intervals, pill counts, and use of abuse-deterrent formulations, on outcomes related to overdose, addiction, abuse, or misuse							
Outcomes related to abuse	None	—	—	—	Insufficient	—	No evidence
Effectiveness of risk prediction instruments on outcomes related to overdose, addiction, abuse, or misuse in patients with chronic pain							
Outcomes related to abuse	None	—	—	—	Insufficient	—	No evidence
Effectiveness of risk mitigation strategies, including opioid management plans, patient education, urine drug screening, use of prescription drug monitoring program data, use of monitoring instruments, more frequent monitoring intervals, pill counts, and use of abuse-deterrent formulations, on outcomes related to overdose, addiction, abuse, or misuse							
Outcomes related to abuse	None	—	—	—	Insufficient	—	No evidence
Comparative effectiveness of treatment strategies for managing patients with addiction to prescription opioids							
Outcomes related to abuse	None	—	—	—	Insufficient	—	No evidence
Effects of opioid therapy for acute pain on long-term use (KQ5)							
Long-term opioid use	New for update: 2 cohort studies (n = 399,852)	Serious limitations	No inconsistency	No imprecision	3	None identified	One study found use of opioids within 7 days of low-risk surgery associated with increased likelihood of opioid use at 1 year (adjusted OR 1.44, 95% CI = 1.39–1.50), and one study found use of opioids within 15 days of onset of low back pain among workers with a compensation claim associated with increased risk of late opioid use (adjusted OR 2.08, 95% CI = 1.55–2.78 for 1 to 140 MME/day and OR 6.14, 95% CI = 4.92–7.66 for ≥450 MME/day).

Abbreviations: CI = confidence interval; ER/LA = extended release/long-acting; HR = hazard ratio; MME = morphine milligram equivalents; OR = odds ratio.
* Ratings were made per GRADE quality assessment criteria; "no limitations" indicates that limitations assessed through the GRADE method were not identified.
† Not applicable as no evidence was available for rating.

TABLE 2. Morphine milligram equivalent (MME) doses for commonly prescribed opioids

Opioid	Conversion factor*
Codeine	0.15
Fentanyl transdermal (in mcg/hr)	2.4
Hydrocodone	1
Hydromorphone	4
Methadone	
1–20 mg/day	4
21–40 mg/day	8
41–60 mg/day	10
≥61–80 mg/day	12
Morphine	1
Oxycodone	1.5
Oxymorphone	3
Tapentadol†	0.4

Source: Adapted from Von Korff M, Saunders K, Ray GT, et al. Clin J Pain 2008;24:521–7 and Washington State Interagency Guideline on Prescribing Opioids for Pain (http://www.agencymeddirectors.wa.gov/Files/2015AMDGOpioidGuideline.pdf).

* Multiply the dose for each opioid by the conversion factor to determine the dose in MMEs. For example, tablets containing hydrocodone 5 mg and acetaminophen 300 mg taken four times a day would contain a total of 20 mg of hydrocodone daily, equivalent to 20 MME daily; extended-release tablets containing oxycodone 10mg and taken twice a day would contain a total of 20mg of oxycodone daily, equivalent to 30 MME daily. The following cautions should be noted: 1) All doses are in mg/day except for fentanyl, which is mcg/hr. 2) Equianalgesic dose conversions are only estimates and cannot account for individual variability in genetics and pharmacokinetics. 3) Do not use the calculated dose in MMEs to determine the doses to use when converting opioid to another; when converting opioids the new opioid is typically dosed at substantially lower than the calculated MME dose to avoid accidental overdose due to incomplete cross-tolerance and individual variability in opioid pharmacokinetics. 4) Use particular caution with methadone dose conversions because the conversion factor increases at higher doses. 5) Use particular caution with fentanyl since it is dosed in mcg/hr instead of mg/day, and its absorption is affected by heat and other factors.

† Tapentadol is a mu receptor agonist and norepinephrine reuptake inhibitor. MMEs are based on degree of mu-receptor agonist activity, but it is unknown if this drug is associated with overdose in the same dose-dependent manner as observed with medications that are solely mu receptor agonists.

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National Pain Strategy

A Comprehensive Population Health-Level Strategy for Pain

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EXECUTIVE SUMMARY

In 2010, the National Institutes of Health (NIH) contracted with the Institute of Medicine (IOM) to undertake a study and make recommendations "to increase the recognition of pain as a significant public health problem in the United States." The resulting 2011 IOM report called for a cultural transformation in pain prevention, care, education, and research and recommended development of "a comprehensive population health-level strategy" to address these issues.[1] In response to the report, the Assistant Secretary for Health, Department of Health and Human Services (HHS) asked the Interagency Pain Research Coordinating Committee (IPRCC) to oversee creation of this National Pain Strategy (NPS). Experts from a broad array of public and private organizations explored areas identified in the core IOM recommendations—population research, prevention and care, disparities, service delivery and reimbursement, professional education and training, and public awareness and communication. A companion effort is underway to address the IOM's call for further research to support the cultural transformation.

As articulated in the IOM report, efforts to reduce the burden of pain in the United States cannot be achieved without an expanded and sustained investment in basic and clinical research on the biopsychosocial mechanisms that produce and maintain chronic pain and development of safe and effective pain treatments. As a first step to respond to the full set of research recommendations of the IOM, the IPRCC and the NIH completed a comprehensive analysis of the existing federal pain research portfolio.[i] The next step is development of the Federal Pain Research Strategy which will complement the NPS. It will identify gaps in our research agenda and recommend directions for new research to guide federal entities in their support of essential pain research programs.

Findings and recommendations from the IOM report[1] guided the development of the National Pain Strategy (NPS). These included:

- The public at large and people with pain would benefit from a better understanding of pain and its treatment in order to encourage timely care, improve medical management, and combat stigmatization.
- Increased scientific knowledge regarding the pathophysiology of pain has led to the conclusion that chronic pain can be a disease in itself that requires adequate treatment and a research commitment.
- Chronic pain is a biopsychosocial condition that often requires integrated, multimodal, and interdisciplinary treatment, all components of which should be evidence-based.
- Data are lacking on the prevalence, onset, course, impact, and outcomes of most common chronic pain conditions. The greatest individual and societal benefit would accrue from a focus on chronic pain.
- Every effort should be made to prevent illnesses and injuries that lead to pain, the progression of acute pain to a chronic condition, and the development of high-impact chronic pain.
- Significant improvements are needed to ensure that pain assessment techniques and practices are high-quality and comprehensive.

[i] The Interagency Pain Research Data Base and Summary Report can be found at: http://iprcc.nih.gov/portfolio_analysis/portfolio_analysis-index.htm

- Self-management programs can improve quality of life and are an important component of acute and chronic pain prevention and management.
- People with chronic pain need treatment approaches that take into account individual differences in susceptibility for pain and response to treatment, as well as improved access to treatments that take into account their preferences and are in accord with best evidence on safety and effectiveness.
- Treatments that are ineffective, whose risks exceed their benefits, or that may cause harm for certain subgroups need to be identified and their use curtailed or discontinued.
- Much of the responsibility for front-line pain care rests with primary care clinicians who are not sufficiently trained in pain assessment and comprehensive, evidence-based treatment approaches.
- Greater collaboration is needed between primary care clinicians and pain specialists in different clinical disciplines and settings, including multispecialty pain clinics.
- Significant barriers to pain care exist, especially for populations disproportionately affected by and undertreated for pain[2,3,4] and need to be overcome.
- People with pain are too often stigmatized in the health care system and in society, which can lead to delayed diagnosis or misdiagnosis, bias in treatment, and decreased effectiveness of care.[5]

The objectives and action plans developed in this report to address the core IOM findings and recommendations are summarized below by work group topics and include:

Population Research

Understanding the significance of health problems in a population is a core public health responsibility. To increase the quantity and quality of what is known about chronic pain within the U.S. population, the NPS recommends specific steps to increase the precision of information about chronic pain prevalence overall, for specific types of pain, and in specific population groups and to track changes in pain prevalence, impact, treatment over time, to enable evaluation of population-level interventions and identification of emerging needs. It also recommends development of the capacity to gather information electronically about pain treatments, their usage, costs, effectiveness, and safety.

Prevention and Care

Prevention of acute and chronic pain, especially primary prevention strategies, needs greater emphasis throughout the health care system, including delivery of long term services and supports, and in environments where injuries are likely to occur (e.g. the workplace), and among people at increased risk of developing chronic pain. When chronic pain develops, treatment should begin with a comprehensive assessment, followed by creation of a care plan that can evolve over time to address the full range of biological, psychological, and social effects of pain on the individual. The NPS recommends strengthening the evidence base for pain prevention strategies, assessment tools, and outcome measures—particularly those relevant for primary care—in part through the development of new, rigorously researched approaches. It also recommends improvements in pain self-management programs that can

help affected individuals improve their knowledge, skills, and confidence to prevent, reduce, and cope with pain, and minimize treatment risks and adverse effects.

Disparities

Pain is more prevalent or disabling and/or care is inadequate in certain vulnerable populations including people with limited access to health care services, racial and ethnic minorities, people with low income or education, children, older adults, and those at increased risk because of where they live or work, or because of limited communication skills.[2,3] Many of these groups face additional problems of stigmatization and bias in pain care.[3,4,5] To eliminate disparities and promote equity in pain assessment and treatment, the NPS recommends efforts aimed at increasing understanding of the impact of bias and supporting effective strategies to overcome it; increasing access to high-quality pain care for vulnerable population groups; and improving communication among patients and health professionals.

Service Delivery and Payment

Evidence suggests that wide variations in clinical practice, inadequate tailoring of pain therapies to individuals, and reliance on relatively ineffective and potentially high risk treatments such as inappropriate prescribing of opioid analgesics, or certain surgical interventions, not only contribute to poor quality care for people with pain, but also increase health care costs.[1,6,7] The NPS recommends a population-based, biopsychosocial approach to pain care that is grounded in scientific evidence, integrated, multimodal, and interdisciplinary, while tailored to an individual patient's needs. Research and demonstration efforts are needed that build on current knowledge, develop new knowledge, and support further testing and diffusion of model delivery systems.

Professional Education and Training

Although pain is one of the most common reasons for health care visits, most health profession education programs have yet to give it adequate attention.[8] The NPS recommends steps to improve discipline-specific core competencies, including basic knowledge, assessment, effective team-based care, empathy, and cultural competency. It encourages educational program accreditation bodies and professional licensure boards to require pain teaching and clinician learning at the undergraduate and graduate levels. The NPS also recommends development of a web-based pain education portal that would contain up-to-date, comprehensive, and easily accessed educational materials. These training efforts should be made in coordination with current HHS efforts to develop tools for providers to recognize the risk factors and symptoms of opioid use disorders.[ii]

[ii] Examples of ongoing government efforts, such as the prescriber training developed as part of opioid risk mitigation strategies appropriate prescribing of extended-release and long-acting (ER/LA) opioid analgesics is included in the FDA Blueprint for Prescriber Education that is part of the FDA-approved Risk Evaluation and Mitigation Strategy for Extended-Release and Long-Acting Opioid Analgesics. http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm163647.htm and the Secretary's Initiative on Opioids: Objectives to improve clinical decision making: http://aspe.hhs.gov/basic-report/opioid-abuse-us-and-hhs-actions-address-opioid-drug-related-overdoses-and-deaths

Public Education and Communication

Key to a cultural transformation in pain care is a greater understanding—among members of the public and people with pain alike—of important aspects of chronic pain and its appropriate treatment. The National Pain Strategy recommends a national public awareness campaign involving public and private partners to address misperceptions and stigma about chronic pain. The learning objectives of the campaign would emphasize the impact and seriousness of chronic pain and its status as a disease that requires appropriate treatment. In addition, an educational campaign on the safer use of pain medications that is targeted to people with pain whose care includes these medications is recommended.

Next Steps for Implementation

Sustained efforts across HHS, working through operating divisions, staff divisions, and also with non-governmental partners, will be required in order to implement the public health, clinical, and research initiatives described in this Strategy. These efforts will help to prevent pain, improve patient care and outcomes, assure appropriate patient and provider education, and advance pain-related applied research. The Office of the Assistant Secretary for Health (OASH), in conjunction with HHS operating and staff divisions, will consider the recommendations included in the Strategy and develop an implementation and evaluation plan based on this process.

THE NATIONAL PAIN STRATEGY: A Vision

The objectives of the National Pain Strategy aim to decrease the prevalence of pain across its continuum from acute to high-impact chronic pain and its associated morbidity and disability across the lifespan. The intent is to reduce the burden of pain for individuals, their families, and society as a whole. The Strategy envisions an environment in which:

- People experiencing pain would have timely access to patient-centered care that meets their biopsychosocial needs and takes into account individual preferences, risks, and social contexts, including dependence and addiction.
- People with pain would have access to educational materials and learn effective approaches for pain self-management programs to prevent, cope with, and reduce pain and its disability.
- Patients, including those with low literacy or communication disabilities, would have access to information they can understand about the benefits and risks of treatment options, such as those associated with prescription opioid analgesics.
- All people with pain would be assured of receiving needed preventive, assessment, treatment, and self-management interventions, regardless of race, color, nationality, ethnicity, religion, income, gender, sex, age (neonatal through end of life), mental health and substance use disorders, physical or cognitive disability, sexual orientation and gender identification, geographic location, education, language proficiency, health literacy, or medical condition. All pain-related services would be provided without bias, discrimination, or stigmatization.

- Americans would recognize chronic pain as a complex disease and a threat to public health and productivity. Individuals who live with chronic pain would be viewed and treated with compassion and respect.
- Clinicians would take active measures to prevent the progression of acute to chronic pain and its associated disabilities.
- Clinicians would undertake comprehensive assessments of patients with chronic pain, leading to an integrated, patient-centered plan of coordinated care, managed by an interdisciplinary team, when needed. Treatment would involve high-quality, state-of-the-art, multimodal, evidence-based practices. While most pain care would be coordinated by primary care practitioners, specialists would be involved in the care of patients who have increased co-morbidities, complexity, or are at risk for dependence or addiction.
- Clinicians would receive better education and training on biopsychosocial characteristics and safe and appropriate management of pain. Clinician's knowledge would be broadened to encompass an understanding of individual variability in pain susceptibility and treatment response, the importance of shared (patient-providers) and informed decision-making, ways to encourage pain self-management, appropriate prescribing practices, how empathy and cultural sensitivity influence the effectiveness of care, and the role of complementary and integrative medicine.
- Payment structures would support population-based care models of proven effectiveness in interdisciplinary settings and encourage multimodal care aimed at improving a full range of patient outcomes.
- Electronic data on pain assessment and treatment would be standardized, and health systems would maintain pain data registries that include information on the psychosocial/functional impact of chronic pain and the costs and effectiveness of pain management interventions. These data resources would be used in an ongoing effort to evaluate, compare, and enhance health care systems, identify areas for further research, and assess therapies for quality and value.
- The evolution toward a public health approach to pain prevention and care would be facilitated by epidemiologic, health services, social science, medical informatics, implementation, basic, translational, and clinical research, informed by clinician/scientist interactions.
- Data on the health and economic burdens of chronic pain would guide federal and state governments and health care organizations in their efforts to work toward these objectives. Such data would lay the groundwork for enhancing the effectiveness and safety of pain care overall and for specific population groups and would enable monitoring of the effectiveness of policy initiatives, public education efforts, and changing treatment patterns.
- A more robust and well trained behavioral health work force would be available to support the needs of patients who suffer from chronic pain, including those at risk who need mental health care and substance abuse prevention and recovery treatment.
- The actions in this strategy would be undertaken in the context of the dual crises of pain and opioid dependence, overdose, and death in the United States. Actions to improve pain care and patient access to and appropriate use of opioid analgesics for pain management would be coordinated and balanced with the need to curb inappropriate prescribing and use practices. To achieve this balance a broad range of stakeholders including those engaged in pain care

and pain care policies, as well as those working in substance use prevention, treatment, and recovery, would be engaged as the actions of the NPS are undertaken.

BACKGROUND

The 2010 Patient Protection and Affordable Care Act (PPACA) Section 4305, required the Secretary of HHS to enter into an agreement with the IOM for activities to increase the recognition of pain as a significant public health problem, identify and reduce barriers to appropriate care, evaluate the adequacy of assessment, diagnosis, treatment, and management of acute and chronic pain across the population, and improve pain care research, education and care. As a result, HHS, working through the NIH, commissioned an IOM study to assess the state of pain care. The IOM report, issued in June 2011,[1] included 16 recommendations for improvements in:

- data collection and reporting
- the availability and effectiveness of pain care
- public, patient, and professional education about pain
- relevant basic, translational, and clinical research

The IOM's emphasis on pain as a significant public health challenge, amenable to population health-level interventions, placed a large share of responsibility for implementing these recommendations on federal health agencies (Institute of Medicine, 2011, p. 5). Specifically, Recommendation 2-2 called for creation of "a comprehensive population health-level strategy for pain prevention, treatment, management, and research."

The following year, HHS created the IPRCC[iii] to coordinate all pain research efforts within HHS and across other Federal Agencies. In October 2012, the Assistant Secretary for Health asked the IPRCC to oversee the creation of the comprehensive population health-level strategy envisioned in IOM Recommendation 2-2. The IPRCC and NIH established a framework for developing a National Pain Strategy, in consultation with the Chair and Vice Chair of the IOM Committee.[iv]

The six key areas addressed in the National Pain Strategy are:

- population research
- prevention and care
- disparities
- service delivery and payment
- professional education and training
- public education and communication

The IPRCC selected expert working group members to address each of these key areas and created an oversight panel (Appendices A and B) to guide and coordinate the working groups' interrelated efforts. Nominations for working group and oversight panel membership were solicited from professional

[iii] A list of the federal agency, scientific, public, and ex-officio members of the IPRCC can be found at http://iprcc.nih.gov/about/committee/committee-roster.htm.

[iv] Philip Pizzo, MD, former dean, Stanford University School of Medicine; Noreen Clark, PhD, Director, Center for Managing Chronic Disease, University of Michigan (deceased).

societies, federal and state agencies, private foundations, advocacy organizations, and through the Federal Register (Appendix C). The goal was broad representation from relevant public and private organizations, health care providers, insurers, and people with pain and their advocates, as recommended by the IOM committee. The body of this report is structured to reflect the results of the work groups' deliberations. Each of the six sections includes a statement of the problem and a set of priority objectives with accompanying discrete and achievable deliverables to address the problem. The time frame for completion of deliverables is presented as short (approximately one year), medium (two to four years), and long term (within five years). Stakeholders best positioned to achieve the deliverables are identified and metrics to assess progress are suggested.

The report is intended to initiate a longer-term effort to create a cultural transformation in how pain is perceived, assessed, and treated—a significant step toward the ideal state of pain care. An ensuing companion strategy to address the crucial contribution of research to the NPS objectives also is being developed by the IPRCC.

Box 1 contains definitions of terms frequently used in this report.

Box 1
Definitions

Acute pain is an expected physiologic experience to noxious stimuli that can become pathologic, is normally sudden in onset, time limited, and motivates behaviors to avoid actual or potential tissue injuries.

Biopsychosocial refers to a medical problem or intervention that combines biological, psychological, and social elements or aspects.

Chronic pain is pain that occurs on at least half the days for six months or more.

Complementary health approaches are mind and body practices and natural products of non-mainstream origin, including chiropractic and osteopathic manipulation, meditation, massage, relaxation, yoga, acupuncture, and naturopathic medicine.

Continuum of pain is the characterization of pain as a temporal process, beginning with an acute stage, which may progress to a chronic state of variable duration.

Disease management refers to a system of integrated, multidisciplinary interventions and communications for populations with chronic disorders in which self-care efforts are significant.

Disparities refers to the definition created by Healthy People 2020,[v] terming disparities "a particular type of health difference that is closely linked with social, economic, and/or environmental disadvantage. Health disparities adversely affect groups of people who have systematically experienced greater obstacles to health based on their racial or ethnic group; religion; socioeconomic status; gender; age; mental health; cognitive, sensory, or physical disability; sexual orientation or gender identity; geographic location; or other characteristics historically linked to discrimination or exclusion." The work group recognizes that this definition is not tailored to the unique nature of pain and, further, that age disparities in this report include those faced by children from infancy to adolescence and those in older adulthood.

High-impact chronic pain is associated with substantial restriction of participation in work, social, and self-care activities for six months or more. This term is introduced in the NPS for development of research tools that will allow population level data collection on the degree to which pain interferes with peoples' lives.

Integrated care is the systematic coordination of medical, psychological and social aspects of health care and includes primary care, mental health care, and, when needed, specialist services.

[v] http://www.healthypeople.gov/sites/default/files/PhaseI_0.pdf

Integrative health care incorporates complementary approaches into mainstream health care to achieve health and wellness.

Interdisciplinary care is provided by a team of health professionals from diverse fields who coordinate their skills and resources to meet patient goals.

Intractable pain is defined as pain that is not relieved by appropriate treatment.

Levels of care are offered by *primary care* practitioners, who provide routine screenings and assessment and management of common pain conditions due to headache, diabetes, arthritis, and low back pain, for example; *pain medicine specialists* who provide secondary-level consultations, which can include multidisciplinary team-based care, including rehabilitation therapy and behavioral health care; and *interdisciplinary pain centers* which provide tertiary care through advanced pain medicine diagnostics and interventions.

Multimodal pain treatment addresses the full range of an individual patient's biopsychosocial challenges by providing a range of multiple and different types of therapies that may include medical, surgical, psychological, behavioral, and integrative approaches as needed.

Opioid Use Disorder occurs when recurrent use of prescription opioid analgesics (opioid based pain relievers) and /or illegal opioids such as heroin, causes clinically and functionally significant impairment and failure to meet major responsibilities at work, school, or home. Diagnosis is based on inability to control or reduce use, social impairment, tolerance and other physiological signs, and pharmacological criteria.

Pain self-management programs address the systematic provision of education and supportive interventions by health care providers to strengthen patients' skills and confidence in medical management, role management, and emotional management of their health problems, including regular assessment of progress and problems, decision making, goal setting, self-monitoring, and problem solving. Specifically for pain self-management, these programs involve acquiring knowledge about pain and building skills and confidence to prevent, cope with, and reduce pain. These programs can include a broad range of complementary health approaches. These programs can stand alone and be individually directed, be integrated into health care settings, or offered by community agencies.

Prevention as it relates to pain addresses three tiers. *Primary prevention* includes efforts to reduce injuries or diseases that may result in pain. *Secondary prevention* includes interventions designed to reduce the likelihood that acute pain transitions into chronic pain. *Tertiary prevention* interventions attempt to limit the development of disabilities and other complications of chronic pain after it has developed.

INTRODUCTION

Acute pain is an unpleasant, though normal sensory experience in response to a noxious stimulus and plays an important protective role by alerting a person to actual or potential physical injury. Painful symptoms often can be self-managed while the underlying cause resolves and recovery occurs. Such instances generally require little or no professional intervention. Acute pain does not always resolve as expected however, especially if it is associated with a serious disease or condition, or begins with an injury that does not receive timely or appropriate medical care. When pain persists after the underlying cause is resolved, it may signal that pain-initiated changes in the central nervous system have occurred. If so, this chronic pain is no longer a symptom of another disorder and has become the disease itself.[9]

The persistence of pain creates a complex biopsychosocial phenomenon that may interfere with many aspects of a person's life—ability to work, social activities, and both physical and mental health.[10,11] Secondary psychosocial and physical problems in turn, can worsen pain, posing escalating threats to health and well-being[12]and chronic pain has been linked to premature death.[13] These overwhelming challenges of living with chronic pain contribute to a suicide rate that is higher than that of the general population.[14,15] Many factors influence the way individual patients perceive and cope with pain and the likelihood they will seek and receive care and respond to treatment. Past experiences, familial and genetic factors (including race, sex, and gender), comorbidities, cultural background, and psychological, economic, and environmental factors all play a role.[16,17] Despite the complexity of pain and its care, pain education, research, and treatment historically have focused narrowly on the pathophysiological mechanisms involved in chronic pain. This approach inadvertently encourages a "magic bullet" approach to treatment, deemphasizing the many other factors that, if overlooked, may result in futile treatment and rehabilitation. Other factors affect quality of patient care throughout the continuum of pain and are exemplified by wide variations that exist in clinical practices related to pain prevention, assessment, and treatment. Care is often fragmented and lacks a comprehensive assessment or treatment plan, and patients may encounter difficulty accessing the full range of potential treatments.[6] According to the IOM report, most Americans who live with chronic pain do not receive appropriate care.[1]

Chronic pain and its treatment can be a lifelong challenge at the individual level and is a significant public health problem. Population level surveys indicate that between 11% and 40% of the U.S. population report some level of chronic pain, with millions suffering from daily, severe, and disabling pain.[18,19,20,21] Some population groups, whether defined by age, sex, gender, race/ethnicity, geographic isolation, socioeconomic status, occupation, or other characteristics are differentially affected by certain pain conditions, have less access to pain prevention, assessment, and treatment services, and experience worse outcomes.[3,4] Nationwide, patients face many systemic hurdles to appropriate care, including those driven by provider attitudes, biases and stereotyping of patients.[5,6] Inadequate provider training and payment policies may contribute to unnecessary diagnostic tests and procedures and ineffective, risky treatments.[6,7] These situations likely contribute to the high health care costs associated with chronic pain. High direct medical care costs, as well as costs associated with disability programs,

lost productivity, and family burden all contribute to the IOM annual cost estimate of $560 billion to $635 billion.[vi,22,23]

More precise assessments of the incidence, prevalence, and disability associated with pain in the U.S. population and subpopulations are needed to establish a reliable basis for population-wide interventions, and a baseline to assess treatments for the physical, psychological, social, and economic burdens of pain, as well as barriers to quality care. Viewing chronic pain from a public health perspective allows patients, families, clinicians, and policymakers to benefit from available public health knowledge and disease models and adds precision to the concept of pain prevention. This melding of a public health mindset and personalized treatment offers the best chance to improve all Americans' access to high-quality and more cost-effective pain care. Public health concerns related to the misuse or diversion of prescription opioid pain medications and risk for dependence and overdose with long term opioid prescribing add another layer of complexity to the management of chronic pain and need to be considered during development of policies and programs related to pain management. As part of a public health effort over the past few decades to improve pain management, the broader prescribing of opioids led to a significant rise in adverse health consequences, including misuse, addiction, and overdose deaths. Prescribing practices, marketing, and misleading information on safety drove a steady and significant increase in the number of opioid prescriptions dispensed, rising from 76 million in 1999 to 219 million in 2011.[24] The amount per prescription, the duration of the supply, and the cumulative dose prescribed also increased.[25] These dramatic increases paralleled rises in opioid-related substance abuse treatment admissions[26] and rates of opioid-involved overdose deaths, which reached 28,647 in 2014.[27,28] Certain behaviors and risk factors that make people vulnerable to prescription opioid pain medication abuse or overdose have been identified.[29] Understanding these factors is important to enable identification of populations at highest risk and for development of and improved access to interventions that target these high-risk groups.

Programs to curb inappropriate prescribing practices and prescription opioid abuse must be balanced with the use of and access to these drugs for appropriate and quality pain management. Primary care physicians treat the majority of chronic pain patients and some primary care physicians report reluctance to prescribe opioids for chronic non-cancer pain because of concerns over dependence, addiction and abuse behaviors.[30,31,32,33] Pharmacy shortages and regulated dispensing policies[34] might result in inadequate treatment for those patients where the benefits of opioids outweigh the risks. While all patients who are on opioid therapy for chronic pain are at risk for opioid use disorder, limited recent studies have shown that most (74-96%) of these patients use their prescriptions without suffering from opioid addiction.[35,36,37] All people with pain should receive adequate care.

In some clinical contexts, opioids can help manage pain when other pain medicines have not or are not expected to provide enough pain relief. A recent conference to assess the safety and efficacy of long-term opioid use for chronic pain found no studies on their long term effects (more than one year) on pain, function, or quality of life. While the report states clearly that there are some patients for whom opioids are the best treatment for their chronic pain, it concluded that further research is needed to guide appropriate patient assessment, opioid selection, dosing strategies, and risk mitigation. However, for

[vi] These cost estimates were based on the U.S. adult non-institutionalized civilian population and, therefore, exclude children, prisoners, people in nursing homes or other institutional settings, and the military.

many more, there are likely to be more effective approaches.[38] The Centers for Disease Control and Prevention is developing a guideline for opioid prescribing for chronic pain outside of active cancer treatment, palliative care, and end-of-life care. Improving the way opioids are prescribed through clinical practice guidelines will help to improve the safety of treatment and reduce risks associated with long-term opioid therapy including abuse, dependence, overdose, and death. Providers also need better training in safer and more effective prescribing practices, recognizing risks of adverse effects, and approaches to proactively facilitate access to addiction treatment for patients at risk. These efforts represent areas in need of more research and development to ensure that pain management is team based, personalized, multidisciplinary, patient-centered, and available to those who need it.

Access to safe and effective care for people suffering from pain remains a priority that needs to be balanced in parallel with efforts to curb inappropriate opioid prescribing and use practices. A population with improved pain prevention and care and less pain would mitigate the need for prescription opioid analgesics. This need for balance underscores the importance of engaging with a broad range of stakeholders, including those engaged in pain care and pain care policies, as well as those working in opioid abuse prevention and treatment, as the actions of the NPS are undertaken.

The NPS recognizes that opportunities to prevent the conditions and events that lead to chronic pain, such as those associated with the work place and lifestyles must not be missed. Furthermore, evidence-based strategies to intervene early to prevent acute pain from becoming a chronic condition and the research to develop them are needed. It notes that effective pain care must emphasize shared decision-making, informed pain assessment, and integrated, multimodal, and interdisciplinary treatment approaches that balance effectiveness with safety. These objectives require a better trained workforce. Even though pain is a leading cause of primary care visits, clinicians are generally under-trained in ways to assess and effectively manage pain. Improvements in professional education about state-of-the-art care for pain, in all its dimensions, including better communication, empathy, cultural sensitivity, and risk management will yield significant care improvements. In parallel with provider training, a robust public education effort may lend support and knowledge to people with pain, and to the clinicians, researchers, and advocates working to prevent and reduce the impact of pain among Americans. This effort will improve understanding of chronic pain and its significance among individuals, families, and society and increase knowledge about the availability of more effective treatment approaches.

The U.S. health care system is evolving toward a care model that is patient-centered, evidence- and outcomes-guided yet personalized, and provided through high-performing, interdisciplinary care teams. This evolution suggests that development of a National Pain Strategy is timely. Opportunities for improvements in care may arise with the increasing emphasis on team-based care and care coordination, facilitated by the adoption of health information technology, including electronic health records (EHRs) continued health services delivery research, and implementation of better models. More effective delivery of services, supported by appropriate health care system features and payment are essential to the “cultural transformation” called for in the IOM report.

IOM underlying principles that informed development of this National Pain Strategy (Box 2)

Box 2
IOM Committee Underlying Principles*

- ***A moral imperative.*** Effective pain management is a moral imperative, a professional responsibility, and the duty of people in the healing professions.
- ***Chronic pain can be a disease in itself.*** Chronic pain has a distinct pathology, causing changes throughout the nervous system that often worsen over time. It has significant psychological and cognitive correlates and can constitute a serious, separate disease entity.
- ***Value of comprehensive treatment.*** Pain results from a combination of biological, psychological, and social factors and often requires comprehensive approaches to prevention and management.
- ***Need for interdisciplinary approaches.*** Given chronic pain's diverse effects, interdisciplinary assessment and treatment may produce the best results for people with the most severe and persistent pain problems.
- ***Importance of prevention.*** Chronic pain can have such severe impacts on all aspects of the lives of people who have it that every effort should be made to achieve both primary prevention (e.g., workplace ergonomics) and secondary prevention (of the transition from the acute to the chronic state) through early intervention.
- ***Wider use of existing knowledge.*** While there is much more to be learned about pain and its treatment, even existing knowledge is not always used effectively, and thus substantial numbers of people suffer unnecessarily.
- ***The conundrum of opioids.*** The committee recognizes the serious problem of diversion and abuse of opioid drugs, as well as questions about their usefulness long-term, but believes that when opioids are used as prescribed and appropriately monitored, they can be safe and effective, especially for acute, post-operative, and procedural pain, as well as for patients near the end of life who desire more pain relief.
- ***Roles for patients and clinicians.*** The effectiveness of pain treatments depends greatly on the strength of the clinician-patient relationship; pain treatment is never about the clinician's intervention alone, but about the clinician and patient (and family) working together.
- ***Value of a public health and community-based approach.*** Many features of the problem of pain lend themselves to public health approaches--a concern about the large number of people affected, disparities in occurrence and treatment, and the goal of prevention cited above. Public health education can help counter the myths, misunderstandings, stereotypes, and stigmatization that hinder better care.

*Institute of Medicine, 2011, *op. cit*., p. 3.

REPORTS FROM THE WORKING GROUPS

Population Research

The 2011 IOM report led to growing recognition of the impact of pain on the health, productivity, and well-being of the U.S. population. Efforts to lower the impact of chronic pain at the individual and population levels need to be guided by population-based data. The quality and quantity of information being gathered on pain and its treatment needs to be improved in order to collect essential data on the prevalence, onset, course, impact, and outcomes for most common chronic pain conditions. These data will help guide policies and initiatives of federal and state governments, health care organizations, and insurers.

A core responsibility of public health agencies is assessing the significance of health problems in the population. These calculations typically reflect a problem's incidence, prevalence, and severity (morbidity, mortality, and disability) in the population as a whole, across the lifespan, and in relevant groups defined by demographic characteristics, geography, or other parameters of interest. For chronic pain, better data are needed to understand the scope of the problem and to guide action, including efforts to reduce the impact of chronic pain through primary, secondary, and tertiary prevention. Such estimates of impact are needed in order to define health care workforce and service delivery needs and priorities for insurance benefits, as well as for monitoring the quality, safety, effectiveness, and costs of relevant programs and policies. Population research is an essential tool in the implementation of the NPS.

The World Health Organization's International Classification of Functioning, Disability and Health (ICF) considers determinants of health and disability from the perspective of the biopsychosocial model.[39] The following ICF concepts are relevant to defining chronic pain:[40,41,42,43]

Impairments: Problems with body structure or function
Activities: The execution of a task or action by an individual
Activity limitations: Difficulties an individual may have in executing activities
Participation: Involvement in a life situation
Participation restrictions: Problems experienced in life situation or social role involvement

Three inter-related manifestations of chronic pain define its overall individual and societal impact: perception, activity limitations, and participation restrictions. Lower to intermediate levels of pain severity are less likely to significantly impact social, recreational and vocational functioning, while more severe levels are associated with activity limitations and participation restrictions.[25] The IOM report emphasized that chronic pain affects to some extent, and estimated that over 100 million adults in the U.S.[1] It is important to differentiate people with *high-impact chronic pain* from those who maintain normal activities although experiencing chronic pain. Accordingly, the pain assessment tools proposed for population research in chronic pain (Appendixes D-F) are designed to identify people in the general population who suffer from chronic pain at various levels of severity, including those who have *high-impact chronic pain* based on the degree to which pain limits their ability to participate in work, social, or self-care activities.

The pain assessment tools proposed for population research use the definitions of chronic pain and high-impact chronic pain, which are based in part on the widely used definition of chronic pain recommended by the International Association for the Study of Pain,[44] modified to account for intermittent pain.

The Problem: Population level data on prevalence, onset, course, impact, and outcomes are not adequate to guide policies, and practices to improve pain care. Improvements in data methods and measures are needed to:

(1) guide efforts to reduce the burden of chronic pain through more accurate estimates of the prevalence of chronic pain and high-impact chronic pain in the general population and within population groups defined by demographic factors (age, sex, gender, race, ethnicity, education, and socioeconomic status) and geographic areas, including identification of risk factors that predispose towards the development of chronic pain;

(2) provide standard methods and metrics for the analysis of electronic health care data related to pain treatment, which can reveal patterns of health services utilization, including over- and under-treatment, costs, and, most important, quality of care; (analyses should consider the need to gather information on use of self-care practices and complementary approaches that are not captured through health records);

(3) develop a system of metrics for tracking changes in pain prevalence, impact, treatment and barriers to treatment, and costs over time that will enable assessment of progress, evaluation of the effectiveness of interventions at the population health level—such as public education or changes in public policy, insurance benefits, treatments, and organization of care—and identification of emerging needs; (analyses should consider the need to track and account for lack of access to services).

The intent of the Population Research section is to provide methods and metrics to guide progress toward achieving improved prevention (primary, secondary, and tertiary) and management of pain in the United States.

Objective 1: **Estimate the prevalence of chronic pain and "high-impact chronic pain" in the general population and in primary care settings, both overall and for anatomically defined pain conditions and for various population groups.** [vii]

Short-term (approximately one year) strategies and deliverables:

- Engage active population researchers to test a set of proposed pain screener questions (Appendix D) and brief self-assessment questions about high-impact chronic pain (Appendix E) in an existing and representative population sample and among those whose pain treatment pattern suggests high-impact chronic pain is likely.
- Convene key stakeholders to review questions related to pain in current national population surveys[45] and make recommendations regarding the appropriateness of standardizing, adding, or revising questions to bring these surveys in line with the NPS-proposed self-assessment questions in Appendixes D and E.

[vii] Stratified by age, sex, gender, race and ethnicity, education, socioeconomic status, health status, and indicators of biopsychosocial resiliencies and vulnerabilities

- Conduct additional evaluative studies of the NPS-proposed self-assessment questions and any alternative questions including cognitive testing and translation into other languages.
- Prepare a manuscript for submission to a peer-reviewed journal reporting the results of the tests of the proposed brief pain self-assessment questionnaire.

Medium-term (two to four years) strategies and deliverables:

- Convene key stakeholders to refine self-assessment questions and measurement strategies and to build support for and facilitate implementation of the proposed population-based measurement and evaluation components of the National Pain Strategy.
- Incorporate a brief pain self-assessment questionnaire resulting from this process into at least one national morbidity survey, and schedule initial implementation of data collection using these items.

Long-term (within five years) strategies and deliverables:

- Use the increasingly refined measures developed to evaluate longitudinal pain outcomes including post-acute care evaluations, the Minimum Data Set, and other comparable population-based tools, from among populations covered through Medicare, Medicaid, and then those privately insured.
- Modify the measures as needed to evaluate longitudinal pain outcomes among vulnerable and special populations (including workers in high risk occupations, pediatric populations, those exposed to early trauma, individuals with physical and cognitive disabilities, and older adults).

Federal Stakeholders:

- Administration for Community Living (ACL), Agency for Healthcare Research Quality (AHRQ), Centers for Disease Control and Prevention (CDC), Centers for Medicare & Medicaid Services (CMS), Department of Defense (DoD), NIH, National Prevention Council (NPC), Veterans Health Administration (VHA)

Collaborators:

- public and private health insurers
- researchers
- health care provider and professional organizations
- patient advocacy organizations and people with pain

Metrics: The screener tool should be validated through a larger population level study (short-term). The progress of the refinement of the assessment tool by expert panels (medium-term) and its incorporation into national morbidity surveys and its application to determining longitudinal pain outcomes among public and private health care beneficiaries (long-term) should be monitored.

Objective 2: **Refine and employ standardized electronic health care data methods to determine the extent to which people with common pain conditions, including those from vulnerable groups, receive various treatments and services, the costs of these services, and the extent of use of treatments that evidence has shown are effective and underused or ineffective and overused.**

Short-term (approximately one year) strategies and deliverables:

- Carry out proof-of-concept analyses with large public and private health care databases to identify patterns of pharmacological and non-pharmacological treatments among people in specified diagnostic clusters[viii] (Appendix F) and their associated costs. This activity would provide insights regarding disparities in pain care, as well as how different payment models affect both patterns of treatment and costs across a sampling of the general population.
- Prepare a manuscript for submission to a peer-reviewed journal reporting the results of the proof-of-concept analyses of health care data on diagnostic clusters and pain treatment indicators and related recommendations.
- Encourage CMS to issue rules to make adequate pain control measures, including clinical quality measures, a component of its Medicare and Medicaid incentive programs for establishing meaningful use of electronic health record (EHR) technology, an action deemed especially helpful in monitoring care for vulnerable populations.

Medium-term (two to four years) strategies and deliverables:

- Refine the initially proposed diagnostic clusters and treatment indicators, including adaptation of the diagnostic clusters to ICD-10 nomenclature.
- Convene key stakeholders to consider standardization and widespread use of the resulting diagnostic clusters and treatment indicators in population research using electronic health care data. Ideally, the resulting analyses would be accompanied by evidence-based characterization of treatment indicators (Appendix G), including the relative value of specific pain treatments, as emphasized in the Service Delivery and Payment section.

Long-term (within five years) strategies:

- Establish a pain research network to study risk factors for the initiation and maintenance of chronic pain and high-impact chronic pain and patterns of pain treatment using the diagnostic clusters and pain treatment indicators.[ix] Use the network to develop data, including EHRs and patient reported outcomes, on trends in pain treatment in different population groups (including vulnerable populations) including and costs of specific pain treatment services and to identify opportunities and priorities for primary prevention.

[viii] Diagnostic clusters refer to clinical groups of painful conditions, grouped on the basis of anatomical location of the pain rather than diagnostic specificity. They allow analysis of electronic data on use of health services for common pain conditions in clinically meaningful groups (e.g., back pain, headache).

[ix] Recognizing that these categories are subject to continued refinement based on experience, new research findings, and external factors, such as the implementation of ICD-10.

Federal Stakeholders:

- ACL, AHRQ, CDC, CMS, DoD, Indian Health Service (IHS), Office of the National Coordinator for Health Information Technology (ONC), NIH, NPC, VHA

Collaborators:

- evidence-based practice centers in universities
- relevant primary care and specialty professional societies
- long-term services and supports providers
- public and private sector health care financing and delivery systems that have large patient and health maintenance organizations and support research
- public and private health insurers
- patient advocacy organizations; and people with pain

Metrics: The progress of the refinement of the diagnostic clusters and related treatment indicators, their incorporation into ICD-10 nomenclature and their standardization and use in population research should be monitored (medium-term). The adoption of diagnostic cluster and pain treatment indicator methodology within CMS and outside government-funded programs should be assessed (long-term). The development of the research network and its subsequent progress in generating quality data on trends in pain treatment in population subgroups, associated costs of specific pain treatment services should be evaluated (long-term).

Objective 3: **Develop a system of metrics for tracking changes in pain prevalence, impact, treatment, and costs over time to assess progress, evaluate the effectiveness of interventions at the population health level—such as public education or changes in public policy, payment, and care—and identify emerging needs. Apply these metrics to evaluate the effectiveness of primary, secondary and tertiary prevention interventions.**

Short-term (within one year) strategies and deliverables:

- Set measurable goals for reducing the prevalence of high-impact chronic pain and for increasing the value of health care and preventive services for chronic pain to be incorporated into Healthy People 2020.
- Coordinate across the federal agencies that gather data related to primary prevention strategies (primarily injury prevention and improved management of certain chronic conditions).

Medium-term (two to four years) strategies and deliverables:

- Develop approaches to assessing pain's impact in longitudinal studies that consider pain perceptions, activity limitations, and participation restrictions in work, social and self-care roles, work productivity, utilization of disability benefits and other services, family effects, and utilization and costs of health care services.
- Evaluate outcomes of Healthy People 2020 chronic pain objectives to inform and guide appropriate objectives/questions for a dedicated chronic pain objective to be included in HP 2030.

Long-term (within five years) strategies and deliverables:

- Encourage health care providers, including long-term services and supports and insurers to use data developed under these initiatives and the collaborative relationships established to guide enhancements to health care and preventive services.
- Encourage health care providers and insurers to use data developed under these initiatives and the collaborative relationships established to evaluate the effectiveness of interventions at the population health level, such as public policy initiatives, demonstration projects in the organization or payment for care, or public education efforts.[x]

Federal Stakeholders:

- ACL, AHRQ, CMS, CDC, DoD, IHS, NIH, NPC, VHA

Collaborators:

- entities that collect data on pain, pain treatment, use of disability programs, and public benefits
- employer and employee organizations
- public and private sector health care financing and delivery systems that have large patient and health maintenance organizations and support research
- patient advocacy organizations, and people with pain

Metrics: The extent of adoption of the pain assessment and treatment metrics and their use in assessing programmatic interventions should be assessed. The adoption of the proposed measures in the Healthy People data tools and reporting system should be monitored and expanded (ongoing). The extent of use of diagnostic clusters in program planning, implementation, and evaluation at the community, state, and federal levels should be assessed.

[x] For example, the Bree Collaborative recently developed strategies to enhance the value of health care for low back pain (see http://www.breecollaborative.org/topic-areas/spine). Washington State's Bree Collaborative provides a model for such collaboration.

Prevention and Care

Preventable causes of acute and chronic pain should be identified and addressed throughout the health care delivery system. When acute pain from injury or disease is present, or when a persistent pain state has developed, clinicians should assess and comprehensively manage it using practice guidelines based upon best available evidence of effectiveness. Current opportunities to manage the continuity of care during transitions across health care settings and to expand real-time access to a carefully selected and synthesized body of relevant evidence should be enhanced in order to improve coordination of care and optimal use of resources.

The quality and quantity of evidence needed to guide appropriate and comprehensive clinical approaches to the prevention, assessment, and treatment of pain across the lifespan is inadequate, in part because of the complex nature of pain. Given that acute pain can progress to chronic pain, which is a disease in itself, certain principles are clear:

- Evidence-based care should follow the public health prevention model and address primary, secondary, and tertiary prevention.
- Evidence-based pain care should involve an interdisciplinary team approach that includes the patient, and family when appropriate, and covers the different levels of pain care—from prevention to self-care to acute to chronic pain management—as needed.
- High-quality pain care should be available to all and in all settings and at all levels of care, from primary care to interdisciplinary pain care centers, to functional rehabilitation settings, and nursing homes as the intensity of pain management efforts increases.

The Problem: Chronic pain can affect people of any age and may begin with an injury, disease process, or procedure that evolves into a persistent painful condition. Often, the cause of its onset is uncertain however, and the mechanisms by which it persists are complex. There is a great need to better understand the factors that cause pain to become persistent and to develop and apply measures to prevent acute pain and its transition to a chronic state. Opportunities to prevent acute to chronic pain progression depend not only on the nature of the initial insult and treatment, but also upon various patient-related risk factors. While there is much more to learn about chronic pain prevention and treatment, existing knowledge could be used more effectively to reduce substantially the numbers of people who suffer unnecessarily. Most people who have pain do not receive appropriate assessments or evidence-based care that is coordinated across providers and personalized for specific higher-risk situations.[1] A robust basic, translational, and health services research effort is needed to validate the effectiveness of pain prevention and management strategies already in use across the spectrum of care settings, and to develop new ones.

The intent of the Prevention and Care section is to advance evidence-based, culturally sensitive and personalized prevention and care of pain, using the biopsychosocial model and providing value determined by accepted, validated, and systematically collected outcomes.

Objective 1: **Characterize the benefits and costs of current prevention and treatment approaches.** A thorough benefit-to-cost analysis of current prevention and treatment approaches, including work place injury prevention programs, self-management methods and programs for prevention and care, should be performed to identify and create incentives for use of interventions having high benefit-to-cost ratios.

Conversely, approaches and treatments with little absolute benefit or a low benefit-to-risk ratio should be identified through clinical studies, and efforts made to dis-incentivize their use. In judging the benefit of treatments, clinicians and payers should bear in mind that an individual may belong to a specific population group in which the treatment may be either more beneficial (or more risky) than in the population at large. Providers and payers should tailor care to address such individual variation in patient response.

Short-term (approximately one year) strategies and deliverables:

- Perform a benefit-to-cost analysis of existing methods and programs to prevent and treat pain for which the best available evidence suggests benefit (and for which benefits outweigh risks). Such an analysis may help guide the choice between therapies that are equally efficacious but whose cost differs.
- Prepare a manuscript for submission to a peer-reviewed journal reporting the results of the benefit-to-cost analyses of current prevention and treatment approaches and related recommendations.

Medium-term (two to four years) strategies and deliverables:

- Develop a best-estimate synthesis of causes of preventable injuries nationwide, including both workplace and non-workplace related injuries and physical trauma by:
  - Identifying areas where more evidence is needed (for example, linking work relatedness to EHRs, evaluate occupational injuries that may be substantially underreported[46]).
  - Reviewing existing programs for primary prevention, the evidence for their effectiveness and the barriers to their implementation.
  - Estimating the number of people with chronic pain whose condition is preventable as a first step in developing more robust preventive efforts.
- Begin research efforts geared toward dissemination of existing effective programs and development of new prevention and treatment methods likely to have high benefit-to-cost ratios.

Long-term (within five years) strategies and deliverables:

- Incorporate the most clinically effective and cost-efficient treatments into practice guidelines and other quality-related efforts, with inclusion of standards-based clinical decision support to enable providers and patients to make decisions in line with best practice guidelines. Followed by:
- Assessment of insurer practices that either deny payment for clinically effective and cost-efficient treatments for patients who could benefit from them or insurer practices that continue to pay for less effective treatments.
  - Development of a patient-centered framework for measuring treatment outcomes on pain, level of disability, and the full range of psychosocial impacts.

Federal Stakeholders: ACL, AHRQ, CDC, CMS, ONC, National Institute for Occupational Safety and Health, Occupational Safety and Health Administration, VHA, and other relevant federal entities

Collaborators:

- private health insurers
- employers, labor unions and trade associations
- patient advocacy organizations, and people with pain

Metrics: The level of integration of effective, cost-efficient pain treatments into the health care system and the impact on outcomes for people with pain should be assessed at five years, which ideally could be compared with baseline data to determine any short-term trends.

Objective 2: **Develop nationwide pain self-management programs.**[xi] Despite evidence to support team-based, self-management programs for pain their implementation has lagged. This is a missed opportunity to provide people with pain the appropriate skills, education, and resources to play an active role in managing their pain, which includes understanding when clinical consultation is needed. These programs should be integrated into the health care systems and other services' networks to bolster their use and prevalence and to guide patients through multiple levels of pain care. Goal setting (action planning), problem solving, decision making and psychosocial aspects of care should be included in the programs. Team based programs should be multidisciplinary including integrative health professionals, patient-centered, developed with provider input and monitoring, and paralleled with clinical care when needed.

Short-term (approximately one year) strategies and deliverables:

- Perform an environmental scan of pain self-management programs[xii] that:
  - cover the continuum of prevention and pain care; foster skills and integrative health self-management approaches to prevent, cope with, and reduce pain; and provide people having pain with the practice and confidence to utilize the core self-management skills of goal setting (action planning), problem solving, and decision making.
  - are offered in differing health care settings, by community agencies (e.g. aging services providers), patient advocacy organizations, or that stand alone.
  - are culturally neutral and sensitive, allow for tailoring of the intervention as needed for special populations, apply across the lifespan to include children and older adults, and are available in multiple languages and formats.

Medium-term (two to four years) strategies and deliverables:

- Evaluate the efficacy of existing pain self-management programs and support research and development of new programs and models, as necessary, to address the continuum of pain.

[xi] See definitions, Box 1. In addition, to meet people's various circumstances and learning preferences, self-management programs must be offered in multiple models (in groups of varying sizes, electronically via smartphone or computer, by mail, or by telephone).

[xii] Specific programs that warrant an evaluation include the American Chronic Pain Association's program, Stanford Patient Education Research Center Programs, and model falls prevention programs. Existing models from integrative healthcare disciplines also should be evaluated.

- Leverage existing programs, such as the extensive number of self-management tools for patients with chronic disease.[xiii]
- Develop new types of patient tools for pain management and provider feedback using, for example, mobile applications, that also integrate with EHRs, personal health records/patient portals, wearable devices, and other technologies.

Long-term (within five years) strategies and deliverables:

- Implement, evaluate, and disseminate nationally evidence-based pain self-management programs that are effective, as documented by high-quality research methods, and that have developed materials and a structure enabling them to be transferred to one or more additional sites.
- Encourage the inclusion of evidence-based programs as covered benefits under public and private integrated health systems, including Patient Centered Medical Homes and the VHA, especially for people with indicators or risk factors for transitioning to chronic pain.
    - Disseminate broadly, information on effective pain self-management programs through various health information directories, such as http://www.health.gov/ and non-governmental resources for patients.
    - Through various means, direct those with indicators or risk factors for transitioning to chronic pain to effective self-management programs.

Federal Stakeholders: ACL, AHRQ, CMS, DoD, IHS, VHA in collaboration with the Health Resources and Services Administration (HRSA, as appropriate to their statutory priorities and within their authority), and other relevant federal agencies

Collaborators:

- private entities that support health care assessments and outcomes monitoring
- the Patient-Centered Outcomes Research Institute (PCORI)
- professional organizations, including those representing rehabilitation medicine, athletic trainers, and licensed complementary and integrative health fields
- public and private payers
- health care provider organizations, and other potential funders
- patient advocacy organizations, and people with pain

Metrics: The short-term progress of the programs should be assessed through data on the outcomes for people with pain and collected through established tools, such as the NIH and Department of Defense's collaborative Pain Assessment Screening Tool and Outcomes Registry/Patient Reported Outcomes Information System PASTOR/PROMIS, the NIH Pain Consortium, Stanford University's Collaborative Health Outcomes Information Registry (CHOIR), and those developed by the Joint Commission; and by innovative use of data from EHRs. The level of integration of

[xiii] Examples of program models include: Stanford's Patient Education Research Center, Arthritis Self-Management Program, and Chronic Pain Self-Management Program ; the University of New Mexico's telehealth program, Project ECHO; the A Matter of Balance program developed by Boston University; or the National Institute of Disorders and Stroke's program for pediatric migraine, under development.

and payment for effective pain self-management into the health care system should be assessed at five years, which ideally could be compared with baseline data (environmental scan).

Objective 3: **Develop standardized, consistent, and comprehensive pain assessments and outcome measures across the continuum of pain.** Pain assessment should be multifaceted and include self-report, as well as clinician examination. Assessment and outcome measures should include relevant pain, physical, psychological, emotional, and social domains of functioning that conform to the biopsychosocial model of pain, as well as patient-reported outcomes and patient-defined goals. Assessments and outcomes should accommodate patient communication challenges (e.g. through behavioral symptoms measures), be used for point-of-care decision-making by clinicians, longitudinal outcomes monitoring, estimations of value of optional treatment approaches, and practice-based effectiveness studies.

Short-term (approximately one year) strategies and deliverables:

- Develop comprehensive quality assessments and outcome measures for the continuum of pain
  - Establish expert working groups to survey and identify gaps in available assessment and outcomes tools for the continuum of pain, including both general assessments and condition-specific modules, as well as opportunities to leverage outcome data from existing resources such as registries, especially taking into consideration their usefulness for primary care providers and for population research.[xiv]
  - Conduct research and developmental studies to create new assessment tools and identify models.
  - Integrate appropriate pain self-assessment tools into EHRs, patient portals, and other forms of health information technology (health IT) to aid providers and patients in clinical decision making.
  - Recommend ways to integrate outcomes measures into existing assessment systems, as necessary.

Medium-term (two to four years) strategies and deliverables:

- Disseminate existing assessment tools and outcome measurement systems that prove most effective and are easily managed, and create incentives for using them.
- Conduct pilot studies of new models that emerge from research.

Long-term (within five years) strategies and deliverables:

- Evaluate the benefits and costs of improved, standardized assessment tools and outcome measures.
- Assess health insurer practices to improve appropriate use of pain treatments, including opioid and non-opioid therapies.

Federal Stakeholders: ACL, AHRQ, CDC, CMS, FDA, ONC, NIH, and other relevant federal entities.

[xiv] The NIH Task Force on Research Standards for Chronic Low Back Pain is an example of such a task force.

Collaborators:

- public and private health insurers
- PCORI
- professional organizations (especially primary care)
- National Committee for Quality Assurance (NCQA) and other relevant health care systems accrediting bodies
- pain advocacy organizations, and people with pain

Metrics: The extent of adoption of improved assessment tools and outcome measurement systems into existing assessment systems, provider practices, EHRs, patient portals, and other forms of health IT should be monitored annually over five years. The costs and benefits of the tools should be evaluated at five years.

Disparities

Pain care disparities are complex, due to myriad contributing factors within and outside the health care sector. Elimination of disparities and equity in care cannot be achieved without increased access to high-quality treatment, development of strategies and expectations for equitable assessment and treatment of pain, and creation of appropriate supporting programs and services (such as effective patient communication strategies, and disability and addiction services as needed) for people with pain. A more robust and well trained workforce is needed to address the need for access to quality care for all people with pain and especially for those in vulnerable populations. Specific needs include expansion of the nation's behavioral health workforce to support the needs of patients with chronic pain and those at risk for substance use and mental health disorders. Also needed is improved communication between service providers and people with pain and their families.

The IOM report, extensive research, and patient reports indicate that substantial disparities in pain prevention, occurrence, assessment, treatment, and outcomes are common; U.S. data indicate a greater prevalence of pain conditions among specific population groups. The Healthy People 2020 current definition of health disparities is included in the Background section of the strategy.

While many factors affect an individual's experience of pain and willingness to seek or adhere to treatment, and while more comprehensive efforts are needed to prevent pain in higher risk groups, this section of the National Pain Strategy focuses on improving the quality of pain care for vulnerable populations, especially as it may be affected adversely by provider attitudes and behaviors that result in discrimination, bias, or stigmatization, which themselves can lead to or exacerbate pain. When this section of the NPS discusses bias, stigmatization, and discrimination, it is referring to all higher-risk groups that comprise vulnerable populations. Examples of patient groups and conditions for which bias has been reported are diverse and widespread and include: women experiencing pain from chronic fatigue syndrome, fibromyalgia, and other conditions; people who are on prescription opioids for intractable pain; children—especially infants and others who cannot communicate; older adults—especially those in nursing home settings who have limited communication; people with substance use and mental health disorders; and patients with sickle cell disease or pain associated with human immunodeficiency virus (HIV) infection.

The Problem: A significant problem facing vulnerable populations arises from conscious and unconscious biases and negative attitudes, beliefs, perceptions, and misconceptions about higher-risk population groups (e.g. sex, gender, age, disability, ethnic, or racial bias) or about pain itself.[6,47,48,49] If held by clinicians, social service program administrators, or other decision-makers, these attitudes can negatively affect the care and services they provide. For example, inappropriate or inadequate treatment may result if clinicians fail to understand or accept that individuals differ in pain sensitivity and treatment response due to a wide range of factors. People with pain who encounter these biases can feel stigmatized, which may decrease their willingness to report pain in a timely way, participate in decisions about their care, adhere to a recommended treatment plan, or follow a self-care protocol. This perception also may negatively affect their psychological state.

An additional barrier to eliminating pain disparities is the lack of sufficient knowledge of behavioral and biological issues that arise from age (infancy through older adults), genomic variability, pharmacokinetic and pharmacodynamics differences, which affect pain onset, chronicity, and management and data to understand patterns of pain and its treatment in higher risk and vulnerable populations.

The intent of the Disparities section is to improve the quality of pain care and reduce barriers for all vulnerable, stigmatized, and underserved populations at risk of pain and pain care disparities.

Objective 1: **Reduce bias (implicit, conscious, and unconscious) and its impact on pain treatment by improving understanding of its effects and supporting strategies to overcome it.**

Short-term (approximately one year) strategies and deliverables:

- Document the evidence base of adverse effects of clinician bias on the pain experience for use in developing, validating and implementing clinician and public education, policy recommendations, and health system reforms:
  - Conduct a baseline survey, using quantitative and qualitative research design, of health care and social services providers to assess their biases, attitudes, beliefs, knowledge, and behavior regarding pain among people from vulnerable populations.
  - Convene an expert group to review evidence on effects of health care, long-term services and supports, and social services provider bias in decision-making regarding integrated, multimodal, and interdisciplinary pain care, strategies to overcome bias (at the patient, clinician, institutional, and health system levels), and to identify gaps in knowledge. These gaps should support a research strategy to improve clinician education, pain care, and direct pain policy.
  - Convene an expert group to assess the state of the science and promote a better understanding of biological variability, including genetic and other influences, affecting pain sensitivity and treatment response across diverse populations.

Medium-term (two to four years) strategies and deliverables:

- Disseminate the proceedings of these groups to health care and social service providers, policy makers, and other stakeholders through a manuscript in a relevant journal and other appropriate means.
- Develop pilot projects, designed to reduce bias in pain care at the provider, health care, long-term services and supports, and social service systems levels, using the conclusions of the expert groups.
- Conduct demonstration projects to evaluate bias reduction strategies in health care systems or other large population-based service delivery systems, based on the results of the pilot projects.

Longer-term (within five years) strategies and deliverables:

- Develop, implement, and evaluate policy recommendations and guidelines on bias reduction for health care, long-term services and supports, and social service providers, based on outcomes of the demonstration projects.

Federal Stakeholders: ACL, AHRQ, HRSA, Office of Minority Health (OMH), NIH

Collaborators:

- professional medical organizations

- researchers (including social sciences)
- health care, long-term services and supports, and social services providers (including licensed practitioners who provide integrative and complementary health approaches)
- state and federal policymakers
- community representatives
- patient advocacy organizations and people with pain

Metrics: Identified knowledge gaps on effects of provider bias in health care outcomes should be included in a long term research strategy. Practices to reduce bias, based on demonstration projects, should be incorporated into health care, long-term services and supports, and social service systems. The extent of implementation of policy recommendations and guideline adoption should be assessed at five years through a follow-up survey to determine changes in health care, long-term services and supports, and social service provider biases, attitudes, beliefs, knowledge, and behavior.

Objective 2: **Facilitate communication among patients and health professionals.**

Short-term (approximately one year) strategies and deliverables:

- Convene an expert group to review and make recommendations on effects of disparities in pain care and means to heighten its national awareness.
- Disseminate findings of the review group to the general public, researchers, health care and social services providers, and professional organizations.

Medium-term (two to four years) strategies and deliverables:

- Improve the health literacy of people with pain through promotion and dissemination of the National Action Plan for Health Literacy and the National CLAS standards to relevant health care providers and health care systems.
- Perform an environmental scan for existing communication guidelines that are specific to pain care and relevant to patients with limited English proficiency or health literacy, communications disabilities, or age related communication limitations.

Long-term (within five years):

- Develop needed communication guidelines in accord with the gaps from the environmental scan, that are consistent with the National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care (National CLAS Standards: www.thinkculturalhealth.hhs.gov).[xv]

[xv] Title VI of the Civil Rights Act of 1964 requires federally assisted programs to take reasonable steps to provide meaningful access for persons who have limited English proficiency which may include the provision of language assistance services at no cost to the person being served. Section 504 of the Rehabilitation Act of 1973 and Title II of the Americans with Disabilities Act of 1990 require that recipients ensure that communication with individuals with disabilities is equally effective as communication with persons without disabilities.

Federal Stakeholders: ACL, AHRQ, HRSA, OASH: ODPH, OMH, Substance Abuse and Mental Health Services Administration (SAMHSA)

Collaborators:

- health care, long-term services and supports, and social service providers' credentialing agencies (certification standards and guidelines) and accrediting bodies (NCQA and other relevant health care systems accrediting bodies)
- health professional training programs and licensing bodies (to promote cultural and linguistic competency)
- patient advocacy organizations and people with pain

Metrics: The establishment of payment models for payment of direct translation and interpreters should be tracked and linked to the number of staff and quality translation services available in pain care settings.

***Objective 3*: Improve the quality and availability of data to assess the impact of pain and under or overtreatment for vulnerable populations, and the costs of disparities in pain care.**

Short-term strategies (approximately one year) and deliverables:

- Develop data standards and definitions to track pain prevalence and treatment across vulnerable populations. These standards and definitions could be applied to EHRs, population-level surveys, and relevant clinical research

Medium-term (two to four years) strategies and deliverables:

- Convene an expert group to assess the current costs of pain care disparities, including costs that result from health care utilization, lost work or educational opportunities, and use of disability and other benefits.

Long-term (within five years):

- Use current and new data standards as developed above to enable national studies of inappropriate, under- and over-treatment among vulnerable populations, and to assess progress toward eliminating it.

Federal Stakeholders: ACL, AHRQ, CDC, HRSA, NIH, ONC

Collaborators:

- private entities (for research using new or existing data sets and data collection standards)
- the pain research community
- patient advocacy organizations and people with pain (for input on data needs, adequacy, and usability)

Metrics: The number of studies published using the data standards and definitions developed to assess prevalence and treatment outcomes should be monitored. Data mining based on these standards and definitions from EHRs, population surveys and clinical studies should be tracked to assess effectiveness of dissemination.

Objective 4: **Improve access to high-quality pain services for vulnerable population groups.**

Short-term (approximately one year) strategies and deliverables:

- Conduct an environmental scan of current patient resources that link people with chronic pain to appropriate care (e.g., health centers, long-term services and supports, social services, and behavioral health providers, and clinician specialists).
- Promote awareness of these resources through stakeholder agencies (e.g. websites, social media) and professional organizations (e.g. websites, membership).
- Develop demonstration projects of ways to improve access to current resources (including means to determine the potential of patient-centered medical homes to serve people who are at risk for disparities in care and aging and disability resource centers.

Medium-term (two to four years) strategies and deliverables:

- Develop a web-based portal of resources to link patients and families to appropriate care (leverage http://healthfinder.gov/, http://eldercare.gov) and self-management tools.
- Develop demonstration projects to evaluate the web-based portal in improving access to high-quality care among vulnerable populations.
- When appropriate, promote and disseminate telehealth for hard-to-reach populations and for clinicians who do not practice where multidisciplinary colleagues are available.
- Coordinate with ongoing efforts to expand the behavioral health workforce capacity for psychological needs related to pain care, mental and substance use disorders, through HHS sponsored programs to attract new students to the field.[xvi]

Long-term (within five years) strategies and deliverables:

- Promote and disseminate effective models from the demonstration projects (access models, web-based tools), and provide incentives to adopt them.
- Develop, test, evaluate, and promote provider-facing clinical decision support tools to identify patients who are vulnerable to disparities in care, and to make treatment and referral decisions that prevent/reduce disparities.

Federal Stakeholders: ACL, CMS, DoD, HRSA, IHS, OMH, VHA

Collaborators:

- private entities to promote awareness of existing programs, develop demonstration projects, and evaluate existing tools
- health care, long-term services and supports, and social service systems
- professional medical organizations
- community representatives
- patient advocacy organizations, and people with pain

[xvi] Examples can be found at http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2741399/

Metrics: The frequency of access to the information gateway portal and telehealth consultation should be tracked annually and outcomes of the demonstrations projects should be used to improve the gateway and the effectiveness of the telehealth programs.

Service Delivery and Payment

A primary objective in enhancing the delivery of quality pain care is to make optimal and personalized pain management accessible to all. Wide variation in clinical practice and in patients' responses to therapies, along with inappropriate or repeated use of relatively ineffective and potentially risky treatments (e.g. prescription opioids and certain procedural/surgical interventions), has been linked to poor quality outcomes and high costs of pain care.[1,6] Given that commonly used single-modality treatments often fail as first-line therapies for chronic pain, attention among leaders in the field has shifted to improving pain assessment and delivery of integrated, multimodal, interdisciplinary care that is effective and safe.[1,6] The IOM report reflected this shift by advocating consistent and complete pain assessments, payment reform to foster coordinated interdisciplinary care, and greater support for primary care clinicians to deliver the most effective, safe, and timely care, including more opportunities for consultations with pain specialists. The recommendations of this workgroup support a framework for which the advances in prevention and care outlined in the IOM report can be provided to all individuals with pain.

Insurance policies have been shown to affect consumer choices of treatments and their adherence to treatment regimens. Payment policies also can affect the clinical strategies adopted by health care providers. Payment policies for different procedures and products, formulary placement of drugs, and managed care arrangements all can affect the choices made by patients and physicians about managing chronic pain. The structure of payment and coverage arrangements can therefore exert powerful effects on how pain is managed.

Patients suffering from chronic pain may have access to complementary and alternative strategies for pain management, but these strategies have diverse economic implications. For example, consider acupuncture, cognitive behavioral therapy (CBT) and use of various prescription opioids. Many insurance plans do not cover acupuncture, and if they do provide coverage, subject it to strict duration limits. Moreover, these treatments are time consuming, must often occur during "work hours" and may require substantial cost sharing (e.g., $20 to $50 per visit in the case of CBT). The cost to consumers of prescription opioid products varies according to the specific drug and its placement on the prescription drug formulary. Some generic products (e.g., methadone) have out- of- pocket costs of as little as $10 to$15 for a 30-day supply. Brand name drugs may have higher out of pocket costs in the range of $20 to $35 for a 30-day supply. Thus, consumers in many insurance plans may gravitate to prescription drugs over complementary or alternative treatments, creating risks for subsequent problems with opioid dependency.

Providers frequently are very constrained in the time they can spend with individual patients. The typical primary care visit is approximately 17 minutes in duration, and fees permitted for brief office visits are fixed. Such visits usually involve attending to a number of clinical issues as well as trying to develop a rational, individualized pain treatment regimen. Capitation schemes create incentives for clinicians to minimize the total resources devoted to addressing complex problems such as pain control. In pay-for-performance systems additional payments are earned based on favorable outcomes being

achieved. In pain management, there are no such systems. Providing referrals for acupuncture or CBT may require primary care providers or specialists to provide clinical services with which they have little experience. Specifically, monitoring such services for referred patients may be difficult, and patient outcomes are more uncertain and require more clinician time to assess. These complexities can create situations where clinical choices for physicians and patients are weighted towards use of prescription drugs.

Ideally, clinicians might face neutral economic consequences as a result of choosing among effective pain control strategies. This could allow reimbursement for longer visits when selecting a therapy that involves more clinician time and less prescription opioid use. Exploring coverage and payment mechanisms that align consumer and provider interests in choosing cost-effective treatment strategies that balance risks and benefits of care for individuals can make an important contribution to implementing an HHS pain management strategy.

The National Pain Strategy endorses a population-based, disease management[xvii] approach to pain care that is delivered by integrated, interdisciplinary, patient-centered teams and is consistent with real-world experience. To succeed, the care model must shift from the current fragmented fee-for-service approach to one based on person-centered care, better incentives for prevention (primary, secondary, and tertiary) and for collaborative care along the continuum of the pain experience—from acute to chronic pain across the lifespan, including at the end of life—at all levels of care and in all settings.

The Problem. Access to high-quality integrated care based on clinical evidence is hindered by many challenges. Pain management often is limited to pharmacological treatment offered by a primary care practitioner or to procedure-oriented and incentivized specialty care that is neither coordinated nor aligned with best available evidence or expected outcomes.[1,7] This situation is especially relevant for people with high-impact chronic pain, where integrated care is likely to be most effective. Even when interdisciplinary care is provided, creating and executing a care plan is often fragmented, with poor communication and collaboration among clinicians and without consideration of patient preferences.[1,7] The clinician or team's choice of therapy may be based on practice experience or insurance coverage, rather than one informed by a comprehensive pain assessment, clinical evidence, or best practices.

More quality research is needed on the effectiveness of interventions, integrated care, models of care delivery, and payment innovations. Also needed are more effective methods to disseminate research findings and incentives to incorporate them into clinical practice. Level-I studies (e.g. high-quality randomized controlled trials or prospective studies) in pain are limited. Patient-reported outcomes are rarely collected outside of clinical trials. Observational data and registry studies sometimes lack detail and relevant outcomes. There is a need for research to enhance drug discovery for safer opioids and non-opioid analgesics, to raise the level of evidence for treatment approaches, and to improve evidence for clinical guidelines.

The incongruity between high-quality care and real-world clinical practice is however, only partly the result of limited evidence to support existing clinical guidelines. Current payment practices complicate use of integrated, interdisciplinary, patient-centered teams. Payers tend to cover mono-therapy

[xvii] *Disease management* refers to a system of integrated, multidisciplinary interventions and communications for populations with chronic disorders in which self-care efforts are significant. (Disease Management Association of America. Disease State Management Definition. Accessed at www.dmaa.org/dm_ definition.asp, March 30, 2006.)

and interventional procedures instead of prevention programs and services that conform to the biopsychosocial model of care. Payment often is not provided for pain self-management programs, patient and family social services support, patient decision making, patient education on the biopsychosocial effects of pain, team-based medication management, psychological counseling, cognitive-behavioral therapy, physical medicine and rehabilitation, and complementary and integrative health approaches. Current payment mechanisms (Appendix H) tied to the fee-for-service payment system generally fail to support more value-driven approaches (for example, the stepped model of pain care and other emerging models of coordinated care).

Further hurdles to quality pain care delivery are lack of access to and payment for medications managed primarily by retail pharmacies and third-party payers. Although analgesics should not be the sole intervention for most pain conditions, they may be essential for improved quality of life. Rationing, medication shortages, and inadequate payment for medication management and monitoring, and the high cost of abuse deterrent formulations decrease patient's access to medications and cause considerable hardship, especially for vulnerable populations.[3,6]

The intent of the Service Delivery and Payment section is to create a payment and delivery environment that facilitates coordinated care across the continuum of pain and throughout the lifespan in order to conform to the biopsychosocial model and provide value, as defined by outcomes of care.

Objective 1: **Define and evaluate integrated, multimodal, and interdisciplinary care for people with acute and chronic pain, and end of life pain, which begins with a comprehensive assessment, creates an integrated, coordinated, evidence-based care plan in accord with individual needs and preferences and patient-centered outcomes, and is supported by appropriate payment incentives.**

Short-term (approximately one year) strategies and deliverables:

- Perform an environmental scan to access quality of care and costs of current treatment approaches and identify the existence of more effective models.
- Convene expert stakeholders to develop strategies to address the shortcomings in quality of care and the high costs of current pain treatment approaches, the existence of more effective models, and the steps that can be taken toward achieving high quality care and outcomes.

Medium-term (two to four years) strategies and deliverables:

- Solicit proposals through the Center for Medicare and Medicaid Innovation for evaluating emerging and innovative models of integrated care for chronic pain conditions.
- Conduct rigorous evaluations of these models through independent evaluators, and others that have been initiated but not yet evaluated, especially those using the stepped model of pain care, the biopsychosocial model, team-based care, pain self-management approaches, and care planning based on comprehensive pain assessments based on a biopsychosocial model that includes the etiology of pain.
- Monitor and evaluate outcomes of the models tested.

Long-term (within five years) strategies and deliverables:

- Evaluate optimal models in federal, state, and private provider contexts and implement as appropriate.

Federal Stakeholders: ACL, CMS, DoD, HRSA, IHS, VHA

Collaborators:

- primary and specialty care clinicians, neuro- and orthopedic surgeons, and licensed integrative health care practitioners)
- professional accreditation entities
- integrated health care systems
- large private third-party payers
- pain advocacy organizations, and people with pain

Metrics: Metrics used to determine positive outcomes from models on measures of physical, psychological, and functional improvement for patients, as well as cost savings relative to conventional care should be used as a measure of progress. Incorporation of validated, successful models into health care systems and clinical practice should be monitored and assessed.

Objective 2: **Enhance the evidence base for pain care and integrate it into clinical practice through defined incentives and payment strategies, to ensure that the delivery of treatments is based on the highest level of evidence, is population-based, and represents real-world experience.**

Short-term (approximately one year) strategies and deliverables:

- Perform an environmental scan to assess barriers to quality care (e.g. identify outcomes of current insurers' practices of prior authorization, fail first protocols, and caps on treatments, and pharmacy benefit managers).

Medium-term (two to four years) strategies and deliverables:

- Solicit population-based studies designed to develop and implement practices for primary care settings, pain self-management programs, and integrative health approaches that are cost-effective, represent real-world settings, and include patient representatives to provide practical approaches for assessing therapeutic effects. Evidence-based outcomes from these studies can be analyzed through available pain data registries, EHRs, population surveys, and other appropriate data sources, including the tools recommended in the Population Research section.
- Leverage existing pain registries or initiate development of new pain registries to track outcomes—including patient-reported outcomes—of the models tested in Objective 1 and develop, standardize and integrate process and outcomes measures into EHRs, which may then be compiled across networks.

Long-term (within five years) strategies and deliverables:

- Integrate and disseminate study results:
    - Compile and integrate outcomes of the population-based studies (above), the models tested (Objective 1), and those from the large national databases recommended in the Population Research section that are relevant to treatment choices.
    - Inform the design of these research projects and integrate their findings with data obtained in the national survey activities described in the Population Research section.

    - Disseminate their results to clinicians, quality improvement initiatives, public-private partnerships, patient and advocacy organizations, and others, to encourage implementation of more appropriate, evidence-based care.
- Expand the pilot pain registries to incorporate over time, findings from other studies, including randomized controlled trials, pragmatic trials, and other high-quality research methods.
- Convene expert stakeholders from appropriate disciplines to consider the outcomes of the pilot studies on emerging models of service delivery and payment and to discuss adoption of consistent clinical guidelines on pain care across clinical specialties.
- Use population-based data to inform national policy for opioid use and monitoring, including comparative effectiveness of opioids versus other forms of treatment, effectiveness of state prescription drug monitoring programs and point-of-care interventions to prevent abuse and misuse, and the effects of regulatory and enforcement policies (Food and Drug Administration and Drug Enforcement Administration), on abuse, misuse, and access to opioid medications.
- Assess the impact of potential changes in policies on opioid use and opioid use disorder.

Federal Stakeholders: ACL, AHRQ, CDC, DoD, FDA, HRSA, NIH, VHA

Collaborators:

- private entities that support population-level research, including PCORI, private payers, integrated health systems
- private agencies and software experts developing electronic medical records and other relevant programs
- health profession organizations
- health, long-term services and supports, and social service provider organizations
- credentialing bodies for primary care and specialty clinicians
- pain advocacy organizations and people with pain

Metrics: The incorporation of validated, successful models and practices from the pilot projects into provider practices and health care systems should be assessed. The outcomes of evaluated interventions and care, including patient and family assessments and costs, as compared to usual treatment should be assessed. The adoption of evidence-based practice guidelines for multiple disciplines should be assessed.

Objective 3: **Tailor payment to promote and incentivize high-quality, coordinated pain care through an integrated biopsychosocial approach that is cost-effective, value-based, patient-centered, comprehensive, and improves outcomes for people with pain.**

Short-term (approximately one year) strategies and deliverables:

- Identify and invest in the development and implementation of models of care that deliver high-value pain care that both maximizes patient benefit and minimizes risk and costs and accounts for potential need for long term and enduring care.

- Identify alternate strategies to serve those most likely to lack access to these innovative models and those with unique needs such as patients with or at risk for addiction, those who have suffered psychological trauma, pediatric populations, and older adults.
- Identify, measure, and recommend means to control variations in pain care and access to pain care that lead to low-quality or high-cost care.
- Develop new tools to facilitate payment for higher quality pain care.[xviii]
- Define, identify, and engage eligible pain care clinicians and health, long-term services and supports, and social service providers willing to participate in quality and utilization reporting that includes pain measures, including those participating in existing programs, such as the Medicare Physician Quality Reporting System, the Advancing Excellence campaign[xix] and all of the other quality reporting systems that CMS hosts.

Medium-term (two to four years) strategies and deliverables:

- Develop and test methodologies for defining episodes of care related to pain conditions to inform payment models and identify where pain should be included as a critical outcome of existing episode-based payment models.
- Develop clinical quality measures and clinical decision support for pain care.
- Assess their impact on outcomes of care to define further refinement of these tools and then discontinue support for tools that are not effective in improving safety or quality, while promoting those that do.

Long term (within five years) strategies and deliverables:

- Develop and support pilot projects to test and rigorously evaluate the impact of payment innovations on pain care quality measures and cost savings. Include evaluation of adverse effects of payment innovations on evidence-based invasive interventions, devices and novel technologies, high cost drugs and access to quality pain care. Develop a plan for assessment of longer term outcomes of the pilots such as cumulative health care costs and comparison of long-term disability to productivity.
- Disseminate results of the pilot projects to public and private payers for consideration in updating their payment policies and practices.
- Make clinical quality measures for pain care and associated decision support part of incentive programs.

Federal Stakeholders: ACL, AHRQ, CMS, DoD, HRSA, National Library of Medicine (NLM), ONC, VHA

Collaborators:

- accountable care organizations
- state Medicaid programs

[xviii] An example would be episode groupers, which are software programs that organize claims data into clinically coherent episodes based, typically, on diagnosis. As designed for use by the Centers for Medicare & Medicaid Services and other payers, they help in identifying high-cost providers and also could be used for payment purposes, much as diagnosis-related groups have been used in hospital payment.

[xix] www.nhqualitycampaign.org

- integrated health care systems
- private agencies and software experts developing electronic medical records and other relevant programs
- health service researchers
- primary care, licensed integrative health care providers, and specialty clinicians, including surgeons
- long term services and supports and social services providers
- private payers
- professional medical organizations
- health care quality organizations
- pain advocacy organizations and people with pain

Metrics: The proportion of payments under the demonstrations that successfully support integrated care data should be monitored and assessed. The development of quality measures for integrated pain care, outcomes of care, including patient and family assessments, and impact on costs (for the demonstrations) should be assessed. The impact of clinical decision support on safety, quality, and outcomes of care should be assessed to guide further refinement of effective clinical decision support tools and allow for identification and discontinuation of support for tools that are not effective in improving safety, quality, or outcomes of care.

Professional Education and Training

Pain is one of the most common reasons for health care visits.[1,50] Nonetheless, most health care professions' education programs devote little time to education and training about pain and pain care.[9] Given "strong indications that pain receives insufficient attention in virtually all phases of medical education," the IOM report found "education is a central part of the necessary cultural transformation of the approach to pain" and recommended improvement in the curriculum and education for health care professionals.[51]

To assure the needed improvement, education and training must allow learners to achieve discipline-specific core competencies, which include empathy and cultural sensitivity across a broad range of disciplines, and prepare them to provide high quality team-based care for pain. Demonstration of competency in pain assessment, safe and effective pain care (including specific training on safe opioid prescribing practices), the risks associated with prescription analgesics, communication of these risks to patients, and prescriber education should be a requirement for licensure and certification of health professionals and should be considered in curriculum review for accreditation of health professional training programs.

Efforts to enhance health care provider knowledge and skills for safer prescribing practices and identification of risks for opioid use disorder should be coordinated with ongoing activities across HHS including the Secretary's Initiative on Prescription Opioids, the pending CDC Guideline for Prescribing Opioids for Chronic Pain, the FDA approved Risk Evaluation and Mitigation (REMS) for Extended-Release and Long-Acting Opioid Analgesic Products, the Office of Disease Prevention and Health Promotion's (ODPHP) Pathways to Safer Opioid Use, SAMHSA's Providers' Clinical Support System for Opioid Therapies, and HHS's Behavioral Health Coordinating Council.

These training enhancements should be developed in collaboration with relevant accrediting bodies and certifying boards to promulgate their use. Sub-specialty training and certification should include training in effective team management for patients with the most complex pain conditions.

The Problem: The high prevalence of pain across the population and its impact on individuals and families creates a significant responsibility for health care professionals. Despite the need to address this public health problem, many health, long-term services and supports, and social service professionals, especially physicians, are not adequately prepared and require greater knowledge and skills to contribute to the cultural transformation in the perception and treatment of people with pain.[9] Education and training of health, long-term services and supports, and social service professionals in the complex etiology, prevention, assessment, safe and effective treatment of pain, and risks associated with poor pain management is insufficient, in part because educators lack access to valid information about pain and pain care. Core competencies in pain care are not fully developed and generally do not inform undergraduate (pre-licensure) curricula in health, long-term services and supports, and social service professions schools or graduate training programs, even those in pain medicine. As a result, practitioners may rely primarily on procedural or pharmacological approaches that alone are not effective and may have significant unintended adverse consequences such as addiction and medication misuse for which many health care providers lack skills and knowledge to identify and manage.

Moreover, cultural bias exists in the medical community against people with pain, especially those with chronic pain, which can negatively affect patient care and reinforce pain stigmatization.[6,21] This bias and the documented decline in empathy as medical training progresses[52] may be interrelated, in the case of pain care, and exacerbated by knowledge deficits, frustration with the limited effectiveness of usual treatments for chronic pain, and the complex nature of pain and pain care and risks associated with treatments.

The intent of the Professional Education and Training section is to anchor an attitudinal transformation toward pain and a reorganization of pain management by the health care system across all care settings and in the education and training of health professionals. The mission includes grounding the pain-related education and training of physicians, nurses, advanced practice nurses, clinical pharmacists, dentists, podiatrists, clinical health psychologists, social workers, physician's assistants, nurse practitioners, physical and occupational therapists, behavioral health specialists for mental health and substance use disorders, and other health, long-term services and supports, and social service professionals in core competencies, and making available easily accessible, evidence-based information for educators to work toward this goal.

Objective 1: **Develop, review, promulgate, and regularly update core competencies for pain care education and licensure and certification at the pre-licensure[xx] (undergraduate) and post-licensure (graduate) levels.**

Short-term strategies and deliverables:

- Convene an expert group that includes all relevant pre-licensure health professions to review, revise, and promote the set of interdisciplinary core competencies that have been developed and widely accepted for pre-licensure education in pain and pain care[53] (Appendix J). The expert group should develop a set of learning objectives to be achieved by the core competencies, devise plans to incorporate the competencies into their programs, beginning with selected sites for piloting curricular changes, and evaluate the effects of the core competencies. The relevant accrediting, certification, and licensing entities should be involved at early planning and subsequent phases of this strategy.
- Examine current specialist training and certification in pain medicine through the planned effort of the Accreditation Council for Graduate Medical Education (ACGME), to assure that pain specialists are effectively trained to lead clinical teams in managing the most complex and challenging patients with acute and chronic pain and to provide needed support for formal and informal clinical medical education. Enhance team management training in currently existing ACGME-accredited programs (e.g. ACGME pain medicine residency requirements). Extend this examination through the planned effort of discipline-specific accrediting and certifying bodies related to nursing, clinical pharmacy, clinical health psychology, and other relevant health, long-term services and supports, and social service professional training schools and programs.

[xx] Pre-licensure (undergraduate) level refers to a health professional currently enrolled in their degree program (e.g. bachelor, master, doctorate) and not yet licensed. Post-licensure (graduate/postgraduate) refers to a health professional who holds a degree in their discipline, has obtained their license and may be enrolled in a clinical residency or training fellowship program (graduate/postgraduate).

- Solicit input from the public, including people with pain, professional organizations, and students, to enhance clinical empathy, cultural competency, and expanded patient-centered communication for people with pain, based on impact, feasibility, and ease of dissemination.

Medium-term strategies and deliverables:

- Promulgate interdisciplinary core competencies (include empathy and cultural sensitivity) for pre-licensure education, professional licensure examinations and educational accreditation standards.
- Convene an expert group from pain-relevant primary care specialties, including internal medicine, family medicine, pediatrics, obstetrics/gynecology, as well as advanced practice nursing and physician assistant fields to develop and promote core primary care competencies by building on the existing undergraduate (short term) interdisciplinary core competencies and to approach ACGME regarding incorporation into relevant ACGME program requirements.
- Convene accrediting (e.g. ACGME, LCME) and certifying entities and related groups relevant to health care providers who provide pain management within the scope of their practice, to develop consensus and an implementation plan on the depth with which competency in pain care is integrated into health professions education, accreditation, and certification.
- Publish and promulgate core competencies in post-licensure fields, including primary care education and training, through the work group convened for this purpose and in collaboration with relevant accrediting bodies.

Long-term (within five years) strategies and deliverables:

- Convene an expert group from pain care specialties to develop and review, promote, and publish core competencies in pain care in relevant specialties, replicating the same general process used in primary care.
- Commission a baseline evaluation of the use of core competencies in pre-and post-licensure primary care and specialty education and training, evaluate them over time to determine progress, and regularly update them.
- Evaluate the projects for enhancing empathy to determine their suitability for widespread use, and implement them accordingly.

Federal Stakeholders: CDC, FDA, SAMHSA, and VHA, in collaboration with HRSA (as appropriate to their statutory priorities and within their authority)

Collaborators:

- relevant state and federal accreditation, certification, and licensing entities for physicians, nursing, dentistry, clinical pharmacy, physical therapy, physician assistants, clinical health psychology, long-term services and other relevant health disciplines
- relevant professional organizations for physicians, nursing, dentistry, clinical pharmacy, physical therapy, physician assistants, clinical health psychology, long-term services and other relevant health disciplines
- pain advocacy organizations and people with pain

- addiction and opioid use disorder advocacy organizations

Metrics: The validity and reliability of core competencies should be evaluated through the pilot projects based on the learning objectives developed by the expert group. The incorporation of core competencies into pre- and post-licensure disciplines should be tracked on an annual basis.

Objective 2: **Develop a pain education portal that leverages current activities and contains a comprehensive array of standardized materials to enhance available curricular and competency tools to address management across the continuum of pain and across the lifespan.** The portal will serve as a central, comprehensive source for pain education materials and will be monitored regularly and updated as new evidence-based guidelines and resources are available. The need for knowledge and skills that address how clinician empathy influences the effectiveness of care should be included in the available educational materials. The portal also should support an expanded knowledge base among providers to assess, identify, and refer individuals at risk for mental health and substance use disorders to behavioral health specialty care when needed.[54]

Short-term strategies and deliverables:

- Convene expert stakeholders to survey current resources, link to other relevant electronic artifact portals, and determine the content for a pain education portal. The portal would contain evidence-based and/or peer reviewed best practices material about pain assessment and care for use by educators and learners across all health, long-term services and supports, and social service settings and for all patients, including vulnerable populations.
- Develop and evaluate a pilot portal that leverages the NIH Pain Consortium Centers of Excellence in Pain Education and the AHRQ's U.S. Health Knowledge Information Database.

Medium-term strategies and deliverables:

- Coordinate efforts and existing resources to launch the publically accessible portal and broadly disseminate and promote its availability and use.
- Reconvene stakeholders to develop an annual survey to measure each school's progress in teaching about pain and to develop learning objectives to assess effects of enhanced pain education. Systematic reviews of studies about pain education would be a starting point in developing the content of the survey.
- Conduct the initial survey of schools.

Long-term (within five years) strategies and deliverables:

- Monitor and continue to update the portal, which would be fully developed over a five-year horizon. Conduct an annual online survey to solicit feedback on quality and utility of the portal.
- Repeat the survey (five year intervals) of schools and otherwise monitor pain education to assure that core competencies are taught.

Federal Stakeholders: AHRQ, CDC, DoD, FDA, HRSA, NIH, NLM, ONC, SAMHSA, VHA (to develop content and architecture and strategies to monitor and promote the portal)

Collaborators:

- professional medical organizations
- educators (to help develop survey and portal content)
- pain advocacy organizations and people with pain

Metrics: Frequency of access to, and downloads from the portal should be monitored and reported annually. Feedback from the annual online survey of the portal should be used to update and improve its quality and utility. Results of the annual survey of school's progress should be promptly reported. Progress in enhancing educational content on core competencies should be linked to achievement of learning objectives.

Public Education and Communication

The Institute of Medicine considered education central to a cultural transformation in pain care and recommended expanded and redesigned programs aimed at increasing public and patient understanding of pain. A national pain awareness campaign could draw on the experience of numerous federal agencies that have managed communications campaigns about public health topics as diverse as childhood immunizations, tobacco control, HIV/AIDS, depression, and nutrition.

Such campaigns generally involve numerous public and private partner organizations, each able to reach different segments of the population, use multiple media (including entertainment and social media), and require careful planning, research on audience segments' attitudes and beliefs and receptivity to test messages, and evaluation. A campaign with multiple components, heavy media buys, and other activities can be costly, which underscores the importance of focused strategy development.

The National Pain Strategy envisions a significant effort to increase public awareness about pain and recommends two campaigns. The priority campaign is an extensive public awareness campaign about pain, to reach all people including patients, their caregivers, and health care, long-term services and supports, and social service providers, and the secondary campaign would promote safer medication use by patients. Both should use a scientific approach, integrate health literacy principles and cross-cultural awareness and be tailored to specific audiences segmented by health status, demographic and cultural characteristics, and preferred informational media.[xxi] These campaigns should be undertaken in such a way that they do not compete.

The Problem: Pervasive stigmatization and misperceptions about pain are a root cause of significant and costly barriers to treatment and make it difficult for people with chronic pain to live productively and with dignity. Education is key to unlocking a necessary cultural transformation in the understanding of chronic pain, its care and treatment and treatment risks. In part, these problems arise because of the lack of high-quality, evidence-based communications campaigns that:

- Increase public awareness and knowledge about the pervasiveness of chronic pain, its complexity, and the importance of access to prompt and effective treatments.
- Change cultural attitudes about chronic pain, debunking stereotypes and myths related to people with chronic pain and various pain treatment options and emphasizing the value of pain self-management programs in enabling people to live better with chronic pain.
- Foster coalitions involving federal agencies, health care, long-term services and supports, and social service professionals and institutions, training and accreditation agencies, insurers, employers, foundations, patient advocate organizations, and others to participate in such campaigns and promote core messages.
- Deliver provider, public and patient education on risks and benefits of pain treatments and safer use of pain medications, including awareness of the risks for opioid use disorders that are associated with these prescription pain medications.

[xxi] In general, the planning and implementation for the campaigns follow the stages outlined in the National Cancer Institute's Making Health Communication Programs Work (http://www.cancer.gov/cancertopics/cancerlibrary/pinkbook/page1).

The intent of the Public Education and Communication section is to assure that chronic pain is recognized as a serious public health issue in the United States and that people with chronic pain have timely access to appropriate, safe pain management.

Objective 1: **Develop and implement a national public awareness and information campaign about the impact and seriousness of chronic pain, in order to counter stigmatization and correct common misperceptions.**

Short-term strategies and deliverables:

- Perform an environmental scan of existing relevant campaigns on chronic conditions and assess their impact in order to draw on successes in the design of this campaign.
- Establish a broadly representative advisory panel of stakeholders, to include patients with pain and members of their families, advocacy groups, professional societies, policy groups.
- Define campaign learning objectives (suggested concepts are in Appendix K), intended audiences, advisory structure, and budget.
- Develop requests for proposals from strategic communications firms to develop and conduct the campaign, review proposals, and select a firm (a separate firm may be engaged to conduct the evaluation).
- The selected firm would, as needed:
  - review available psychographic information regarding attitudes about pain (in the general population, in population subsets of interest, and in key stakeholder groups) and commission additional research, including surveys.
  - review available evidence about settings, channels, and activities best suited to reach these audiences, and commission additional research.
  - review existing information and educational materials.
  - develop a communications strategy based on behavior change theories for each targeted audience.
  - work with the advisory board to identify and recruit partner organizations and define their roles in the campaign.
- Based on this preliminary work, develop and pretest messages and materials using, wherever possible, information developed by other components of the National Pain Strategy.

Medium-term strategies and deliverables:

- Implement the program, including partner participation strategies, spokesperson training, and program-related services (e.g., pain self-management programs suggested in the Prevention and Care section), media (news, entertainment, social) strategies, and promotional materials.
- Monitor audience reach, feedback and partner engagement; adjust strategies as necessary.

Long-term (within five years) strategies and deliverables:

- Conduct an outcome evaluation to assess campaign effectiveness, as measured by changes in public opinion related to the campaign's learning objectives.
- Prepare a report based on the campaign evaluations for submission to a peer-reviewed scientific journal.

- As funds are available, continue to monitor, implement, assess, and adapt campaign components, as needed, and report on campaign outcomes in a peer-reviewed journal.

Federal Stakeholders: ACL, CDC, FDA, NPC, OASH (ODPHP, Office of the Surgeon General, Regional Health Administrators)

Collaborators:

- public health organizations
- professional organizations
- private and public insurers
- human resources professionals
- health care providers
- patient advocacy organizations and people with pain
- employee assistance programs

Metrics: the outcome evaluations would provide data on changes in public (and those of relevant demographic or other subgroups) attitudes based on campaign learning objectives, which are to be developed by the advisory panel, which ideally could be compared with baseline data to determine any short-term trends and refined and updated over time to maintain the campaign messaging based on achievements of the learning objectives.

Objective 2: **Develop and implement a national educational campaign to promote safer use of all medications, especially opioid use, among patients with pain.**

Short-term strategies and deliverables:

- Identify an HHS team and select an advisory board with broad representation, including people with pain, as well as experts in health communications and public relations, to develop, plan, implement, and evaluate the campaign. The selected team would:
  - define the advisory structure and budget.
  - review existing information and educational materials.
  - review available research on attitudes, knowledge, and medication practices of patients with chronic pain who take prescription medications, especially opioids.
  - review available evidence about settings, channels, and activities best suited to reach these patients, and commission additional research, as needed.
  - develop a communications strategy.
  - identify and recruit partner organizations.
- Align campaign messages and approaches with ongoing HHS efforts to promote safer and more appropriate use of prescription medications by patients and prescribers, such as:
  - promoting appropriate, safer, and effective use of opioids to manage chronic pain through the interactive tool *Pathways to Safer Opioid Use*[xxii]
  - electronic prescribing of controlled substances (EPCS).
  - facilitating use of state prescription drug monitoring programs.

[xxii] http://health.gov/hcq/trainings/pathways/

  - promoting clinical prescribing guidelines, such as the pending CDC Guidelines for Prescribing Opioids for Chronic Pain and the FDA Medication Guide for ER/LA Opioids (REMS [xxiii]).
- Cover the learning objectives and outcomes outlined in Appendix L in the campaign.
- Develop and pretest messages and materials based on preliminary work.

Medium-term strategies and deliverables:

- Implement the program, including partner participation strategies, spokesperson training, program-related services (e.g., a hotline), media (news, entertainment, social) strategies, and promotional materials.
- Monitor campaign reach and feedback and partner engagement; adjust strategies as necessary.

Long-term (within five years) strategies and deliverables:

- Conduct an outcome evaluation through nationally representative surveys and when appropriate through pre- and post-test surveys, using outcome measures tailored to the learning objectives to assess campaign effectiveness.
- Continue to implement, assess, and adapt campaign components as needed.
- Conduct a five year progress assessment of the issue of safer use of pain medications.
- Prepare reports based on the campaign evaluations for submission to a peer-reviewed scientific journal.

Federal Stakeholders: CDC, FDA, NPC, OASH (ODPHP, Office of the Surgeon General, Regional Health Administrators), and SAMHSA

Collaborators:

- public health organizations
- professional organizations
- health, long-term services and supports, and social services providers
- public and private insurers
- human resources professionals
- health care providers
- credentialing bodies
- major retail pharmacy chains
- National Association of Boards of Pharmacy
- professional pharmacy organizations and pharmacists
- pain patient advocacy organizations and people with pain
- addiction and opioid use disorder advocacy organizations

Metrics: the outcome evaluations would provide current data on the medication practices of patients with pain based on campaign learning objectives, which ideally could be compared with baseline data

[xxiii] http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm163647.htm

to determine any short-term trends and refined and updated over time to maintain the campaign messaging based on achievements of the learning objectives.

APPENDICES

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G. Pain treatment indicators: Health care services for pain measurable with electronic health care data

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J. Core competencies for pain education

K. Public education general campaign learning objectives

L. Learning objectives and potential outcome measures for an educational campaign on safe use of pain medications

M. Conflicts of Interests/Financial Disclosures

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Appendix C. Member nomination process and conflict of interest disclosure

The National Pain Strategy (NPS) is a nationwide plan to address the core recommendations of the Institute of Medicine's (IOM) report, *Relieving Pain in America*, on pain prevention, treatment, management, education, and research. The entity charged by HHS to address the IOM recommendations is the Interagency Pain Research Coordinating Committee (IPRCC), which was established under the ACA and, as such, is subject to rules and guidelines of the Federal Advisory Committee Act (FACA). The IPRCC's Task Force of experts, established to develop the NPS plan, also falls under the FACA rules and guidelines.

The Task Force is organized into six thematic working groups and an oversight panel and comprises approximately 80 members, with broad representation and expertise in accord with the recommendations of the IOM committee. Screening and selection of the NPS Task Force members was a multi-step process, performed according to FACA's requirements. A call for nominations was made through distribution to advocacy groups, professional societies, website notification, and email distribution. It was published as a Federal Register Notice as well. Candidates were selected based on expertise and knowledge, and the overall Task Force representation fulfilled IOM recommendations. A working group of the IPRCC screened and approved the slate of working group members.

Nominees were informed of the nature of conflicts of interests that would preclude their service and were required to disclose any potential conflicts and the nature of the conflicts. They were also required to disclose whether they were registered lobbyists, which precludes service under FACA. Conflict of interest disclosures were reviewed by the FACA Committee Management Officer and the IPRCC's Designated Federal Officer. If potential conflicts were identified, the nominee's conflict situation was reviewed by the NINDS Deputy Ethics Counselor to determine eligibility for service on the working group.

The working groups were advised of the needs and guidelines to protect the confidentiality of discussions to develop the NPS. Requests from all outside entities to present or provide unsolicited information to the working groups during the process were directed to the IPRCC's Designated Federal Officer.

Appendix D. Chronic pain screener questions

Definition	Item	Criteria
Pain on at least half the days for 6 months	Over the last six months, on about how many days have you had pain? ☐ I have not had pain ☐ I have had pain, but on less than half the days ☐ I have had pain on more than half the days, but not every day ☐ I have had pain every day, but not all the time ☐ I have had pain all day, every day, without break	Chronic pain is pain on at least half the days over the past six months.
Chronic pain severity (mild, moderate, severe)	In the past 7 days, how would you rate your pain on average? 0=No pain 10= Worst imaginable pain In the past 7 days, how much did pain interfere with <u>your day-to-day activities</u>? 0=No interference 10=Completely interferes In the past 7 days, how much did pain interfere with <u>your enjoyment of life</u>? 0=No interference 10=Completely interferes	Mean or sum of the three 0-10 pain ratings. **<u>Mean</u>** **<u>Sum</u>** Mild < 4 < 12 Moderate 4 to < 7 12 to 20 Severe 7 to 10 21 to 30 NOTE: If only two pain ratings are available, divide by the sum by two and multiple by 3 to obtain an estimated sum score.

Appendix E. Operational questions for determining high-impact chronic pain

<table>
<tr><td colspan="3">Among people with chronic pain (as determined by screener questions in Appendix D), high-impact chronic pain is operationally defined by enduring participation restrictions because of pain, including:</td></tr>
<tr><td>Participation restrictions because of pain</td><td>• Over the past 6 months because of pain…

I have had trouble doing my usual work (including work for pay, work around the home, volunteer work).

Never Rarely Sometimes Usually Always

• I have had trouble doing my regular social and recreational activities (such as visiting friends, going to the movies, attending clubs or religious activities).

Never Rarely Sometimes Usually Always

• I have had trouble taking care of myself (for example dressing, bathing, or feeding myself).

Never Rarely Sometimes Usually Always</td><td>At least one item rated “usually” or “always”</td></tr>
</table>

Appendix F. Diagnostic clusters for population pain research

1. Back pain
2. Neck pain
3. Limb/extremity pain, arthritis disorders (including osteoarthritis and joint pain)
4. Fibromyalgia and wide-spread muscle pain
5. Headache
6. Orofacial, ear, and temporomandibular disorder pain
7. Abdominal pain and bowel pain
8. Chest pain
9. Urogenital, pelvic, and menstrual pain
10. Fractures, contusions, sprains and strains
11. Other painful conditions. This includes sickle cell disease, Complex Regional Pain Syndrome, systemic lupus erythematosus, acquired deformities (excluding spinal disorders), spinal cord injury, Lyme disease, Neuropathic pain. Note: Cancer pain is included here, but relevant diagnostic codes need to be identified.

Appendix G. Pain treatment indicators: Health care services for pain measurable with electronic health care data

Type of service	Sub-types	Notes	Identification
Professional services	Primary care visits		Provider codes in combination with Diagnostic Clusters
	Pain specialist visits	Differentiate type of specialist (e.g. neurology, orthopedic surgery, rehabilitation medicine, anesthesiology, rheumatology)	
	Physical therapy visits		
	Occupational therapy visits		
	Psychologist visits		
	Chiropractic visits	These may not be routinely available in many electronic health care databases.	
	Alternative/complementary care visits		
Oral medications	Opioids	Differentiate short-acting and extended release. Chronic use may be defined by 70+ days supply in a 90 day period, receiving 6+ dispensings in a year, or other indication of sustained use.	National Drug Classification (NDC) codes) in combination with Diagnostic Clusters when necessary
	NSAIDS	Only available when prescribed, not over-the-counter.	
	Sedatives, anti-anxiety agents, sleep medications and muscle relaxants	Chronic use may be defined by 45+ days supply in a 90 day period or other indication of sustained, frequent use.	
	Triptans		
	Anticonvulsants		
	Antidepressants	SSRI, SNRI, Tricyclic antidepressants and other heterocyclic medications may be differentiated.	
	Aspirin and acetaminophen	These will not be adequately captured by electronic health care data because they are generally taken over-the-counter.	
Procedures	Surgery	Differentiate anatomical site of surgery (back, hip, knee, shoulder, etc.) and type of surgery within	Procedure codes in combination with

		anatomical site (e.g. laminectomy, fusion, discectomy for back surgery).	Diagnostic Clusters when necessary
	Injections, blocks and infusions	Differentiate type (e.g., epidural steroid injections, selective nerve root blocks, trigger point injections, facet point injections, sympathetic nerve root blocks, joint injections, peripheral nerve blocks).	
	TENS, spinal cord stimulation, deep brain stimulation		
Inpatient care	Surgical admission		Diagnostic codes identifying primary reason for admission
	Non-surgical admission		

Appendix H. Public and private payer coverage and payment methodologies for pain-related treatments

Public & Private Payer Coverage of Pain-Related Treatments						
Payer	**Pain-related Treatments**					
	Medications	**Regional Anesthetic Interventions**	**Surgery**	**Psychological Therapies**	**Rehabilitative/Physical Therapy**	**Complementary and Alternative Medicine (CAM)**
Medicaid	X	No state specific data found	X	X	X	X[5]
Medicare	X	X	X	X[3]	X[4]	X[5]
Private Insurers (BCBSM example)	X	X	X	X	X	X
Veterans Health Administration (VHA)	X	X	X	X	X	X[6]
U.S. Department of Defense (DoD)/ TRICARE[1]	X	X	X	X	X	X[7]
Federal and State Workers' Compensation Programs[2]	*State:* X *Federal:* X	*State:* X *Federal:* X	*State:* X *Federal:* X	*State:* No state specific data found *Federal:* X	State: X *Federal:* X	*State:* No state specific data found *Federal:* X

"X" indicates the payer offers coverage for procedure(s) within the treatment category

[1] TRICARE is the health care program of the DoD Military Health System and is administered through managed care support contracts. The program offers service members and their families three main health plan options (TRICARE Prime, TRICARE Standard, and TRICARE Extra) that allow them to receive care from private health care providers.

[2] The Federal Employees' Compensation Act (FECA) is the workers' compensation program for federal employees and provides medical benefits to employees who are injured or become ill in the course of their federal employment. FECA covers all medical costs associated with the treatment of the work-related injury or illness. FECA benefits are paid out of the congressionally appropriated Federal Employees' Compensation Fund. In contrast, state workers' compensation programs are regulated by the state and provided through private insurance, state insurance funds, or self-insurance. Policies and programs vary widely among states.

[3] In 2014 and 2015, Medicare beneficiaries were responsible for a 20% coinsurance for outpatient psychological counseling services. Before 2014, the coinsurance was 35 to 50 percent.

[4] Most health plans have limitations on physical therapy and occupational therapy services. For 2015, Medicare had a $1,940 combined annual cap for physical therapy and speech-language pathology services, and a $1,940 annual cap for occupational therapy services. Many Medicare Advantage plans have chosen not to institute a therapy cap.

[5] Medicare and most state Medicaid programs only cover chiropractic services for manual manipulation of the spine to treat a subluxation (when one or more bones in the spine move out of position). A few state Medicaid programs, such as Florida and Rhode Island, have covered other CAM services, including acupuncture and massage therapy.

[6] Every VHA provider has a specific requirement to make chiropractic services available onsite.

[7] While some military medical facilities may offer services like acupuncture and chiropractic care, these are reserved for active duty members only. CAM services are largely excluded under TRICARE.

Sources: Kaiser Family Foundation, State Facts, Medicaid Benefits, 2011; Centers for Medicare & Medicaid Services; BCBSM; TRICARE; VHA; Department of Defense, Report to the Congress: Complementary and Alternative Medicine within the Military Health System, 2011; Department of Defense, Report to the Congress: The Implementation of a Comprehensive Policy On Pain Management by the Military Health Care System; Congressional Research Service, The Federal Employees' Compensation Act (FECA): Workers' Compensation for Federal Employees, June 2013.

Public & Private Payment Methodologies for Pain-Related Treatments						
Payer[1]	**Pain-related Treatments**					
	Medications	**Regional Anesthetic Interventions**	**Surgery**	**Psychological Therapies**	**Rehabilitative/Physical Therapy**	**Complementary and Alternative Medicines (CAM)**
Medicaid[2]	Pharmacies are reimbursed for the acquisition cost of the drug plus a dispensing fee, both of which can vary by state. For states that contract with a managed care entity (MCE) to provide drug benefits, the MCE would negotiate payments.	No state specific data found	Varies by state	35 states use fee-for-service to pay for psychologist services for individuals enrolled in adult Medicaid.	33 states use fee-for-service to pay for occupational therapy services for individuals enrolled in adult Medicaid. 35 states and DC use fee-for-service to pay for physical therapy services for individuals enrolled in adult Medicaid.	26 states use fee-for services to pay for chiropractic services for individuals enrolled in adult Medicaid.
Medicare	Medicare Part D plans negotiate prices with pharmacies and manufacturers. The negotiated price includes the ingredient cost and dispensing fee.	Fee schedule and/or Prospective Payment System (depending on setting)	Fee schedule and/or Prospective Payment System (depending on setting)	Fee schedule and/or Prospective Payment System (depending on setting)	Fee schedule and/or Prospective Payment System (depending on setting)	Fee schedule
Private Insurers (BCBSM example)	Fee-for-Service	Fee-for-Service	Fee-for-Service	Fee-for-Service	Fee-for-Service	Fee-for-Service
Veterans Health Administration (VHA)[3]	VA negotiates pricing and purchases directly from wholesalers and manufacturers.	Global Budget	Global Budget	Global Budget	Global Budget	Global Budget
U.S. Department of Defense (DoD)/ TRICARE[4]	DoD negotiates prices with pharmacies and manufacturers.	Fee-for-Service	Fee-for-Service and Prospective Payment System	Fee-for-Service	Fee-for-Service and Prospective Payment System	Fee-for-Service
Federal and State Workers' Compensation Programs[5]	*State:* Varies by state *Federal:* Based on the Average Wholesale Price (AWP) for prescription drugs plus a dispensing fee, or on the Usual and Customary charge amount (whichever is less).	*State:* Fee-for-Service *Federal:* Fee-for-Service	*State:* Varies by state *Federal:* Fee-for-Service and Prospective Payment System	*State:* Fee-for-Service *Federal:* Fee-for-Service	*State:* Varies by state *Federal:* Fee-for-Service and Prospective Payment System	*State:* Fee-for-Service *Federal:* Fee-for-Service

[1] All payers appear to be relying largely on single modality approaches.

[2] In July 2011, almost 75% of Medicaid beneficiaries were enrolled in some type of managed care program. Benefits that are not included in a state's managed care contract are often provided on a fee-for-service basis or by a non-comprehensive prepaid health plan.

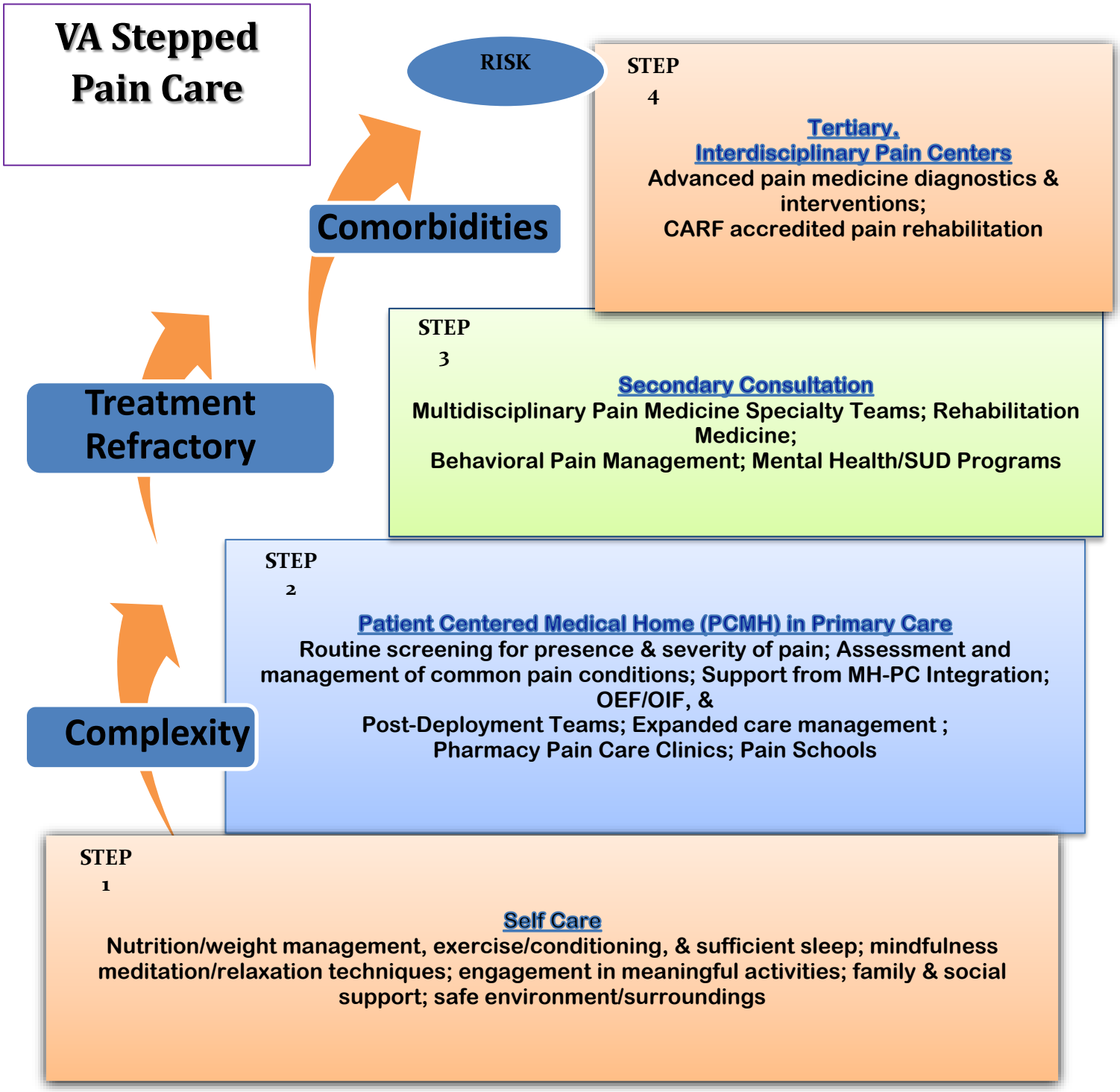
[3] The VHA, within the Department of Veterans Affairs, is appropriated a fixed amount of funds by Congress. Those funds are distributed to 23 regional service networks. The amount distributed to each region is determined by the Veterans Equitable Resource Allocation (VERA) system, an allocation method based on the number of patients served in the region and the severity of their conditions. VHA facilities do bill third-party payers (e.g., private insurance) for non-service-connected care. The funds generated from third-party payers go to the billing VHA facility. The VHA does reimburse for care provided at non-VHA facilities, using fee-for-service, when a veteran is unable to access care at a VHA facility in emergencies, if a covered service cannot be provided at a VHA facility, or due to geographic inaccessibility.

[4] Payment rates for TRICARE are generally aligned with Medicare. Health care providers who are employed at military medical facilities are salaried, like the VHA, and do not receive payment from TRICARE for the care they provide.

[5] Payment rates for the services covered by FECA are determined by the Department of Labor's Office of Workers' Compensation Programs fee schedule, which are generally aligned with Medicare. Similar to FECA, fee-for-service is the most common payment method among state workers' compensation programs. Payments made under state programs are generally greater than Medicare payments.

Sources: Kaiser Family Foundation, State Facts, Medicaid Benefits, 2011; Centers for Medicare & Medicaid Services; BCBSM; Congressional Research Service, Military Medical Care: Questions and Answers, January 2014; Congressional Research Service, Health Care for Veterans: Answers to Frequently Asked Questions, February 2014; Government Accountability Office, Access to Civilian Providers under TRICARE Standard and Extra, June 2011; U.S. Department of Labor, OWCP Medical Fee Schedule 2013.

Appendix I. The VA Stepped Care Model of pain care



Appendix J. Core competencies for pain education

Core competencies for pain management from an inter-professional consensus summit have been endorsed widely and supported by national healthcare organizations across the major health professions.[51] They provide a starting point for accrediting and credentialing organizations to help guide educators to develop and revise curriculum that advances care for effectively preventing and managing pain.

Box 1 Pain management domains and core competencies

Domain one
Multidimensional nature of pain: What is pain?
This domain focuses on the fundamental concepts of pain including the science, nomenclature, and experience of pain, and pain's impact on the individual and society.

1. Explain the complex, multidimensional, and individual-specific nature of pain.
2. Present theories and science for understanding pain.
3. Define terminology for describing pain and associated conditions.
4. Describe the impact of pain on society.
5. Explain how cultural, institutional, societal, and regulatory influences affect assessment and management of pain.

Domain two
Pain assessment and measurement: How is pain recognized?
This domain relates to how pain is assessed, quantified, and communicated, in addition to how the individual, the health system, and society affect these activities.

1. Use valid and reliable tools for measuring pain and associated symptoms to assess and reassess related outcomes as appropriate for the clinical context and population.
2. Describe patient, provider, and system factors that can facilitate or interfere with effective pain assessment and management.
3. Assess patient preferences and values to determine pain-related goals and priorities.
4. Demonstrate empathic and compassionate communication during pain assessment.

Domain three
Management of pain: How is pain relieved?
This domain focuses on collaborative approaches to decision-making, diversity of treatment options, the importance of patient agency, risk management, flexibility in care, and treatment based on appropriate understanding of the clinical condition.

1. Demonstrate the inclusion of patient and others, as appropriate, in the education and shared decision-making process for pain care.
2. Identify pain treatment options that can be accessed in a comprehensive pain management plan.
3. Explain how health promotion and self-management strategies are important to the management of pain.
4. Develop a pain treatment plan based on benefits and risks of available treatments.
5. Monitor effects of pain management approaches to adjust the plan of care as needed.
6. Differentiate physical dependence, substance use disorder, misuse, tolerance, addiction, and nonadherence.
7. Develop a treatment plan that takes into account the differences between acute pain, acute-on-chronic pain, chronic/persistent pain, and pain at the end of life.

Domain four
Clinical conditions: How does context influence pain management?
This domain focuses on the role of the clinician in the application of the competencies developed in domains 1–3 and in the context of varied patient populations, settings, and care teams.

1. Describe the unique pain assessment and management needs of special populations.
2. Explain how to assess and manage pain across settings and transitions of care.
3. Describe the role, scope of practice, and contribution of the different professions within a pain management care team.
4. Implement an individualized pain management plan that integrates the perspectives of patients, their social support systems, and health care providers in the context of available resources.
5. Describe the role of the clinician as an advocate in assisting patients to meet treatment goals.

Appendix K. Suggested learning objectives for a public awareness campaign

To increase public awareness about pain and people with pain, the committee recommends developing a campaign that will cover the following learning objectives (listed in order of priority):

1. Chronic pain is a disease.
2. Chronic pain is manageable.
3. Chronic pain is more prevalent than cancer, diabetes, and heart disease combined.
4. Chronic pain is real.
5. Most Americans will experience chronic pain or care for someone with chronic pain.
6. People in chronic pain deserve respect, compassion, and access to timely treatment.
7. Many people in chronic pain nevertheless live productive lives.
8. The goal for chronic pain management is to alleviate pain and restore function. Patients should be aware of realistic treatment expectations.
9. Chronic pain may cause depression and depression increases the severity of pain.
10. Chronic pain may require a spectrum of medical and surgical treatments and/or non-medical interventions, including self-management strategies along with the active participation of people with chronic pain in their own pain care management.
11. Appropriate chronic pain management may involve prescription medications, which require knowledge of risks for adverse effects such as dependency and addiction.
12. Activity level and mood may vary depending on the intensity of chronic pain (good days and bad days).
13. Awareness of conditions and activities that contribute to injury, especially in the workplace, can prevent pain.

Appendix L. Learning objectives and potential outcome measures for an educational campaign on safer use of pain medications

Learning Objectives

Increasing the number of people with chronic pain who report that they:

1. Talk with their clinician about their hopes and expectations and share activities of daily living or function that are important to them.
2. Work with their clinician to develop a plan of treatment consistent with their goals.
3. Know that analgesic medications can be an appropriate pain management option in selected and monitored patients and they are not the only option.
4. Know their prescription medication is only for them and do not share it with others.
5. Store their medicine in a safe place where children or pets cannot reach it.
6. Dispose of unused medication properly.
7. Take medicine only if it has been prescribed or approved by their doctor.
8. Do not take more medicine or take it more often than instructed. They call their doctor if their pain worsens.
9. Know how to understand and recognize expected and unexpected adverse effects such as dependency and addiction and to discuss risks with their doctor.
10. They talk to their doctor before taking prescription medications in combination with other drugs, including alcohol, sleeping pills, or anti-anxiety medication.
11. Have discussed with family and friends how to recognize and respond to overdose, including the use of naloxone.
12. Encourage family and friends to utilize Poison Control Centers as a confidential resource and to report possible opioid exposure and/or abuse by calling the Poison Help line [24]

Potential Outcome Measures

Where possible, existing data sources should be employed to monitor measures such as:*

1. Proportion of patients who
    a. discuss daily activities (quality of life) with their provider
    b. discuss expectations about the outcomes of pain treatment and side effects with their provider
    c. have a functional contract (defined) with their provider and discuss with their provider other appropriate treatments
2. Number of patients taking opioids who:
    a. report storing their medication safely
    b. do not save expired un-wanted, or unused medications (CPDA)
    c. report calling their doctor if pain worsens
    d. dispose of unused medication properly (CPDA)
    e. take opioids not prescribed for them
    f. take higher or more frequent doses than prescribed
    g. report mixing pain medicines with alcohol, sleeping pills, or any illicit substance
3. Number of overdoses reported in national emergency department data
4. Number of reports to the National Poison Data System

*A potential data source for some of these research questions is Research America's National Poll on Chronic Pain and Drug Addiction (CPDA).

[24] Poison Control Hot Line (1-800-222-1222).

Appendix M. Conflicts of Interests/Financial Disclosures

The following members reported no conflicts of interest:

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