2019 ARIZONA
MEDICAL LICENSURE PROGRAM

TARGETED SERIES OF CME FOR LICENSE RENEWAL

PROGRAM INCLUDES

3 CREDITS
OPIOIDS/SUBSTANCE ABUSE/ADDICTION

15 TOTAL CREDITS
AMA PRA CATEGORY 1 CREDITS™

NEW MANDATORY CME REQUIREMENT
FOR LICENSE RENEWAL
3 CREDIT HOURS ON OPIOIDS/SUBSTANCE ABUSE/ADDICTION

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2019 ARIZONA

01 PRESCRIBER EDUCATION FOR EXTENDED-RELEASE AND LONG-ACTING OPIOID ANALGESICS
   COURSE ONE | 3 CREDITS*

44 REDUCING DIAGNOSTIC ERROR IN MEDICINE
   COURSE TWO | 12 CREDITS

113 SELF-ASSESSMENT & EVALUATION SURVEY
   REQUIRED TO RECEIVE CREDIT

*This course satisfies the Arizona Boards of Medicine, Osteopathic Examiners and Physician Assistants mandatory (3) three AMA PRA Category 1 Credits™ or equivalent on Opioids/Substance Abuse/Addiction.

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CONTINUING MEDICAL EDUCATION FOR LICENSE RENEWAL

Physicians (MD’S) must complete (40) forty credit hours of continuing medical education during the two calendar years preceding license renewal. All of these credits must be AMA PRA Category 1 Credits™ or equivalent. Currently, for all licensed physicians their license will expire at midnight on the licensee's birthday in even or odd years.

Physicians (DO’S) must complete (40) forty credit hours of continuing medical education during the two years preceding license renewal. This must include at least (24) twenty-four credits of AOA Category 1-A and the remaining credit hours may consist of AMA PRA Category 1 Credits™ or equivalent. Currently for all licensed physicians (DO’s) their license will expire on December 31 in even or odd years.

Physician assistants (PA’S) must complete (40) forty credits of continuing medical education during their two year licensure period. All of these credits must be AMA PRA Category 1 Credits™ or equivalent. Currently, for all licensed physician assistants their license will expire at midnight on their birthday in even or odd years.

NEW MANDATORY CME ON CONTROLLED SUBSTANCES

Recently enacted legislation and regulatory actions requires all licensed physicians (MD/DO) and physician assistants who have an active DEA registration, to complete a minimum of (3) three AMA PRA Category 1 Credits™ or equivalent related to opioids, substance abuse or addiction. Effective April 26, 2018, licensees must complete this mandatory CME requirement prior to their next license renewal.

What does that mean for you?

For all physicians (MD/DO) and physician assistants, with an active DEA registration, a prerequisite for license renewal is the completion of (3) three credit hours related to opioids, substance abuse or addiction. These credits must be AMA PRA Category 1 Credits™ or equivalent and count toward overall CME requirements for license renewal and thereafter each licensure period. See respective board website for additional information.

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<th>COMPLETION DEADLINE</th>
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<td>Prior to your next license renewal.</td>
<td>Opioids, Substance Abuse or Addiction.</td>
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Dear Arizona Medical Professionals,

InforMed is pleased to offer this collection of CME activities for physicians that are licensed by the state of Arizona. The uniquely tailored curriculum is customized to the educational needs of Arizona medical professionals. Participants earn AMA PRA Category 1 Credit™ through these self-directed, on-demand courses.

The CME series is designed to streamline the education requirements of the Arizona Boards of Medicine, Osteopathic Examiners and Physician Assistants. Licensees who complete this program optimize their learning path while satisfying professional credentialing requirements for (3) three credit hours related to opioids, substance abuse or addiction. All activities are independently sponsored by InforMed Continuing Medical Education without commercial support.

Thank you for choosing InforMed as your CME provider. Please do not hesitate to contact us with any questions.

-InforMed CME Team

For more than 45 years InforMed has been providing high level education activities to physicians and other healthcare providers. Through our level of engagement with a wide variety of stakeholders, including our physician association, we have become the foremost public health policy continuing medical education organization in the United States. We are recognized as the leading provider of mandatory CME activities to physicians as a means of updating knowledge, improving competencies and fulfilling requirements for federal, state, regulatory and license renewal.

Completion Instructions

**Online:** Visit AZ.CME.EDU, select NETPASS to begin.

- After receiving a passing score on the test(s), claim your credit and print your verified certificate.

**Mail:** Use the enclosed envelope to mail self-assessment answer sheet, course evaluations and payment information to InforMed. If the envelope has been misplaced, please mail to the following address:

1015 Atlantic Blvd #301
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**Fax:** Fax self-assessment answers, course evaluation and payment information. Scores of 70% or higher will receive a verified certificate. For answers submitted via fax, please allow us 24 hours to process your request.
This course is designed for all physicians (MD/DO), physician assistants, nurse practitioners, and other health care professionals.

The purpose of this course is to educate prescribers about Risk Evaluation and Mitigation Strategies (REMS) in accordance with the FDA Blueprint for Prescriber Education related to extended release (ER) and long-acting (LA) opioid analgesics. This course is designed in accordance with the FDA's Blueprint for Prescriber Education for Extended-Release and Long-Acting (ER/LA) Opioid Analgesics.

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

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**TARGET AUDIENCE**

This course is designed for all physicians (MD/DO), physician assistants, nurse practitioners, and other health care professionals.

**COURSE OBJECTIVE**

The purpose of this course is to educate prescribers about Risk Evaluation and Mitigation Strategies (REMS) in accordance with the FDA Blueprint for Prescriber Education related to extended release (ER) and long-acting (LA) opioid analgesics. This course is designed in accordance with the FDA's Blueprint for Prescriber Education for Extended-Release and Long-Acting (ER/LA) Opioid Analgesics.

**LEARNING OBJECTIVE**

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

1. Describe how to assess patients for treatment with ER/LA opioid analgesics.
2. Recognize how to initiate therapy, modify dose, and discontinue use of ER/LA opioid analgesics.
3. Explain how to manage ongoing therapy with ER/LA opioid analgesics.
4. Discuss how to counsel patients and caregivers about the safe use of ER/LA opioid analgesics, including proper storage and disposal.
5. Identify general and product-specific drug information concerning ER/LA opioid analgesics.
6. Describe the two major competing responsibilities of clinicians related to the prescription of opioid pain medications.
7. List 3 advantages of creating written patient/provider opioid agreements.
8. Explain the value of function-based treatment goals as opposed to pain-relief goals.
9. List 2 ways to potentially address unpleasant or intolerable opioid side effects.

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- Read the course materials
- Complete the self-assessment questions at the end. A score of 70% is required.
- Return your customer information/answer sheet, evaluation, and payment to Informed by mail, phone, fax or complete online at course website under NETPASS.
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- Paul J. Christo, MD has received honoraria from Grunenthal, Quest Diagnostics, Revo Pharma, Daiichi Sankyo, Collegium Pharma, and Insys Therapeutics

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INTRODUCTION

Opioid analgesic medications are important tools for relieving moderate to severe pain arising from a wide range of conditions, disease states, or medical procedures. These drugs, however, may also be misused and abused, and overprescribing these agents can result in opioid use disorder or death from fatal overdose. The recognition of these problems has led in recent years to a re-thinking about the proper role of opioids, particularly for treating chronic non-cancer pain, and, specifically, about ER/LA opioid analgesics.

In February, 2016, for example, Dr. Robert Califf, Deputy FDA Commissioner for Medical Products and Tobacco, along with other FDA leaders, announced a “far-reaching action plan” to reassess the agency’s approach to opioid medications with the aim of reversing the epidemic of abuse and overdose while still providing patients in pain with access to effective relief. The new initiative will:

• Re-examine the risk-benefit paradigm for opioids.
• Develop changes to immediate-release opioid labeling similar to the ER/LA opioid labeling that is currently required.
• Update REMS requirements after hearing recommendations from a new advisory committee that will review current requirements.
• Improve access to naloxone and medication-assisted treatments such as methadone and buprenorphine for patients with opioid use disorders.
• Support non-opioid, alternative pain management strategies.

Also in 2016, the Centers for Disease Control and Prevention released its Guideline for Prescribing Opioids for Chronic Pain, which was developed using up-to-date data about the risks of opioids and an unusually comprehensive scientific review process. While acknowledging the continuing need for providing patients with adequate pain relief, the CDC guidelines go further than previous documents in recommending a very cautious approach to using opioids for chronic pain.

AN EPIDEMIC OF OPIOID ABUSE

The newly-announced steps by the FDA, as well as the new CDC guidelines, have come in response to the dramatic rise in the prescription and use of opioid analgesics in the past 20 years in the United States. Between 1999 and 2010, the use of opioids quadrupled. Much of this increase has been for the treatment of pain other than moderate-to-severe acute pain or intractable end-of-life pain, which have traditionally been seen as appropriate targets for opioids. In the past two decades, opioids have become widely-prescribed for chronic non-cancer conditions, such as back pain, osteoarthritis, fibromyalgia, and headache, despite an evidence base that is much weaker than has been generally appreciated by many physicians until recently.

As opioid prescriptions rose, so, too, did rates of opioid abuse, addiction, and diversion for non-medical use. This is why the current level of prescription opioid abuse has been described as an “epidemic” by the Centers for Disease Control and Prevention. Some data now suggest that prescriptions of opioids may have peaked in 2012. The data research firm IMS Health reported in May of 2016 that opioid prescriptions fell about 12% nationally between 2013 and 2015. Thus far, however, the reduced numbers of prescriptions has not resulted in fewer opioid-related overdose deaths—approximately 28,000 people died from such overdoses in 2014 (this figure includes deaths from both prescription opioids and heroin).

Significantly, despite the pronounced increase in opioid analgesic prescriptions in the U.S. over the past two decades, no overall national improvements in disability rates or health status measures among patients prescribed opioids has been demonstrated.

BALANCING RISKS AND BENEFITS

The rising tide of problems associated with opioid analgesics has created tension for some prescribers, who must balance an awareness of the ongoing problems of opioid over-prescription and abuse with the equally compelling need to relieve their patients’ pain. Pain remains the most common reason people seek health care. In fact, the incidence of chronic pain in the U.S. is estimated to be greater than that of diabetes, heart disease, and cancer combined. Inadequately treating pain can lead to a wide range of adverse consequences (in addition to causing needless suffering) including diminished quality of life, and a higher risk for anxiety or depression. Pain is also a major cause of work absenteeism, underemployment, and unemployment.

FIGURE 1. RATES* OF OPIOID PAIN RELIEVER (OPR) OVERDOSE DEATH, TREATMENT ADMISSIONS, AND KILOGRAMS SOLD IN THE UNITED STATES, 1999-2014

*Age-adjusted rates per 100,000 population for OPR deaths, crude rates per 10,000 population for OPR abuse treatment admissions, and crude rates per 10,000 population for kilograms of OPR sold.
Nonetheless, ER/LA opioid analgesics pose many risks, including:13

- Overdose (since most ER/LA formulations contain more opioid than immediate-release formulations)
- Life-threatening respiratory depression
- Abuse by patient or household contacts
- Misuse and addiction
- Physical dependence and tolerance
- Interactions with other medications and substances
- Risk of neonatal opioid withdrawal syndrome
- Inadvertent exposure/ingestion by household contacts, especially children
- Hypogonadism (decreased levels of FSH, LH, estrogen, testosterone)

Balancing the potential risks and benefits of a treatment is common in medicine. In the case of opioids, however, decisions are complicated by the fact that the drugs are potentially addictive and avidly sought by recreational users. But many guidelines exist that map out reasonable and practical ways to consider opioid analgesics for patients in pain. The 2016 CDC Guidelines, for example, make the following recommendations to clinicians about responsible opioid prescribing:1

- Do not prescribe ER/LA opioids for acute pain.
- Use opioid medications for acute or chronic pain only after determining that alternative therapies do not deliver adequate pain relief.
- The lowest effective dose of opioids should be used, and, for acute pain, the amount of opioids prescribed should be strictly limited to cover only the expected duration of severe pain (3 days or less will often be sufficient; more than 7 days will rarely be needed).
- In addition to behavioral screening and the use of patient-provider opioid agreements, consider random, periodic, urine testing for opioids and other drugs for patients with non-cancer pain being treated with opioids for more than six weeks.
- If your state has a prescription drug monitoring program (PDMP), periodically request, or check, a report on the history of opioid prescriptions to your patients by other providers.
- Use caution when prescribing opioids at any dosage, and carefully reassess evidence of benefits and risks when increasing dosage to ≥ 50 morphine milligram equivalents (MME)/day, and avoid increasing the dose to ≥ 90 MME/day.

Consider offering naloxone when factors that increase risk of opioid overdose are present.

This CME program summarizes these and other evidence-based recommendations for prescribing opioid analgesics, with a focus on ER/LA opioid formulations, which have been associated with higher levels of abuse and/or overdose.

**FUNDAMENTAL CONCEPTS**

Traditionally, pain has been classified by its duration. Acute pain lasts for only a matter of days or, at most, a few weeks, arises from obvious tissue injury, and usually fades with healing.5 Chronic pain, in contrast, lasts longer than would be anticipated for the usual course of a given condition. The International Association for the Study of Pain defines this as pain lasting 3 months or longer.14 The labels “acute,” and “chronic,” however, do not provide any information about the etiology or biological of the pain being experienced.

Pain, therefore, is also classified on the basis of its pathophysiology. Nociceptive pain is caused by the activation of nociceptors (pain receptors), and is generally, though not always, short-lived, and associated with the presence of an underlying medical condition in response to injury.

Neuropathic pain, on the other hand, results either from an injury or disease affecting the somatosensory system or from inadequately-treated nociceptive pain. It is an abnormal response to a stimulus caused by aberrant neuronal firing in the absence of active tissue damage. It may be continuous or episodic and varies widely in how it is perceived. Neuropathic pain is complex and can be difficult to diagnose and to manage because available treatment options are limited.

Both nociceptive and neuropathic pain can arise from, or be exacerbated by, sensitization, which is a state of hyperexcitability in either peripheral nociceptors or neurons in the central nervous system. Sensitization may lead to either hyperalgesia (heightened pain from a stimulus that normally provokes pain) or allodynia (pain from a stimulus that is not normally painful).15 Sensitization may arise from intense, repeated, or prolonged stimulation of nociceptors, or from the influence of compounds released by the body in response to tissue damage or inflammation.16 Many patients—particularly those with chronic pain—experience pain that has both nociceptive and neuropathic components, which complicates assessment and treatment.

It’s important for clinicians to distinguish between nociceptive and neuropathic pain because the two types respond differently to pain treatments. Neuropathic pain, for example, typically responds poorly to both opioid analgesics and non-steroidal anti-inflammatory (NSAID) agents.17 Other classes of medications, such as anti-epileptics, antidepressants, or local anesthetics, may provide more effective relief for neuropathic pain.18

Pain associated with cancer is sometimes given a separate classification, even though the pain itself is either nociceptive or neuropathic (or both). Cancer-related pain includes pain caused by the disease itself, painful diagnostic or therapeutic procedures, or side effects from cancer therapies such as chemotherapy or radiation. ER/LA opioids often play a role in treating cancer-related pain because such pain may be of exceptional severity and duration.

Chronic non-cancer pain may be caused by many kinds of conditions or disease states such as musculoskeletal injury, lower back trauma, dysfunctional healing from a wound or surgery, or from autoimmune system disorders. With chronic non-cancer pain, the severity of pain experienced by a patient may not correspond well—or at all—to identifiable levels of tissue damage.

Related to the nomenclature of pain itself are terms used in the context of opioid analgesic medications. The American Society of Addiction Medicine (ASAM), the American Academy of Pain Medicine (AAPM), and the American Pain Society (APS) have recommended the following definitions:19

**Tolerance.** A state of adaptation in which exposure to a drug induces changes that result in a diminution of one or more of the drug’s effects over time.

**Physical Dependence.** A state of adaptation that often includes tolerance and is manifested by a drug class-specific withdrawal syndrome that can be produced by abrupt cessation, rapid dose reduction, and/or administration of an antagonist.

**Addiction** (also known as substance use disorder). A primary, chronic, neurobiological disease, with genetic, psychosocial, and environmental factors influencing its development and manifestations. It is characterized by behaviors that include one or more of the following: impaired control over drug use, compulsive use, continued use despite harm, and craving.
EXERCISE 1

Instructions: Read the case below and complete both learning activities that follow.

Ralph is an 83-year-old who lives at home with his wife. He has a history of cardiovascular disease and, 10 years earlier, had successful quadruple bypass surgery. He takes the following medications: fish oil, a statin, a thiazide diuretic, low-dose aspirin, and a non-benzodiazepine sedative to help him sleep. Lately he has been complaining of increasing pain and stiffness in his right knee and hip. He is physically deconditioned due to a lack of exercise, in part because walking is painful. He asks if you can prescribe something to ease his pain.

Part 1 – Application: Take 5 minutes reviewing the scenario as it relates to either your clinical practice or the systems of care in which you work.

I. Evaluate application, or options for planned application, as it would apply in your own practice.

II. Consider the expected outcome(s) of those applications.

OVERVIEW OF PAIN MANAGEMENT STRATEGIES

Although this monograph focuses on ER/LA opioid analgesics, a review of the many pharmacologic and non-pharmacologic approaches to treating painful conditions is appropriate because such options should usually be tried, or at least considered, before an opioid is considered. Pain treatment options should be employed using the following general principles:

- Identify and treat the source of the pain, if possible, although treatment can begin before the source of the pain is determined. In some cases of chronic pain, an identifiable source of pain may not be found.
- Initiate non-pharmacologic approaches first, such as physical therapy. If medications are offered, try medications with the least severe potential side effects first (i.e., non-opioid).
- Establish a function-based management plan if treatment is expected to be long-term.

Five basic pain-management approaches exist, each of which will be more fully described below:

- Cognitive-behavioral approaches (may help patients monitor and evaluate negative or inaccurate thoughts and beliefs about their pain).
- Rehabilitative approaches (may improve physical function, alter physiological responses to pain, help prevent recurrence of injury, and help reduce fear and anxiety).
- Complementary and alternative therapies (can reduce pain, induce relaxation, and enhance a sense of control over the pain or the underlying disease).
- Interventional approaches (wide range of surgical and other interventional approaches to pain management including: trigger point injections; epidural injections; facet blocks; joint injections, sympathetic nerve blocks, targeted nerve blocks, radiofrequency denervation, pulsed radio frequency therapy, spinal cord stimulators; pain pumps, peripheral nerve stimulators, laminectomy; spinal fusion; and deep brain implants).
- Pharmacotherapy (NSAIDs, acetaminophen, topical agents, cannabis, antidepressants, anticonvulsants, opioids).

These modalities can be used alone or in combination to maximize pain control and functional gains. Which options are used in a given patient depends on the type of pain, the duration and severity of pain, patient preferences, co-occurring disease states or illnesses, patient life expectancy, cost, and the local availability of the treatment option.

COGNITIVE-BEHAVIORAL APPROACHES

Psychological therapies of all kinds can be critical for managing chronic non-cancer and cancer pain. Cognitive therapy techniques may help patients monitor and evaluate negative or inaccurate thoughts and beliefs about their pain. For example, some patients engage in an exaggeration of their condition called “catastrophizing” or they may have an overly passive attitude toward their recovery which leads them to inappropriately expect a physician to “fix” their pain without active self-management on their part. Individual, group, or family psychotherapy may be extremely helpful for addressing this and other psychological issues, depending on the specific needs of a patient. In general, psychological interventions may be best-suited for patients who express interest in such approaches, who feel anxious or fearful about their condition, have a history of trauma, or whose personal relationships are suffering as a result of chronic or recurrent pain.
Unfortunately, the use of psychological approaches to pain management can be hampered by such barriers as provider time constraints, unsupportive reimbursement policies, lack of access to skilled and trained providers, or a lack of awareness on the part of patients and/or physicians about the utility of such approaches for improving pain relief and overall functioning. Ideally this treatment modality should be provided by a trained pain psychologist who can help the patient set pain-specific self-management goals as part of his or her treatment plan.

**REHABILITATIVE APPROACHES**

In addition to relieving pain, a range of active rehabilitative therapies can improve physical function, alter physiological responses to pain, and help reduce fear and anxiety. Treatments used in physical rehabilitation include exercises to improve strength, endurance, and flexibility, gait and posture training, stretching, and education about ergonomics and body mechanics. Exercise programs that incorporate Tai Chi, swimming, yoga, or core-training work may also be useful. Other noninvasive, more passive, physical treatments for pain include thermotherapy (application of heat), cryotherapy (application of cold), counter-irritation, and electroanalgesia (e.g., transcutaneous electrical stimulation). Other types of rehabilitative therapies, such as occupational and social therapies, may be valuable for selected patients.

**INTERVENTIONAL APPROACHES**

Although beyond the scope of this CME program, many surgical and other interventional approaches to pain management exist, including: trigger point injections; epidural injections; facet blocks; joint injections; sympathetic nerve blocks; targeted nerve blocks; radiofrequency denervation; pulsed radio frequency therapy; spinal cord stimulators; pain pumps; peripheral nerve stimulators; laminectomy; spinal fusion; deep brain implants, and regenerative therapies such as platelet rich plasma and stem cell therapies. Many of these novel strategies may offer very effective options for pain relief in selected patients.

**NON-OPIOID PHARMACOTHERAPY**

Many options exist to treat both acute and chronic pain that do not involve opioids. These options should be thoroughly explored before an opioid is considered.

**ACETAMINOPHEN**

Acetaminophen, first introduced in the US market in 1953, provides predictable, if modest, pain relief, and is often recommended as a first-step treatment. It is used as an analgesic and antipyretic (fever reducer), but has poor anti-inflammatory properties. A Cochrane review found acetaminophen superior to placebo in pain reduction in patients with hip/knee osteoarthritis (OA). Although “extra strength” doses are widely promoted, evidence suggests that doses of 1000 mg are no better than 650 mg in relieving mild to moderate pain, which is significant because higher doses increase the potential for adverse events, especially in combination with other acetaminophen-containing products.

Although acetaminophen’s overall side effect profile is benign, this analgesic can pose risks for hepatotoxicity. Acetaminophen liver damage is the leading cause of drug-induced acute liver failure in the US. More than 35,000 acetaminophen-related overdose hospitalizations occur in the US every year, and acetaminophen accounts for 5% of all calls to US poison control centers. The most commonly implicated products in overdoses are acetaminophen/opiate combinations.

The threshold dose for acetaminophen liver toxicity has not been established, although the FDA recommends that the total adult daily dose should not exceed 4 g/day in patients without liver disease (although a ceiling of 3 g/day is suggested for older adults). Although acetaminophen is available over the-counter, it is not recommended as a treatment for acute pain.

**NSAIDS**

Non-steroidal anti-inflammatory drugs (NSAIDs) have analgesic, anti-pyretic, and anti-inflammatory properties. They are some of the most commonly-prescribed medications in the U.S., with over 111 million prescriptions written annually, in addition to widespread use of the over-the-counter (OTC) NSAIDs. NSAIDs are moderately effective in reducing pain from a variety of conditions. While most studies compare an NSAID with a placebo, no consistent evidence shows that any NSAID confers greater analgesic efficacy than any other, at equipotent doses. A Cochrane review found celecoxib to be significantly better than placebo in reducing pain in rheumatoid arthritis and osteoarthritis. In the treatment of chronic low back pain, NSAIDs are also significantly better than placebo, with a mean difference (between groups) in pain scale scores of 12 (on a 100 point scale).

The most serious NSAID side effects involve the GI tract, heart, and kidneys. The risk of GI bleeding may be mitigated by adding a proton-pump inhibitor (PPI). In 2015, the FDA strengthened existing “black box” warning for all NSAIDs that these agents can increase the chance of a heart attack or stroke.

**TOPICAL AGENTS**

Topical capsaicin and topical salicylates can both be effective for short term pain relief and generally have fewer side effects than oral analgesics, but their long term efficacy is not well studied. Topical NSAIDs and lidocaine have been reported to be effective for short term relief of superficial pain with minimal side effects, although both are more expensive than topical capsaicin and salicylates. None of the topical agents are useful for non-superficial pain. Topical lidocaine and topical high dose capsaicin are FDA approved for postherpetic neuralgia, and topical diclofenac is FDA approved for osteoarthritis.

**ANTIDEPRESSANTS**

Some antidepressants exhibit analgesic properties that do not depend on antidepressant activity, and antidepressants are equally effective in patients with and without depression. While analgesia may occur at lower doses and sooner than antidepressant activity, maximum efficacy may require high antidepressant doses and treatment of potentially lengthy duration.

Tricyclic antidepressants (TCAs) such as amitriptyline, nortriptyline, and imipramine, are used to treat a variety of types of chronic and neuropathic pain. Although often considered most effective for continuous burning pain or hypersensitivity conditions, TCAs also may relieve lancinating neuropathic pain. All TCAs are limited by anti-cholinergic side effects (dry mouth, urinary retention) and somnolence, which are dose-dependent. These side effects are less common with nortriptyline and desipramine than with amitriptyline. Side effects occur more commonly in elderly, so doses should be titrated cautiously. TCAs can also cause cardiac conduction abnormalities and should be avoided in patients with existing cardiac disease.

Selective norepinephrine reuptake inhibitors (SNRIs) are effective for a variety of neuropathic pain syndromes and myofascial pain conditions, with duloxetine having the most efficacy data for a variety of pain syndromes including diabet-

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ic peripheral neuropathy, fibromyalgia, and the non-neuropathic condition of musculoskeletal pain. The benefits of SNRIs appear to arise because of norepinephrine uptake effects in the spinal cord. The data for venlafaxine primarily support their use in diabetic neuropathy, and for milnacipran primarily for fibromyalgia. All SNRIs are limited by GI and CNS side effects, and should be taken on a full stomach.

The selective serotonin reuptake inhibitors (SSRIs) paroxetine and citalopram appear to be superior to placebo in relieving neuropathic pain, based on 2 small randomized trials (<50 patients each), but fluoxetine is not better than placebo in diabetic neuropathy. The SSRIs are associated with weight gain, sexual dysfunction, and a minor increase in the risk of bleeding due to platelet dysfunction. In general, the SSRIs are not particularly effective for pain, although they may be appropriate for patients with both chronic pain and a depressive disorder.

**ANTICONVULSANTS**

The increasing use of antiepileptic drugs (AEDs) for neuropathic pain is based on their ability to reduce membrane excitability and suppress abnormal discharges in pathologically altered neurons. The exact mechanism of action for their analgesic effects, however, is unclear. It does not appear to be specifically related to their antiepileptic activity. Other drugs that suppress seizures (e.g., barbiturates) do not relieve pain, and some AEDs with effective antiepileptic activity do not necessarily have good analgesic activity.

AEDs are used to treat neuropathic pain, especially lancinating (i.e., episodic shooting, stabbing, or knife-like) pain from peripheral nerve syndromes (e.g., diabetic neuropathy or fibromyalgia) and neuropathic pain arising from spinal cord injury. A Cochrane review of pregabalin for analgesia found a daily dose of 150 mg to be no more effective than placebo, but daily doses of 300-600 mg were significantly better than placebo. The most common side effects include peripheral edema, weight gain, and CNS side effects (including dizziness, somnolence, ataxia, and headache).

Gabapentin also effectively reduces diabetic neuropathic pain and other forms of neuropathic pain. In a trial comparing gabapentin to placebo, pain on 10-point scale decreased from 6.4 to 3.9 in the treatment group as compared to 6.5 to 5.1 in the placebo group after 8 weeks of treatment. Side effects are similar to pregabalin. The optimal dose of gabapentin is 600 – 1200 mg three times daily. The dose should be reduced in patients with severe kidney insufficiency. A Cochrane review assessed 14 studies evaluating the efficacy of carbamazepine in the treatment of neuropathic pain (e.g., diabetic neuropathy and postherpetic neuropathy) and found that 70% of carbamazepine patients had some improvement in pain (versus 12% of placebo). Carbamazepine is the standard of care for the treatment of trigeminal neuralgia pain.

**CANNABIS**

Cannabis sativa has been used for centuries to treat ailments ranging from nausea to glaucoma. Cannabinoids act, at least in part, through the cannabinoid receptors CB-1 and CB-2, and an opioid receptor mechanism that increases dopamine concentrations in the nucleus accumbens. The primary pain-relieving cannabinoid is cannabidiol, which is not psychoactive. A meta-analysis of 18 randomized trials of cannabis use in various chronic pain syndromes (1/3 of which were cancer) found a standardized mean difference in pain improvement of -0.61 (-0.84 to -0.37) indicating a moderate treatment effect. However, the individual studies were small (sample size ranging from 10-177), short-term (mean duration 25 days) and of overall poor methodological quality. Many of the studies had an “open phase” in which patients took the drug before randomization, to screen out those with low tolerance for side effects. No significant differences for dysphoria were observed between cannabis and placebo. Side effects of cannabis included euphoria, alterations in perception, events relating to cognitive function, and events concerning motor function.

Lynch et al., in a 2011 systematic review of RCTs of cannabinoids for CNCP (e.g., neuropathic pain, fibromyalgia, and rheumatoid arthritis), found that 15 of 18 trials demonstrated “significant analgesic effects compared to placebo.” Adverse effects in this review were generally well-tolerated, and cannabinoids were found to be “moderately effective” in neuropathic pain.

Cannabis has been used to help stabilize patients on methadone maintenance treatment and cannabis use has been associated with modest reductions in opioid withdrawal symptoms for such patients. Cannabis use has also been associated, on a state-wide level, with reduced rates of opioid overdose. Bachhuber et al., in a time-series analysis, found that between 1999 and 2010 states with medical cannabis laws had a 24.8% lower mean annual opioid overdose mortality rate (95% CI: -37.5% to -9.5%; p=0.003) compared with states without medical cannabis laws.

Smoking cannabis has been associated with twice the odds of pulmonary symptoms (cough, sputum, wheezing) but not associated with changes in lung function. Acutely, marijuana can impair short term memory, motor coordination, and judgement. Psychosis and paranoid ideation can also occur. Retrospective cohorts have found cannabis use may be associated with an “amotivational syndrome” and reproductive system changes (including reduced testosterone and libido in men, and increased prolactin in women). Amotivation can be particularly problematic for patients who have chronic pain because it can impair their ability to perform self-care. The use of cannabis can also lead to the development of marijuana use disorder, which in severe cases can take on the form of addiction.

**OPIOIDS**

**OPIOID MECHANISMS OF ACTION**

Opioid analogues work by binding to one or more of the three major types of opioid receptors in the brain and body: mu, kappa, and delta receptors. Opioids inhibit both ascending transmission of nociceptive information as well as descending pain control circuits. The most common opioid pain medications are “mu agonists” because they bind to and activate mu opioid receptors. Mu agonists include morphine, codeine, hydromorphone, oxycodone, and hydrocodone. The antagonists naloxone and naltrexone competitively bind to opioid receptors, blocking or disrupting agonists without causing the receptor to respond.

The binding of mu agonist opioids to receptors in various body regions results in both therapeutic effects (such as pain relief) and side effects (such as constipation). Tolerance develops for some effects of opioids, but not others. For example, some tolerance develops to respiratory suppressant effects within 5-7 days of continuous use, whereas tolerance to constipating effects never occurs. Tolerance to analgesia may develop early, requiring an escalation of dose, but tolerance may lessen once an effective dose is identified and administered regularly, as long as the associated pathology or condition is stable. Prescribers should understand the specific opioid tolerance criteria defined in product labeling, and summarized in Table 1 of this document.
GENERAL CONSIDERATIONS IN OPIOID SELECTION

Opioids as a class include many specific agents available in a wide range of formulations and routes of administration, (all of them scheduled under the Controlled Substances Act) including:

- Oral (e.g., tablets, capsules, solutions, lozenges)
- Transdermal
- Transmucosal
- Rectal
- Intrathecal
- Intravenous
- Epidural

Little evidence exists that specific analgesic formulations or dosing schedules affect efficacy or addiction risk, so selection of agent should be based on the patient’s pain complaint, lifestyle, and preferences. Generally, if opioids are used at all, it is better to offer short-acting opioids PRN as these are believed to present a lower risk of abuse or addiction. Long-acting (LA) or extended-release (ER) opioids may be helpful for patients who have difficulty managing an “as needed” regimen, or who are physically dependent on opioid analgesics and require continued use to maintain their functioning. (Prescribers, of course, should be aware of all relevant federal and state regulations pertaining to opioids prior to prescribing.)

Scheduled long-acting opioids have the advantage of producing a steady state, without the cycling effect of pain relief and withdrawal associated with short-acting opioids, which could, theoretically, lead to problematic behavior patterns.

With ER/LA agents, however, patients may end up using more drug than is actually needed, and adaptations to the steady state may ultimately decrease efficacy. Clinicians should warn patients that oral ER/LA opioids should not be broken, chewed, or crushed, and patches should not be cut or torn prior to use, since this may lead to rapid release of the opioid and could cause overdose or death.

AVOID ER/LA OPIOIDS FOR ACUTE PAIN

As mentioned earlier, ER/LA opioids should NOT be used to treat acute pain. However, cautious use of short-acting opioids for moderate or severe acute pain may be considered for carefully-selected patients whose pain is not controlled with acetaminophen or NSAIDs, or for whom such medications are contraindicated. The opioid should be used at a minimum effective dose, and for a limited period of time, usually less than 2-3 days. Opioids should be used only as one part of a comprehensive pain care plan, and extended release opioids should be avoided in acute pain patients.

Studies show that physicians routinely over-prescribe opioids for acute pain. For example, Rodgers et al., found that after outpatient orthopedic surgery, most patients were prescribed 30 pills of an opioid analgesic, although the mean patient consumption of those analgesics was only 10 pills. Another study found that 72% of people who had been prescribed an opioid had leftover medication. This guideline recommends that no more than a one-week supply be prescribed following surgery.

By definition, treatment of acute pain should not last longer than the time required for the healing or resolution of the trauma or condition. Hence, it is unlikely that opioids, or any other analgesic, will be needed beyond 90 days from initiation of treatment. Research shows that after 90 days of continuous opioid use, treatment is more likely to become life-long. The 90-day mark, therefore, should be considered a “red flag” point at which use should be re-evaluated and patients should be offered opioid taper.

CAUTIONS ABOUT OPIOIDS FOR CHRONIC NON-CANCER PAIN

A broad consensus is developing that opioid analgesics are not, in fact, suited for many patients with chronic non-cancer pain. Clinical guidelines for the use of opioids in chronic non-cancer pain have shifted to stress the risks of opioids and strengthen procedures that prescribers should use to reduce the risk of addiction and misuse.

Little evidence supports the assertion that long-term use of opioids provides clinically significant pain relief or improves quality of life or functioning. The Agency for Healthcare Research and Quality (AHRQ), for example, recently found no studies that compare opioid therapy with either a placebo or a non-opioid treatment for long-term (>1 year) pain management. A Cochrane review of opioids for long-term treatment of non-cancer pain found that many patients discontinue long-term opioid therapy (especially oral opioids) due to adverse events or insufficient pain relief.
Much evidence, on the other hand, shows that opioids pose many significant risks for adverse effects, abuse, addiction, and accidental overdose leading to death from respiratory depression. Estimating the magnitude of such risks is difficult because rigorous, long-term studies in patients without co-existing substance-use disorders have not been conducted. A few surveys conducted in community practice settings, however, estimate rates of prescription opioid abuse of between 4% to 26%. Risk rises with higher doses and longer durations. A 2011 study of a random sample of 705 patients undergoing long-term opioid therapy for non-cancer pain found a lifetime prevalence rate of DSM-5-defined opioid-use disorder of 35%. The variability in such results probably reflects differences in opioid treatment duration, the short-term nature of most studies, disparate study populations, and different measures used to assess abuse or addiction. Nonetheless, the levels of risk suggested by these studies are significant enough to warrant extreme caution in the prescription of any opioid for a chronic pain condition.

Caution is also required because many patients do not use opioids as prescribed by their physicians. Fleming et al., conducted in-depth interviews with 801 patients receiving long-term opioid therapy and found the following. 39% of patients increased their dose without direction from a health care provider, 26% engaged in purposeful over-sedation, 20% drank alcohol concurrent with opioid use, 18% used opioids for purposes other than pain relief, 12% hoarded their pain medications, 8% obtained extra opioids from other doctors.

As already mentioned, the risk of overdose with opioid analgesics is significant and, as with risk of opioid use disorder, rises with both dose and duration. In addition to the risks already mentioned, opioids can exert a wide range of uncomfortable or harmful adverse effects, the most common of which are neurologic (somnolence, dizziness), endocrine (hypogonadism), gastrointestinal (nausea, vomiting, and constipation), sexual (erectile dysfunction), and cutaneous (pruritus). In randomized trials of opioids, 50%-80% of patients report a side effect, and about 25% withdraw due to an adverse event. Although less common, there is also a dose-dependent increase in risk of fractures among patients prescribed opioids compared to patients not prescribed opioids, with risk highest just after an opioid was started. Another concern is the possibility that chronic opioid use may be immunosuppressive. Dublin et al., in a population-based case-control study, found a significantly higher risk of pneumonia in immunocompetent older adults who were prescribed opioids. The risk was particularly high for adults taking ER/LA opioids. Finally, prescription opioid use in pregnant women has been associated with a range of adverse newborn outcomes, including low birth weight, premature birth, and hypoxic-ischemic brain injury, although it is difficult to separate the effects of opioid use from other maternal factors that may contribute to these adverse outcomes.

There are two specific situations in which opioids are contraindicated in current guidelines: clinicians should avoid using intravenous or intramuscular opioid injections for patients with exacerbations of chronic non-cancer pain, and opioids should also be avoided pre-surgically in instances of acute trauma or chronic degenerative diseases.

WHEN, AND HOW, TO PRESCRIBE OPIOIDS FOR CHRONIC NON-CANCER PAIN

The risks reviewed above suggest that only a minority of patients with chronic non-cancer pain should be considered as potential safe candidates for opioid therapy. Nonetheless, an opioid may be appropriate for chronic pain in certain limited circumstances, such as: when the pain is severe and refractory to other treatments; when

<table>
<thead>
<tr>
<th>FIGURE 2. PERCENT OF ANNUAL OVERDOSE RATES RISES WITH DAILY OPIOID DOSE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Percent of annual overdose rate</td>
</tr>
<tr>
<td>No recent opioids</td>
</tr>
<tr>
<td>Percent of annual overdose rate</td>
</tr>
<tr>
<td>0.04</td>
</tr>
<tr>
<td>0</td>
</tr>
</tbody>
</table>
it adversely impacts function or quality of life; when other pharmacologic agents are contra-
indicated, and when the potential therapeutic benefits outweigh, or are likely to outweigh, po-
tential harms. In these cases, clinicians should follow published guidelines to maximize the ef-
fectiveness of an opioid and minimize its risk to the patient and to society at large. This section reviews these steps in detail.

PATIENT SELECTION AND RISK STRATIFICATION

Pain assessment includes recording of: chief complaint; nature and intensity of pain; history of present illness; past medical, surgical, and psychosocial history; past treatments; co-morbid conditions; family history; physical examination; and examination of imaging and other diagnostic studies or tests (Table 2). As with every patient, clinicians should take the time to look beyond the specific complaint or body part/system and evaluate holistically the broader mental, cultural, and socioeconomic contexts within which the chief complaint may be embedded.

PAIN ASSESSMENT TOOLS

Unidimensional pain scales (e.g., numeric or “faces”) are seldom useful for guiding a deci-
sion to treat chronic pain because such pain is variable and scores from pain assessment tools are highly subjective. Multidimensional tools provide more information, such as the effects of pain on daily life. These tools can typically be administered in an office, examination room, or other clinical setting by either a physician or another health care professional, or they could be filled out by the patient, if appropriate. Examples of some multidimensional tools include:

- Initial Pain Assessment Tool
- Brief Pain Inventory
- McGill Pain Questionnaire (short-form available)
- Pain, Enjoyment, and General Activity Scale

ASSESSING ABUSE RISK

Another key component of assessment is ascer-
taining the patient’s risk of substance abuse, misuse, or opioid use disorder. Although the available evidence base is weak, professional guidelines suggest that the following patients or pain conditions are unlikely to benefit from opioid analgesics:

- Poorly-defined pain conditions
- Daily headache
- Fibromyalgia
- A likely or diagnosed somatoform disorder
- Patients with unresolved workers compensa-
tion or legal issues related to pain or injury

<table>
<thead>
<tr>
<th>Region</th>
<th>Rationale, Methods, and Potential findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>General</td>
<td>Observe and/or identify:</td>
</tr>
<tr>
<td></td>
<td>Patient’s general appearance and vital signs</td>
</tr>
<tr>
<td></td>
<td>Evidence of overt abnormalities (e.g., weight loss, muscle atrophy, deformities, trophic changes)</td>
</tr>
<tr>
<td></td>
<td>Any subjective manifestations of pain (e.g., grimacing, splinting)</td>
</tr>
<tr>
<td>Site of pain</td>
<td>Inspect the pain site(s) for abnormal appearance or color of overlying skin or visible muscle spasm</td>
</tr>
<tr>
<td></td>
<td>Palpate the site(s) to assess for tenderness and correlate tenderness with any associated subjective or objective findings</td>
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<tr>
<td></td>
<td>Use percussion (or jarring) to elicit, reproduce, or evaluate the pain and any tenderness on palpation</td>
</tr>
<tr>
<td></td>
<td>Use the brush, pinch, pin prick, and/or scratch tests to assess for allodynia, hyperalgesia, or hyperesthesia</td>
</tr>
<tr>
<td></td>
<td>Determine the effects of physical factors (e.g., motion, applied heat or cold, deep breathing, changes in position) on pain</td>
</tr>
<tr>
<td>Other regions</td>
<td>Examine other regions as directed by the patient history or assessment of pain site</td>
</tr>
<tr>
<td>Neurological system</td>
<td>At minimum, perform a screening neurological examination (i.e., assess cranial nerves, spinal nerves, sympathetic nervous system function, coordination, and mental status) to screen for:</td>
</tr>
<tr>
<td></td>
<td>Sensory deficits (e.g., impaired vision or hearing) or abnormal sensations (e.g., paresthesia, dysesthesia, allodynia, hyperpathia)</td>
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<tr>
<td></td>
<td>Motor abnormalities or deficits (e.g., weakness, exaggerated or diminished reflexes)</td>
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<tr>
<td></td>
<td>Lack of coordination</td>
</tr>
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<td></td>
<td>Evidence of sympathetic nervous system dysfunction (e.g., skin flushing, unusual sweating)</td>
</tr>
<tr>
<td></td>
<td>Abnormalities or deficits in orientation, recent or remote memory, parietal sensory function, language function, and mood</td>
</tr>
<tr>
<td>Musculoskeletal system</td>
<td>Observe and/or identify:</td>
</tr>
<tr>
<td></td>
<td>Body type, posture, and overall symmetry</td>
</tr>
<tr>
<td></td>
<td>Abnormal spine curvature or limb alignment and other deformities</td>
</tr>
<tr>
<td></td>
<td>Abnormal movements and/or irregular gait during walking</td>
</tr>
<tr>
<td></td>
<td>Range of motion (spine, extremities)</td>
</tr>
<tr>
<td></td>
<td>For muscles in neck, upper extremities, trunk, and lower extremities:</td>
</tr>
<tr>
<td></td>
<td>Assess multiple parameters (e.g., tone, volume, contour, strength and power, range of motion)</td>
</tr>
<tr>
<td></td>
<td>Observe for any abnormalities (e.g., weakness, atrophy, hypertrophy, irritability, tenderness, trigger points)</td>
</tr>
</tbody>
</table>
Assessing a patient’s risk of opioid use disorder is at least somewhat subjective, and opinions differ about which patients should be more rigorously assessed. Some favor a “universal precautions” approach, in which all pain patients are considered to have some degree of vulnerability to opioid use disorder and, hence, all patients are given the same screenings and diagnostic procedures. Some patient characteristics, however, do appear to be predictive of a potential for drug abuse, misuse, or other aberrant behaviors, particularly a personal or family history of substance use disorder. Some studies also show that younger age and the presence of psychiatric conditions are associated with aberrant drug-related behaviors.

Relatively brief, validated tools can help formalize assessment of a patient’s risk of having a substance use problem (Table 3) and these should be considered for routine clinical use.

### USE A HOLISTIC APPROACH TO PSYCHOSOCIAL EVALUATION

Pain can perturb all aspects of a patient’s life, hence clinicians need to be alert to the ways pain may be impacting, or may be affected by, psychosocial elements of a patient’s life. For example, clinicians must check for signs of depression or anxiety, which are common in pain patients. Be particularly alert for suicidal tendencies.

### EXERCISE 2

**Instructions:** Read the case below and complete the activities that follow.

Hannah is a 62-year-old woman who has been coping with persistent pain for more than a year since she was involved in a car accident. Her initial severe neck and low back pain was thought to be due to cervical and lumbar sprain/strain. She was prescribed a short-acting opioid, which she said helped with the pain, but led to constipation. After three months of using the opioid, Hannah decided to stop because she did not like the constipation and “brain fog” from the drug. She tried several types of alternative therapies, such as massage and acupuncture, both of which provided short-term relief, although the pain later returned. At 6 months post-accident, X-ray and MRI imaging revealed no obvious spinal pathophysiology, although Hannah reported the pain was spreading to her legs and arms. Hannah has a BMI of 31 and has been diagnosed with metabolic syndrome. She is physically inactive but currently takes no medications.

**Part 1 – Application:** Take 5 minutes reviewing the scenario as it relates to either your clinical practice or the systems of care in which you work.

I. Evaluate application, or options for planned application, as it would apply in your own practice.
II. Consider the expected outcome(s) of those applications.

**Part 2 - Questions and Considerations:** Spend 5 minutes considering the following questions as they relate to the case presented.

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

2. Does the lack of obvious pathophysiology on imaging suggest that Hannah is a hypochondriac?

3. Would Hannah be a good candidate for an ER/LA opioid? Why or why not?

### TABLE 3. TOOLS FOR INITIAL PATIENT RISK ASSESSMENT

<table>
<thead>
<tr>
<th>Tool</th>
<th>Who Administers?</th>
<th>Length</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diagnosis, Intractability, Risk, Efficacy (DIRE)</td>
<td>Clinician</td>
<td>7 items</td>
</tr>
<tr>
<td>Opioid Risk Tool (ORT)</td>
<td>Clinician or patient self-report</td>
<td>5 yes/no questions</td>
</tr>
<tr>
<td>Screener and Opioid Assessment for Patients with Pain, Version 1 and Revised (SOAPP, and SOAPP-R)</td>
<td>Patient self-report</td>
<td>24 items</td>
</tr>
</tbody>
</table>
thoughts since the risk of suicide is roughly double for patients with chronic pain. Some free instruments for gathering a psychiatric history are the Depression Anxiety & Positive Outlook Scale (www.dapos.org) or the Patient Health Questionnaire (PHQ Screeners (www.phqscreener.com). Referral to a mental-health professional is warranted if you suspect a patient has active psychological issues beyond your expertise.

Clinicians should also probe for ways in which pain may be affecting the patient’s family system, work, or social activities. Pain can seriously erode these spheres of life and evaluating these challenges and addressing them during treatment (for instance by referral to a vocational counselor or social worker) is just as important as treating the more immediate medical issues that may be contributing to chronic pain.

PATIENT/PROVIDER AGREEMENTS
An opioid “medication agreement” or “management plan” can help educate patients, clarify expectations, and establish goals, all of which may help a patient adhere to a pain management regimen. These agreements should be written and signed by the provider and the patient. (Table 4)

Avoid framing patient/provider agreements in terms of punishments for misbehaviors and avoid using language that is stigmatizing, dominating, or pejorative. Since written agreements must be clearly understood by the patient, they should be written at the sixth- to seventh-grade level, and translated into the patient’s language, if possible (in-person translators may also be used). When administering an agreement, allow time for patients to ask questions, and to ensure patients understand what they are being told. Some, or all, of these tasks may be handled by trained personnel (or staff members) rather than physicians.

Be aware that although the terms “agreement” or “plan” are more patient-friendly than the word “contract,” from a legal standpoint, any written or oral agreement between a prescriber and a patient may be considered a binding “contract.”

TAKE A FUNCTIONAL APPROACH
Since pain itself cannot be measured objectively, opioid management plans and provider/patient agreements should not be framed solely in terms of pain relief; functional goals are preferable. Chronic pain often impairs functioning in daily life, such as the ability to be physically active, mentally focused, and well-rested. Even relatively modest reductions in pain (e.g., a 20% reduction on a pain score) can allow for significant functional improvements. By using functional goals a prescriber can make more objective decisions about prescribing, dose adjustments, and/or treatment termination. Objective data can be used such as attendance at physical therapy appointments, number of days sleeping in a bed instead of a chair, or distance walking (a pedometer is a good way to measure this). Taking a functional approach to pain management may also help you spot patients who are addicted to an opioid because addiction typically leads to decreased functioning, while effective pain relief typically improves functioning.

Functional treatment goals should be realistic and tailored to each patient. Because patients with long-standing chronic pain are frequently physically deconditioned, progress in achieving functional goals can be slow or interrupted with “setbacks.” It is better to set goals slightly too low than slightly too high. Raising goals after a patient has “succeeded” is preferable—and more motivational—than lowering goals after a patient has “failed.”

INFORMED CONSENT
Informed consent is a fundamental part of ethical treatment, and is particularly important when considering an opioid or other controlled substance, given their potential risks. Well-crafted informed consent documents that are explained clearly and carefully can actually improve the clinician/patient relationship. In creating and using informed consent documents, keep the following four questions in mind:

1. Does the patient understand their treatment options?
2. Has the patient been told of the potential benefits and risks associated with each of those options?
3. Is the patient free to choose among those options (meaning free from coercion by the healthcare professional, the patient’s family, or others?)

4. Does the patient have the cognitive and sensory capacity to communicate his or her preferences—verbally or in other ways?

Informed consent can be documented on paper or electronically, and the informed consent language can be incorporated into a larger treatment plan or patient/provider agreement.

**WHO ARE PAIN MEDICINE SPECIALISTS?**

Pain Medicine is the medical specialty dedicated to the prevention, evaluation and treatment of people with chronic pain. While most physicians, advanced practice nurses, and physician assistants have some training and experience in the management of chronic pain, Pain Medicine Specialists (physicians) have fellowship training from The American Board of Medical Specialties (ABMS), the American Osteopathic Association (AOA), or additional training in pain medicine sufficient to obtain ABPM diplomat status. Current protocols regarding the delineation of prescribing authority to and supervision of Advanced Practice Nurses with certificate of fitness for prescribing and Physicians Assistants for prescribing to treat chronic pain continue to apply. Pain Medicine Specialists may deal with patients being treated with more than 90 milligram morphine equivalents daily dose because they are at least eleven times more likely to suffer an adverse effect including overdose death.

**INITIATING OPIOIDS**

Before prescribing any opioid, confirm that:

- Other treatments with more optimal risk-benefit profiles have been exhausted
- The patient’s physical and psychosocial condition has been fully assessed
- Level of opioid tolerance has been determined or estimated (see below)
- Informed consent has been obtained and a management plan is in place

Opioid selection, initial dosing, and titration must be individualized to the patient’s health status, previous exposure to opioids, and treatment plan. Patients who are opioid-naïve or have modest previous opioid exposure should be started at a low dose, generally of a short-acting opioid because these confer a lower risk of overdose, and titrated slowly upward to decrease the risk of opioid-related adverse effects. If it is unclear whether a patient has recently been using opioids (either prescribed or non-prescribed), the clinician should assume that the patient is opioid-naïve (i.e., not tolerant) and proceed as just described. Some patients, such as frail older persons or those with comorbidities, may require an even more cautious therapy initiation. Prescribers should understand the warning signs and symptoms of significant respiratory depression (i.e., shallow, slow breathing, pinpoint pupils, cyanosis), communicate this information to patients, and be alert for the possibility of respiratory depression at the time of treatment initiation or dosage increase.

Prescribe opioids cautiously in patients with conditions that may be complicated by adverse effects from opioids, such as chronic obstructive pulmonary disease (COPD), congestive heart failure, sleep apnea, current or past substance use disorder, mental illness, advanced age, or patients with a history of renal or hepatic dysfunction.

Because of the risk of neonatal opioid withdrawal syndrome with prolonged use of an opioid during pregnancy, newly pregnant women should have a urine drug test administered to ascertain previous use, and, for women who are not pregnant, providers should discuss a birth control plan to prevent unintended pregnancy. In general, opioids should be avoided in this population.

Opioid prescriptions should be handled by a single provider or practice and all prescriptions should be filled in a single pharmacy, unless the provider is informed and agrees that the patient can go to another pharmacy for a specific reason. Prescribers should tell patients and caregivers to read the specific ER/LA opioid analgesic Medication Guide that they receive from the pharmacy and to tell their doctor about any side effects or adverse events they experience. An initial trial of an opioid should be assessed using the following outcome measures:

- Progress toward meeting functional goals
- Presence and nature of adverse effects
- Changes in the underlying pain condition
- Changes in medical or psychiatric comorbidities
- Degree of opioid tolerance in the patient
- Identification of aberrant behaviors, misuse, or diversion

Further studies are needed to confirm more consistent control of pain and improved adherence to prescribed therapy with use of ER/LA opioids. Although low-dose, short-acting opioids may offer the greatest safety for initiating opioid therapy, clinicians must recognize that short-acting opioids are not intrinsically safer than other formulations, and stress to their patients the importance of strict adherence to prescribed doses/administration.

The CDC recommends that patients on opioid doses of 90 morphine-equivalent dose/day (MEDD) or greater should be referred to a pain specialist for consultation and/or management. If a provider cannot make the required consultation, it is recommended that he/she should clearly document why not. (Note: a pain specialist is a physician who has undergone fellowship training from the American Board of Pain Medicine or other training sufficient to obtain diplomat status.) In general, current guidelines suggest that doses of >90 MEDD should be avoided.

**PATIENT EDUCATION**

Whenever an opioid is prescribed, the patient should be thoroughly educated about the safe use, storage, and disposal of opioid medications. This can be done by a non-physician, if desired, and the key points can be included in patient/provider agreements or treatment plans. (Prescribers should use the Patient Counseling Document as part of the discussion when prescribing opioid analgesics—see Table 11). Safe use means following clinician instructions about dosing (including how to handle missed doses), not using concurrent alcohol or sedatives, not sharing medications, not breaking, chewing, or crushing medicines, and not using transdermal products if they are broken or torn. (If a patient cannot swallow a capsule whole, prescribers should refer to the product labeling to determine if it is appropriate to sprinkle the contents of a capsule on applesauce or administer via a feeding tube.) Patients should also be warned not to abruptly discontinue or reduce their ER/LA opioid analgesic, and be informed about the potential risks of falls, driving, and working with heavy machinery (particularly after dose initiation or an upward change in dose).

Prescribers should instruct patients and caregivers to tell all of their doctors about all medications the patient is taking. Furthermore, prescribers should strongly discourage the use of benzodiazepine medications and other respiratory depressants, including alcohol, concurrent with an opioid. Safe storage means reminding patients that pain medications are sought-after by many people, and that opioids should be stored in a locked cabinet or other secure storage unit. If a locked unit is not available, patients should, at least, not keep opioids in a
place that is obvious to, or easily accessed by others, since theft by friends, relatives, and guests is a known route by which opioids become diverted. Storage areas should be cool, dry, and out of direct sunlight.

Proper disposal means getting rid of unused medications by: returning the medications to a pharmacy, health center, or other organization with a take-back program; flushing them down a toilet (unless prohibited by state law); or mixing the medication with an undesirable substance and putting it in the trash. In 2014, the DEA loosened regulations to allow pharmacies, hospitals, clinics, and other authorized collectors to serve as drop-off sites for unused prescription opioid drugs.

**OPIOID SELECTION**

Opioid analgesics are available in a wide range of formulations and routes of administration (Table 6). Little evidence exists that specific analgesic formulations affect efficacy or risk of opioid use disorder, so selection of an agent should be based on the patient’s pain complaint, lifestyle, and preferences. Generally, if opioids are used at all, it is better to offer short-acting opioids used on an as-needed basis. ER/LA opioids produce a more steady state of analgesia without the cycling effect of pain relief and withdrawal associated with short-acting opioids, which may be helpful for certain patients. With ER/LA agents, however, patients may end up using more drug than is actually needed, and physiological adaptations to the steady state may ultimately decrease analgesic efficacy.

Prescribers should educate themselves about the general characteristics, toxicities, and drug interactions for ER/LA opioid products. For detailed information on current ER/LA opioid analgesics, see the FDA Blueprint for Prescriber Education at the end of this document. For example, some ER/LA formulations may rapidly release opioid (dose dump) when exposed to alcohol. In addition using opioids with monoamine oxidase inhibitors (MAOIs) may increase the risk of respiratory depression and serotonin syndrome. Opioids can reduce the efficacy of diuretics by inducing the release of antidiuretic hormone (ADH).

Combination products join an opioid with a non-opioid analgesic, usually for use in patients with moderate pain. Using a combination product when dose escalation is required risks increasing the adverse effects from the non-opioid co-analgesic, even if an increase of the opioid dose is appropriate. In such cases, using a pure opioid is preferable. Particular care must be made to not exceed maximal daily doses of acetaminophen.

**THE SPECIAL CASE OF METHADONE**

Methadone has received growing attention because it is frequently involved in unintentional overdose deaths. These deaths have escalated as methadone has increasingly been used as an analgesic drug for chronic pain. At one time, methadone had been used almost exclusively in opioid maintenance therapy programs to treat opioid use disorder. Its relatively long plasma elimination half-life compared to its relatively short analgesic half-life makes it optimal for maintenance, allowing for once-daily dosing. But methadone only exerts potent analgesic effects in the early phase of its elimination half-life (about 4 hours), and this, along with the fact that it is among the least expensive opioids, has led to a dramatic increase in its use for alleviating chronic non-cancer pain.

Methadone has unique pharmacokinetic and pharmacodynamic characteristics that add substantial risk to its use. Although its chemical structure is different from classic opioids such as morphine, methadone acts on the same set of opioid receptors, though with different affinities for the various opioid receptor subtypes.

In addition, methadone possess non-opioid receptor effects that may explain some of its potential special efficacy. These varied effects across opioid receptors, along with its non-opioid properties, have garnered methadone the reputation of being a “broad spectrum opioid.” For a number of reasons, however, methadone must be titrated very carefully in order to avoid overdose. These reasons include:

- An analgesic half-life much shorter than its elimination half-life (leading to accumulation)
- Metabolism by a group of liver enzymes that differ from those associated with most other opioids, hence leading to unexpected drug-drug interactions
- Significant genetic variations in the liver enzymes that metabolize methadone, which contribute to the unpredictability of methadone’s effects and side effects
- Metabolism may be affected by cigarette smoking (which accelerates elimination) and alcohol consumption (which can augment methadone toxicity acutely and accelerate metabolism with chronic use)

The APS/AAPM guidelines recommend a starting dose in most opioid-naive patients of 2.5 mg every 8 hours, with dose increases occurring no more frequently than weekly. The lowest possible dose titration should be followed even in opioid-tolerant patients because methadone appears to be more potent in patients who have been using higher doses of the pre-switch opioid. The total daily dose of methadone on the first day of treatment should not ordinarily exceed 30-40 mg/d regardless of prior exposure. In older patients or those with renal or hepatic comorbidities, lower starting doses, less frequent dosing, and more cautious dose titration are recommended. Because of its long half-life and variable pharmacokinetics, methadone is not recommended to treat breakthrough pain or as an as-needed medication.

When rotating from another opioid to methadone, extreme caution must be used when referring to equianalgesic conversion tables. The consensus recommendations from an expert panel suggest a 75 to 90% decrement in the equianalgesic dose from conventional conversion tables when a switch is made from another opioid to methadone.

Because the risk of overdose is particularly acute with methadone, patients should be educated about these risks and counseled to use methadone exactly as prescribed. They should also be warned about the dangers of mixing unauthorized substances with their medication. Benzodiazepines, in particular, pose a threat. Death investigations often find that benzodiazepines have been used in combination with methadone and other opioids. Other respiratory depressants, including alcohol, pose similar risks. Dosing should, therefore, be conservative and cautious until patients demonstrate the ability to tolerate and use the drug safely.

In 2006, the FDA issued a public health advisory warning that methadone can cause serious cardiac conduction disturbances, including QT interval prolongation and Torsades de Pointes, a potentially fatal ventricular arrhythmia. It appears that methadone-related corrected QT (QTc) interval prolongation (>450 ms) and cardiac arrhythmias can occur at any dose but are more likely at higher doses or with concomitant use of drugs that interact with methadone or that themselves prolong QTc. Although uncommon, the cardiac arrhythmias that can be induced by methadone can be lethal if not detected. The cardiac health of patients who are candidates for methadone should be assessed, with particular attention paid to any history of heart disease or arrhythmias. An initial ECG may be advisable prior to starting methadone, particularly if a patient has a specific cardiac disease or cardiac risk factors or is taking agents that may interact with methadone. Alternative treatments should be considered when the QTc is >450 ms.
<table>
<thead>
<tr>
<th>ROUTE</th>
<th>DEFINITION AND NOTES</th>
<th>DRUG TYPES</th>
<th>COMMENTS</th>
</tr>
</thead>
</table>
| Oral                  | By mouth (per os) \*
Requires functioning GI tract, intact swallowing mechanism, sufficient GI tract for absorption to occur | NSAIDS, opioids, adjuvant analgesics (TCA, Antiepileptics, SNRI) | Advantages: convenient, noninvasive, usually cost-effective, flexible, less discomfort than injections with comparable efficacy
Disadvantages: requires functional GI system; slow onset of action and relatively delayed peak effects; requires patient compliance |
| Rectal                | Insertion of suppository into rectum                                                 | Opioids                                 | Useful in patients who cannot take medications by mouth
Any opioid may be compounded for rectal administration |
| Intramuscular         | Injection into large muscle (e.g., gluteus or vastus lateralis)                      | Opioids                                 | IM administration should not be used, especially for chronic treatment, due to multiple disadvantages:
• Painful injections
• Wide fluctuations in drug absorption make it difficult to maintain consistent blood levels
• Rapid fall-off of action compared with PO administration
• Chronic injections may damage tissue (fibrosis, abscesses) IV and SC injections are appropriate alternatives |
| Intravenous           | Injection into vein; may be single or repetitive bolus or continuous infusion with or without PCA | NSAIDS, opioids, ketamine, acetaminophen | IV is most efficient ROA for immediate analgesia and permits rapid titration
IV bolus produces rapid onset of effect, but shorter duration of action than IM; not recommended for drugs with long half-lives
Continuous IV infusion provides steadier drug blood levels, which maximize pain relief while minimizing side effects |
| Subcutaneous          | Placement of drug just under skin with small needle \*
Continuous SC infusion can be obtained with a small needle | Some opioids                            | Advantages: produces steady blood levels; time until onset of effect is comparable to IM administration and effects are longer lasting, with less painful administration; cheaper than IV administration; obviates need for GI function
Disadvantages: slower onset and offset and lower peak effects than IV administration, time consuming, often disliked by patients |
| Topical               | Applied directly to the skin, where the drug penetrates                              | NSAIDs, local anesthetics(e.g., lidocaine patch and gel, EMLA®), capsaicin | Advantages: local effect (i.e., no significant serum levels) limits side effects to local reactions; no drug-drug interactions; easy to use, no titration needed
Disadvantages: may cause local skin reactions |
| Transdermal           | Absorbed through skin with gradual release into the systemic circulation             | Some opioids                            | Advantages: convenient, noninvasive, provides prolonged, relatively stable analgesia
Disadvantages: delayed onset of action with first dose, drug absorption influenced by internal or external heat, may cause skin irritation |
| Oral transmucosal     | Delivery of drug to mouth, including sublingual (under tongue) and buccal/gingival administration | Some opioids                            | Advantages: easy, requires little staff supervision; avoids significant liver metabolism associated with oral opioids
Disadvantages: variable absorption, bitter taste, dose is limited |
| OTFC                  | Fentanyl incorporated into a sweetened matrix on a stick for consumption             | Fentanyl                                | Some absorption via oral mucosa, but most via GI tract; yields higher drug levels and better bioavailability than oral fentanyl |
| Intranasal            | Small aerosol device placed inside nostril that delivers a calibrated dose of a drug | Butorphanol, sumatriptan, fentanyl, naloxone | Takes advantage of rich blood supply to nose and also avoids significant liver metabolism associated with some drugs |
| Intraspinal           | Epidural and intrathecal administration (see Table 29)                               |                                         |                                                                                                                                                                                                     |
| Other(-sublingual, vaginal) | Placement of drug under the tongue (sublingual) or in the vagina                  | Opioids, benzodiazepines (intravaginal) | Most opioids can be absorbed sublingually or vaginally in patients who have problems such as impaired swallowing, short gut syndrome, or poor IV access |
ABUSE-DETERRENT FORMULATIONS

Concern about opioid misuse and abuse has spurred efforts to create abuse-deterrent opioid formulations. Three agents are currently available, which are co-formulated with an opioid antagonist: Targiniq ER (oxycodone and naloxone), Embeda ER (morphine and naltrexone), and Troxyca ER (oxycodone HCL-naltrexone capsules). Abuse-deterrent forms of oxycodone ER, Hysingla ER, Zohydro ER, Exalgo, Opana ER, and Xtampza ER contain a variety of substances that make the pills difficult to crush, snort, or melt or which inactivate the opioid in other ways if a pill or capsule is altered. Transdermal opioid formulations were thought to be less vulnerable to misuse, but such formulations can be abused.97

PATIENT MONITORING

If an opioid medication appears to be beneficial (as determined by the functional goals outlined in the management plan) and therapy is continued, regular review and monitoring should be performed for the duration of treatment based on the needs and characteristics of each patient. Clinicians must evaluate progress against agreed-upon treatment goals for both pain relief and function, assess for physical and behavioral adverse effects, and confirm adherence to prescription regimens by performing medication reconciliation as indicated. Clinicians should also re-evaluate a patient’s underlying medical condition if the patient’s clinical presentation changes with time.13

The intensity and frequency of monitoring is guided, in part, by the clinician’s assessment of the patient’s risk for abuse, diversion, or addiction. Tools and techniques similar or identical to those used during an initial assessment of a patient’s risk can be used to re-assess or monitor risk on an ongoing basis.

Patients who may need more frequent or intense monitoring include:

- Those with a prior history of an substance use disorder or other aberrant use
- Those in an occupations demanding mental acuity
- Older adults
- Patients with an unstable or dysfunctional social environment
- Those with comorbid psychiatric or medical conditions
- Patients on higher doses of opioids (>90 mg MEDD)

Patient monitoring includes re-evaluation of the patient’s underlying medical condition if the clinical presentation changes over time.

EXERCISE 3

Instructions: Read the case below and complete both learning activities that follow.

Zeke is a 25-year-old construction worker who is currently taking worker’s compensation to recover from a compound fracture of his right foot and ankle sustained when a cement block slipped off of a pallet and landed on his foot. The fractures required two surgeries to correct, with the implantation of several internal fixation devices. Zeke was prescribed a short-acting opioid after each surgery, which he has continued to use. He has been regularly attending physical therapy sessions to restore muscle tone in his right leg, but has come into the clinic today seeking an ER/LA opioid. The short-acting medication, he says, is “choppy” and allows his pain to return at the end of each dosing cycle. He says friends have suggested that a long-acting opioid would be easier to use and would provide him more steady pain relief.

Part 1 – Application: Take 5 minutes reviewing the scenario as it relates to either your clinical practice or the systems of care in which you work.

I. Evaluate application, or options for planned application, as it would apply in your own practice.

II. Consider the expected outcome(s) of those applications.

CAUTION ABOUT DOSE ESCALATION

When treating chronic pain with opioids, dose escalation has not been proven to reliably reduce pain or increase function, but it can increase risks.96 Prescribing high-dose opioid therapy (≥90 mg MEDD) is not supported by strong evidence, and, indeed, a recent cohort study of 9,940 patients receiving opioid analgesics for chronic non-cancer pain found that patients receiving 100 mg or more per day had an 8.9-fold increase in overdose risk compared to patients receiving 1-20 mg. of opioids per day.13 No randomized trials show long-term effectiveness of high opioid doses for chronic non-cancer pain. Many patients on high doses continue to have substantial pain and related dysfunction.98 As noted earlier, higher doses of opioids are associated with increased risks for adverse events and side effects including overdose, fractures, hormonal changes, and increased pain sensitivity.

URINE DRUG SCREENS

Urine drug testing is an imperfect science, but such testing can be a helpful component of responsible opioid prescribing. Drug testing should be conducted in a consensual manner as part of an agreed-upon opioid management plan and with the idea that such testing benefits both the patient and the provider. The potential benefits of urine drug testing include:

- Serving as a deterrent to inappropriate use
- Providing objective evidence of compliance with prescribed drugs, or evidence that non-prescribed drugs are being used
- Evaluating for diversion
- Monitoring response to treatment
- Helping patients allay concerns by family members, employers, or law-enforcement
- Demonstrating to regulatory authorities a clinician’s dedication to “best practices”
In primary care settings, unobserved urine collection is usually acceptable, however, clinicians should be aware of the many ways in which urine specimens can be adulterated. Specimens should be shaken to determine if soap products have been added, for example. The urine color should be noted on any documentation that accompanies the specimen for evaluation, since unusually colored urine could indicate adulteration. If possible, urine temperature and pH should be measured immediately after collection.\textsuperscript{99}

Prescribers should be familiar with the metabolites associated with each opioid that may be detected in urine, since the appearance of a metabolite can be misleading. A patient prescribed codeine, for example, may test positive for morphine because morphine is a codeine metabolite. Similar misunderstandings may occur for patients prescribed hydrocodone who appear positive for hydromorphone or patients prescribed oxycodone who test positive for oxymorphone. In the event of an unexpected urine drug screen, prescribers should consider a differential diagnosis that includes: drug abuse or addiction; self-treatment of poorly-controlled pain; psychological issues; or diversion (which may be suggested by absence of prescribed opioids).\textsuperscript{5}

### PROTECTING AGAINST OPIOID-INDUCED ADVERSE EVENTS

The Veterans Administration/Department of Defense (VA/DoD) clinical practice guideline outlines a number of evidence-based strategies to reduce opioid-related adverse effects, summarized in Table 7.\textsuperscript{100} Prophylaxis for constipation—the most common opioid-induced adverse event—has been facilitated by the approval of methylnaltrexone subcutaneous administration and naloxegol oral administration for patients with chronic non-cancer pain. Note that one of the potential complications of treatment is opioid use disorder, and practitioners should be prepared to educate patients about this risk and to provide direct addiction treatment or referral to an addiction treatment program if needed.

<table>
<thead>
<tr>
<th>Constipation</th>
<th>Methylnaltrexone or naloxegol Prophylactic mild peristaltic stimulant (e.g. bisacodyl or senna) If no bowel movement for 48 hours, increase dose of bowel stimulant If no bowel movement for 72 hours, perform rectal exam If not impacted, provide additional therapy (suppository, enema, magnesium citrate, etc.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nausea or vomiting</td>
<td>Consider prophylactic antiemetic therapy Add or increase non-opioid pain control agents (e.g. acetaminophen) If analgesia is satisfactory, decrease dose by 25% Treat based on cause</td>
</tr>
<tr>
<td>Sedation</td>
<td>Determine whether sedation is due to the opioid Eliminate nonessential CNS depressants (such as benzodiazepines) Reduce dose by 10-15% Add or increase non-opioid or non-sedating adjuvant for additional pain relief (such as NSAID or acetaminophen) so the opioid can be reduced Add stimulant in the morning (such as caffeine) Change opioid</td>
</tr>
<tr>
<td>Pruritus</td>
<td>Consider treatment with antihistamines Change opioid</td>
</tr>
<tr>
<td>Hallucination or dysphoria</td>
<td>Evaluate underlying cause Eliminate nonessential CNS acting medications</td>
</tr>
<tr>
<td>Sexual dysfunction</td>
<td>Reduce dose Testosterone replacement therapy may be helpful (for men) Erection-enhancing medications (e.g., sildenafil)</td>
</tr>
</tbody>
</table>

### OPIOID ROTATION

Switching from one opioid to another may be needed to reduce side effects, improve efficacy, avoid dose limitations of co-compounded acetaminophen, or because of a patient’s inability to absorb the medication in its present form. Opioid rotation must be done cautiously because of the many pharmacokinetic and pharmacodynamic variables involved.\textsuperscript{63} An equianalgesic chart should be used when changing from one opioid to another or from one route of administration to another. Such charts must be used carefully, however. A high degree of variation has been found across the various charts and online calculators, and may account for some overdoses and fatalities.\textsuperscript{92} The optimal dose for a specific patient must be determined by careful titration and appropriate monitoring, and clinicians must remember that patients may exhibit incomplete cross-tolerance to different types of opioids because of differences in the receptors or receptor sub-types to which different opioids bind. Do not simultaneously switch both an agent and a route of administration or type of release (e.g., ER/LA).

### MANAGING PAIN FLARE-UPS

Pain is dynamic, and ER/LA analgesics may not control pain flare-ups. Having patients track flare-ups with paper or electronic pain diaries can help them spot correlations between the flare-ups and variables in their lives. If specific triggers are identified, patients may be able to make changes that will reduce the prevalence of episodes without recourse to increased medication.\textsuperscript{63}

Non-opioid methods of dealing with pain flare-ups (e.g., cold or warmth, massage, yoga, acupuncture, meditation, electrical stimulation) should be tried—or at least considered—before the dose of an opioid is increased. As with the management of the underlying chronic pain condition, clinicians should use an agreed-upon set of functional goals as a way to monitor, and if necessary, adjust, the use of as-needed opioid medications for pain flares.

### USING PRESCRIPTION MONITORING PROGRAMS

Prescription drug monitoring programs (PDMPs) offer point-of-care access to pharmacy dispensing records of controlled substances from prescribers. From these, clinicians can quickly assess patterns of prescription drug use that can be helpful in confirming or refuting suspicions of aberrant behaviors. Information from the PDMP may also reveal that a patient is being prescribed medications whose combinations are contraindicated. By reviewing the PDMP each prescriber can identify other prescribers involved in the care of their patient. This can be
especially useful for new patients to a practice on high dose opioids, with suspect or concerning behaviors.

**ADDRESSING CONCERNS ABOUT PRESCRIPTION ACTIVITY**

Suspicion that a patient is non-adherent to a prescription or is engaging in aberrant drug-related behaviors should prompt a thorough investigation of the situation, including an honest evaluation of the patient/provider relationship, which may be strained by such behaviors. Possible reasons for non-adherence include:

- Inadequate pain relief
- Misunderstandings of the prescription
- Misunderstandings related to lack of fluency with English
- Attempts to “stretch” a medication to save money
- Cultural or familial pressure not to take a medication
- Stigma about taking a pain medication
- Patient fears about addiction
- Misuse, abuse, addiction
- Diversion

Here are some possible ways to respond to concerns about a patient’s prescription activity:

- Discuss the situation with the patient: express concern over the pattern of behavior; discuss how opioid use disorder begins; and emphasize its negative consequences on health, employment, finances, friends and family, etc.
- Clarify expectations (e.g., receiving controlled medications from only one prescriber, using only one pharmacy) and review existing patient/provider agreements
- Increase the intensity of patient monitoring (e.g., urine toxicology, pill counts and early refills) and establish limits on refills or lost medications

For persistent non-compliance, options include one or more of the following:

- Tapering drug therapy over several weeks to avoid withdrawal; consider incorporating non-opioid pain treatments
- Referral to specialists, e.g., a pain specialist, for evaluation of continued controlled substance prescribing
- Referral to an addiction management program

Patients with opioid use disorder and/or complex chronic pain problems should maintain a relationship with a primary care provider, even if the management of the pain and/or opioid use disorder will be conducted by specialists. Providers are not required to take action that they believe to be contrary to the patient’s best interests. If the provider believes that a crime has been committed, he or she has the right to contact law enforcement and/or other providers. In criminal matters HIPAA restrictions generally do not apply. Legal input in difficult cases may be helpful.

**DISCONTINUING OPIOID THERAPY**

Stopping long-term opioid therapy is often more difficult than starting it.\(^5\) For most patients, a slow weaning is preferred (reducing MEDD by 10% weekly) although a faster weaning (i.e., 25% MEDD reduction weekly) may be possible in selected patients. The longer the patient has been on the drug, and the higher the initial dose, the slower should be the taper.\(^5\) Use caution when discontinuing opioids in patients with unstable angina or who are pregnant. Withdrawal symptoms can be eased with clonidine (0.2 mg po Bid) or buprenorphine (2 mg po TID).

Discontinuing an opioid may be needed for a variety of reasons, including the healing of an injury or condition, an inability to achieve adequate analgesia, the lack of progress toward functional goals, or the experience of intolerable side effects. If inappropriate use of an opioid is confirmed, treatment must usually be suspended, although provisions should be in place for continuing some kind of pain treatment and/or referral to other professionals or members of a pain management team. Discharge solely for opioid use disorder is not acceptable.

Some clinicians may be willing and able to continue a regimen of opioid therapy even after the discovery of aberrant behavior, although this would require intensified monitoring, patient counseling, and careful documentation of all directives. This level of vigilance and risk management, however, may exceed the abilities and resources of primary care physicians. In such cases, referral to a provider with specialized skill or experience in dealing with high-risk patients may be prudent.

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**EXERCISE 4**

**Instructions:** Read the following case and complete the activities that follow.

Clara is a 77-year-old who has been diagnosed with lumbar spinal stenosis, which is causing a burning pain that radiates across her back and down into her buttocks. She has stage 2 kidney failure, although she is not on dialysis. In the previous two years, she has fallen twice at home, sustaining a subdural hematoma on one occasion and a sprained shoulder on the other. She lives alone and is fiercely independent, continuing to drive and adequately maintaining activities of daily living. She has tried numerous non-drug treatments for her pain, including physical therapy, acupuncture, massage, yoga, and even medical cannabis (which she said did help with the pain, but which she didn’t continue because she didn’t like the cognitive effects). She continues to have pain which disrupts her sleep and reduces her incentive to walk.

**Part 1 – Application:** Take 5 minutes reviewing the scenario as it relates to either your clinical practice or the systems of care in which you work.

I. Evaluate application, or options for planned application, as it would apply in your own practice.

II. Consider the expected outcome(s) of those applications.

**Part 2 - Questions and Considerations:** Spend 5 minutes considering the following questions:

1. Would treatment with an NSAID be appropriate for Clara? Why or why not?

2. Would treatment with an ER/LA opioid be appropriate for Clara? If so, what specific route of administration and/or agent might be best?

3. What aspects of Clara’s case should be considered when thinking about an initial dose selection of an ER/LA medication?
PATIENTS ON WORKERS’ COMPENSATION

Opioids and other associated analgesic medications represent a very significant portion of Workers’ Compensation claims, and the use of opioids is associated with longer periods of disability and lost-work time. Effective oversight and appropriate use of these medications reduce their abuse and diversion, return injured workers to employment sooner, decrease long term disability, improve longevity, and improve patient function.

This population of patients presents its own unique circumstances. Injured workers are generally sent to an occupational medicine facility for treatment. Ideally, the injured worker recovers and returns to work in full capacity. If recovery or healing does not occur as expected, early triage and appropriate, timely treatment is essential to restore function and facilitate a return to work.

The use of opioids in this population of patients can be problematic. Some evidence suggests that early treatment with opioids may actually delay recovery and a return to work. Conflicts of motivation may also exist in patients on worker’s compensation, such as when a person may not want to return to an unsatisfying, difficult, or hazardous job. Clinicians are advised to apply the same careful methods of assessment, creation of treatment plans, and monitoring used for other pain patients but with the added consideration of the psycho-social dynamics inherent in the workers’ compensation system. Injured workers should be afforded the full range of treatment options that are appropriate for the given condition causing the disability and impairment.

When a Workers’ Compensation patient is being prescribed chronic opioids, and that patient is also being prescribed other scheduled medications for a co-morbid mental or sleep disorder by a non-psychiatrist, use of chronic opioids for pain is generally not appropriate. If a co-morbid mental illness appears during tapering to re-treatment by a non-psychiatrist, use of chronic opioids for other pain patients but with the added considerations of the psycho-social dynamics inherent in the workers’ compensation system. Injured workers should be afforded the full range of treatment options that are appropriate for the given condition causing the disability and impairment.

The physician should do a face-to-face examination at least six times yearly if the patient is on any schedule II or III medication concurrently for chronic pain management and mental illness.

Reexamination must be performed by the authorized treating physician/qualified physician/pain medicine specialist in person at least every 90 days (except in the special cases of catastrophic injury and persistent pain syndromes on long term stable opioid use for over two years).

In order to justify the continued use of opioids, the treating physician must document that with the use of opioids, the pain level has been measurably improved (based on Visual Analog Scores, in comparison of pain levels without use of opioids) and there has been a definite improvement in function with the use of the opioids, as measured by an objective functional assessment tool/questionnaire (such as the Physical Functional Ability Questionnaire).

In the absence of objective functional improvement, the physician must give a written opinion that “the present regimen is the best that can be done and that without it, deterioration in function or daily activities would likely occur.” An annual attempt should still be made to wean/taper the scheduled medications.

PEDIATRIC PATIENTS

Because of their more robust inflammatory response and immature central inhibitory influences, infants and young children may actually experience greater pain sensations and pain-related distress than adults. Effective pain management in the pediatric population is critical since children and adolescents experience a variety of acute and chronic pain conditions associated with common childhood illnesses and injuries, as well as some painful chronic diseases that typically emerge in childhood such as sickle cell anemia and cystic fibrosis.

The same basic principles of appropriate pain management for adults apply to children and teens, which means that opioids have a limited place in the treatment armamentarium. Developmental differences can make opioid dosing challenging, especially in the first several months of life. In the first week of a newborn’s life, for example, the elimination half-life of morphine is more than twice as long as that in older children and adults, as a result of delayed clearance. For older children, dosing must be adjusted for body weight.

The American Pain Society and the American Academy of Pediatrics have issued the following recommendations for pain management in children and teens:

- Provide a calm environment for procedures that reduce distress-producing stimulation
- Use age-appropriate pain assessment tools and techniques
- Anticipate predictable painful experiences, intervene, and monitor accordingly
- Use a multimodal approach (pharmacologic, cognitive, behavioral, and physical) to pain management and use a multidisciplinary approach when possible
- Involve families and tailor interventions to the individual child
- Advocate for the effective use of pain medication for children to ensure compassionate and competent management of their pain

OTHER DRUGS OF CONCERN RELATED TO PAIN MANAGEMENT

In addition to opioids, three other drug classes are of concern to public health officials: benzodiazepines; barbiturates; and the muscle relaxant carisoprodol.

- Benzodiazepines and barbiturates are generally used as anti-anxiety medications and share with opioids the potential for abuse, addiction, and respiratory depression. For this reason they should not be prescribed concurrently with any opioid analgesic, and patients should be educated about the hazards of combined use.
- Carisoprodol is a centrally-acting skeletal muscle relaxant. It’s primary active metabolite is meprobamate, which is a controlled substance (carisoprodol itself is classified in Schedule IV). Meprobamate has an addictive potential similar to benzodiazepines and is pharmacologically similar to barbiturates. Its clinical effectiveness is low and its side effect profile is high.
- Patients have been reported to substitute the easily-obtained carisoprodol for the more strictly controlled opioids and benzodiazepines.

OPIOIDS AND PREGNANCY

There are no adequate and well-controlled studies of ER/LA opioid analgesics in pregnant women. Current American Pain Society-American Academy of Pain Medicine (APS-AAPM) guidelines suggest that clinicians should avoid prescribing opioids during pregnancy unless the potential benefits outweigh risks. Some data suggest an association between the use of long-term opioid therapy during pregnancy and adverse outcomes in newborns, including low birth weight and premature birth, though co-related maternal factors may play a role in these asso-
Acetaminophen is considered the drug of choice for mild-to-moderate pain in older adults because it lacks the gastrointestinal, bleeding, renal toxicities, and cognitive side-effects that have been observed with NSAIDs in older adults (although acetaminophen may pose a risk of liver damage). Opioids must be used with particular caution, and clinicians should “Start low, go slow” with initial doses and subsequent titration. Clinicians should consult the American Geriatrics Society Updated Beers Criteria for Potentially Inappropriate Medication Use in Older Adults for further information on the many medications that may not be recommended. Early referral and/or consultation with geriatric specialists or pain specialists may be advisable.

**REDUCING THE RISK OF OVERDOSE**

Opioid overdose is reversible through the timely administration of the medication naloxone. Naloxone is a prescription drug, but it is not a controlled substance and has no abuse potential. It is regularly carried by medical first responders and, in many states, can be prescribed like any other medication.

As an opioid antagonist, naloxone can quickly restore normal respiration to a person whose breathing has slowed or stopped as a result of heroin or prescription opioid overdose. It’s critical to point out, however, that if a person was using an ER/LA medication, the duration of the opioid effect may last longer than the duration of the naloxone antagonism and, hence, the patient may regress into respiratory depression.

As of 2010, programs that distribute naloxone to nonmedical personnel had reported more than 10,000 overdose reversals nationwide since 1996. As of November 2014, 23 states had statutes allowing for “third-party” prescriptions of naloxone (i.e. the prescription can be written to a friend, relative, or person in a position to assist a person at risk of experiencing an opioid overdose).

Given the effectiveness of naloxone in overdose reversal, the FDA has encouraged innovations in more user-friendly naloxone delivery systems such as auto-injectors, made particularly for lay use outside of health care settings. The FDA approved such an auto-injector in 2014 (Evzio), and an intranasal form called Narcan in 2016.

**OLDER ADULTS**

The prevalence of pain among community-dwelling older adults has been estimated between 25% and 50%. The prevalence of pain in nursing homes is even higher. Unfortunately, managing pain in older adults is challenging due to: underreporting of symptoms; presence of multiple medical conditions; polypharmacy; declines in liver and kidney function; problems with communication, mobility, and safety; and cognitive and functional decline in general.

Acetaminophen is considered the drug of choice for mild-to-moderate pain in older adults because it lacks the gastrointestinal, bleeding,

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**TABLE 8: POTENTIAL PATIENT-CENTERED GOALS OF CARE**

<table>
<thead>
<tr>
<th>Goal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Longer life</td>
</tr>
<tr>
<td>Symptom relief</td>
</tr>
<tr>
<td>Time at home</td>
</tr>
<tr>
<td>Ability to travel</td>
</tr>
<tr>
<td>Mental clarity</td>
</tr>
<tr>
<td>Physical mobility</td>
</tr>
<tr>
<td>Ability to interact with loved ones</td>
</tr>
<tr>
<td>Minimizing burdens on loves ones</td>
</tr>
<tr>
<td>Personal/Spiritual growth</td>
</tr>
<tr>
<td>“Dignity” (though meanings will vary)</td>
</tr>
</tbody>
</table>

SPECIFIC DRUG INFORMATION FOR ER/LA OPIOID ANALGESIC PRODUCTS

Prescribers should be knowledgeable about general characteristics, toxicities, and drug interactions for ER/LA opioid analgesic products. Table 9 provides general drug information common to the class of ER/LA opioid analgesics.

In addition, prescribers should know specific characteristics of the ER/LA opioid analgesic products they prescribe, including the drug substance, formulation, strength, dosing interval, key instructions, specific information about conversion between products where available, specific drug interactions, use in opioid-tolerant patients, product-specific safety concerns, and relative potency to morphine. Table 10 provides specific drug information for extended-release and long-acting opioid analgesics.

Exercises 5 and 6 covers general and specific information for ER/LA Opioid Analgesics, including Table 9 and Table 10. PLEASE SPEND THE ALLOTTED TIME COMPLETING THESE EXERCISES.

For detailed information, prescribers can refer to prescribing information available online via DailyMed at www.dailymed.nlm.nih.gov or Drugs@FDA at www.fda.gov/drugsatfda.

Conclusions

ER/LA opioid analgesics can play an important, although limited, role in the treatment of patients with cancer pain, and end-of-life pain. Their use for treating chronic non-cancer pain is more problematic because of their known risks of abuse, addiction, and overdose, as well as the possibility of their being diverted for recreational or unprescribed use. The clinical evidence base supporting the use of ER/LA opioids for chronic non-cancer pain is much weaker than is often assumed, while the evidence for the many risks involved in long-term use of opioids is strong.

The risks of ER/LA opioids are amplified among older adults; those with impaired renal or hepatic function; individuals with COPD, cardiopulmonary disorders, sleep apnea, or mental illness; and in patients who are likely to combine opioids with other respiratory depressants such as alcohol or benzodiazepines.

This monograph summarizes established methods for appropriately prescribing opioid analgesics, a task that can be challenging, but it is not inherently different from what physicians face in other treatment settings.
EXERCISE 5
DRUG INFORMATION COMMON TO THE CLASS OF ER/LA OPIOID ANALGESIC PRODUCTS

Instructions: Spend 20-25 minutes completing the following

1. Conduct a detailed review of the information regarding general characteristics, toxicities, and drug interactions for ER/LA opioid analgesic products.
2. Read and review Table 9 which includes additional general drug information common to ER/LA opioid analgesics.
3. Complete the learning questions below related to General Drug Information for ER/LA Opioid Analgesic’s after completing steps 1 and 2.

LEARNING QUESTIONS EXERCISE 5
COMPLETE ONLY AFTER CONDUCTING STEPS 1 AND 2 ABOVE

1. Are ER/LA opioids recommended for treating acute pain? Why or Why Not?

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

2. Can ER/LA opioids be safely stopped or tapered rapidly? What methodology is recommended for discontinuing opioid treatment?

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

3. Name three classes of drugs that should be avoided by patients who have been prescribed an ER/LA opioid analgesic. Describe the underlying reasoning for avoiding concurrent use of the drugs.

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________
Prescribers should be knowledgeable about general characteristics, toxicities, and drug interactions for ER/LA opioid analgesic products. For Example:

a. ER/LA opioid analgesic products are scheduled under the Controlled Substances Act and can be misused and abused.
b. Respiratory depression is the most important serious adverse effect of opioids as it can be immediately life-threatening.
c. Constipation is the most common long-term side effect and should be anticipated.
d. Drug-drug interaction profiles vary among the products. Knowledge of particular opioid-drug interactions, and the underlying pharmacokinetic and pharmacodynamic mechanisms, allows for the safer administration of opioid analgesics.
   i. Concomitant use of opioids with benzodiazepines or other central nervous system (CNS) depressants, including alcohol, may result in profound sedation, respiratory depression, coma, and death. Reserve concomitant prescribing for use in patients for whom alternative treatment options are inadequate; limit dosages and durations to the minimum required; and follow patients for signs and symptoms of respiratory depression and sedation.
   ii. Some ER opioid formulations may rapidly release opioid (dose dump) when exposed to alcohol. Some drug levels may increase without dose dumping when exposed to alcohol. See individual product labeling.
   iii. MAOI interactions with opioids may manifest as serotonin syndrome or opioid toxicity (e.g., respiratory depression, coma). Certain ER/LA opioids are contraindicated with MAOIs (tapentadol, morphine). See individual product labeling.
   iv. Opioids can reduce the efficacy of diuretics by inducing the release of antidiuretic hormone (ADH).
   v. Some opioids (methadone, buprenorphine) can prolong the QTc interval.
   vi. Concomitant drugs that act as inhibitors or inducers of various cytochrome P450 enzymes can result in higher or lower than expected blood levels of some opioids.
e. Tolerance to sedating and respiratory-depressant effects of opioids is critical to the safe use of ER/LA opioid analgesics.
   i. For ER products, patients must meet the criteria for opioid tolerance, described in the table 10, before using:
      a. certain products,
      b. certain strengths,
      c. certain daily doses, and
      d. in specific indicated patient populations (e.g., pediatric patients).
   ii. See the (table 10) for product-specific information.
f. ER/LA opioid analgesic tablets must be swallowed whole. ER/LA opioid analgesic capsules should be swallowed intact or when necessary, the pellets from some capsules can be sprinkled on applesauce and swallowed without chewing.
g. For transdermal products, external heat, fever, and exertion can increase absorption of the opioid, leading to fatal overdose. Transdermal products with metal foil backings are not safe for use in MRIs.
h. For buccal film products, the film should not be applied if it is cut, damaged, or changed in any way. Use the entire film.
i. Follow the instructions for conversion in the Dosage and Administration section (2.1) in the Prescribing Information of each product when converting patients from one opioid to another.
### Table 9: Drug Information Common to the Class of Extended-Release and Long-Acting Opioid Analgesics (ER/LA opioid analgesics)

<table>
<thead>
<tr>
<th>ER/LA Opioid Analgesics</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arymo ER (morphine sulfate ER tablets)</td>
<td></td>
</tr>
<tr>
<td>Avinza (morphine sulfate ER capsules)</td>
<td></td>
</tr>
<tr>
<td>Belbuca (buprenorphine buccal film)</td>
<td></td>
</tr>
<tr>
<td>Butrans (buprenorphine transdermal system)</td>
<td></td>
</tr>
<tr>
<td>Dolophine (methadone HCl tablets)</td>
<td></td>
</tr>
<tr>
<td>Duragesic (fentanyl transdermal system)</td>
<td></td>
</tr>
<tr>
<td>Embeda (morphine sulfate ER-naltrexone capsules)</td>
<td></td>
</tr>
<tr>
<td>Exalgo (hydromorphone HCl ER tablets)</td>
<td></td>
</tr>
<tr>
<td>Hysingla ER (hydrocodone bitartrate ER tablets)</td>
<td></td>
</tr>
<tr>
<td>Kadian (morphine sulfate ER capsules)</td>
<td></td>
</tr>
<tr>
<td>MorphaBond (morphine sulfate ER tablets)</td>
<td></td>
</tr>
<tr>
<td>MS Contin (morphine sulfate ER tablets)</td>
<td></td>
</tr>
<tr>
<td>Nucynta ER (tapentadol HCl ER tablets)</td>
<td></td>
</tr>
<tr>
<td>Opana ER (oxymorphone HCl ER tablets)</td>
<td></td>
</tr>
<tr>
<td>OxyContin (oxycodone HCl ER tablets)</td>
<td></td>
</tr>
<tr>
<td>Targiniq ER (oxycodone HCl/naloxone HCl ER tablets)</td>
<td></td>
</tr>
<tr>
<td>Troxyca ER (oxycodone HCl-naltrexone capsules)</td>
<td></td>
</tr>
<tr>
<td>Vantrela ER (hydrocodone bitartrate ER tablets)</td>
<td></td>
</tr>
<tr>
<td>Xtampza ER (oxycodone ER capsules)</td>
<td></td>
</tr>
<tr>
<td>Zohydro ER (hydrocodone bitartrate ER capsules)</td>
<td></td>
</tr>
</tbody>
</table>

#### Dosing Interval

◊ Refer to individual product information.

#### Key Instructions

◊ Limitations of usage:
- Reserve for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain.
- Not for use as an as-needed analgesic.
- Not for mild pain or pain not expected to persist for an extended duration.
- Not for use in treating acute pain.
- Individually titrate to a dose that provides adequate analgesia and minimizes adverse reactions.
- The times required to reach steady-state plasma concentrations are product specific; refer to product information for titration interval.
- Continually reevaluate to assess the maintenance of pain control and the emergence of adverse reactions.
- During chronic therapy, especially for non-cancer-related pain, periodically reassess the continued need for opioids.
- If pain increases, attempt to identify the source, while adjusting the dose.
- When an ER/LA opioid analgesic is no longer required, gradually titrate downward to prevent signs and symptoms of withdrawal in the physically-dependent patient. **Do not abruptly discontinue these products.**
- Solid oral dosage forms:
  - Swallow tablets and capsules whole: crushing, chewing, breaking, cutting or dissolving may result in rapid release and absorption of a potentially fatal dose of opioid.
  - Some capsules can be opened and pellets sprinkled on applesauce for patients who can reliably swallow without chewing and used immediately. See individual product information.
- Exposure of some products to alcoholic beverages or medications containing alcohol may result in the rapid release and absorption of a potentially fatal dose of opioid.
- Dispose of unused product by flushing down the toilet.
- Transdermal dosage forms:
  - Avoid exposure to external heat. Patients with fever must be monitored for signs or symptoms of increased opioid exposure.
  - Location of application must be rotated.
  - Prepare skin by clipping, not shaving hair, and washing area only with water.
- Buccal film dosage form:
  - Do not use if the package seal is broken or the film is cut, damaged, or changed in any way.
- See individual product information for the following:
- Dosage reduction for hepatic or renal impairment.
| Drug Interactions Common to the Class | • Concomitant use of opioids with benzodiazepines or other central nervous system (CNS) depressants, including alcohol, may result in profound sedation, respiratory depression, coma, and death. Reserve concomitant prescribing for use in patients for whom alternative treatment options are inadequate; limit dosages and durations to the minimum required; and follow patients for signs and symptoms of respiratory depression and sedation.  
• Avoid concurrent use of mixed opioid agonist/antagonists (i.e., pentazocine, nalbuphine, and butorphanol) or partial opioid agonists (buprenorphine) in patients who have received or are receiving a course of therapy with a full opioid agonist. In these patients, mixed opioid agonist/antagonists and partial opioid agonists may reduce the analgesic effect and/or may precipitate withdrawal symptoms.  
• Opioids may enhance the neuro muscular blocking action of skeletal muscle relaxants and produce an increased degree of respiratory depression.  
• Concurrent use with anticholinergic medication increases the risk of urinary retention and severe constipation, which may lead to paralytic ileus. |
| --- |
| Use in Opioid-Tolerant Patients | ◊ Adult patients considered opioid-tolerant are those receiving, for one week or longer at least:  
• 60 mg oral morphine/day  
• 25 mcg transdermal fentanyl/hour  
• 30 mg oral oxycodone/day  
• 60 mg oral hydrocodone/day  
• 8 mg oral hydromorphone/day  
• 25 mg oral oxymorphone/day  
• Pediatric patients (11 years and older) considered opioid-tolerant are those who are already receiving and tolerating a minimum daily opioid dose of at least 20 mg oxycodone orally or its equivalent (applicable to OxyConti’s pediatric indication only)  
◊ See individual product information for which products:  
• Have strengths or total daily doses only for use in opioid-tolerant patients.  
• Are only for use in opioid-tolerant patients at all strengths. |
| Contraindications | • Significant respiratory depression  
• Acute or severe asthma in an unmonitored setting or in the absence of resuscitative equipment  
• Known or suspected paralytic ileus  
• Hypersensitivity (e.g., anaphylaxis)  
• See individual product information or additional contraindications. |
| Relative Potency To Oral Morphine | • These are intended as general guides.  
• Follow conversion instructions in individual product information.  
• Incomplete cross-tolerance and inter-patient variability require the use of conservative dosing when converting from one opioid to another: halve the calculated comparable dose and titrate the new opioid as needed. |

EXERCISE 6
SPECIFIC DRUG INFORMATION FOR ER/LA OPIOID ANALGESIC PRODUCTS

Instructions: Spend 20-25 minutes completing the following

1. Conduct a detailed review of table 10, which includes information regarding Specific Drug Information for Extended-Release and Long-Acting Opioid Analgesics Review
2. Complete the learning questions below related to Specific Drug Information for ER/LA Opioid Analgesic’s only after completing step 1.

LEARNING QUESTIONS EXERCISE 6
COMPLETE ONLY AFTER CONDUCTING STEP 1

1. Describe Interactions with other medications and substances for the following; Butran, Dolophine, Hysingla ER, MS Contin.

2. Discuss product safety concerns for the following: Arymo ER, Duragesic, Opana ER, Targiniq ER?

3. List and describe which products and which doses are indicated for use only in opioid-tolerant patients. Which products are indicated for use only in opioid tolerant-patients?

SPECIFIC DRUG INFORMATION FOR ER/LA OPIOID ANALGESIC PRODUCTS

Prescribers should be knowledgeable about specific characteristics of the ER/LA opioid analgesic products they prescribe, including: Drug Substance, Formulation, Strength, Dosing Interval, Key Instructions, Specific Information About Conversion Between Products Where Available, Specific Drug Interactions, Use In Opioid-Tolerant Patients, Product-Specific Safety Concerns, And Relative Potency To Morphine.

The following Table (TABLE 10) is a reference. For detailed information, prescribers can refer to prescribing information available online via DailyMed at www.dailymed.nlm.nih.gov or Drugs@FDA at www.fda.gov/drugsatfda.
### Arymo ER

**Morphine Sulfate**  
Extended-Release Tablets, 15 mg, 30 mg, 60 mg

#### Dosing Interval
Every 8 or 12 hours

#### Key Instructions
- Initial dose in opioid-naïve and opioid non-tolerant patients is 15 mg every 8 or 12 hours.
- Dosage adjustment may be done every 1 to 2 days.
- Take one tablet at a time, with enough water to ensure complete swallowing immediately after placing in the mouth.

#### Specific Drug Interactions
P-gp inhibitors (e.g. quinidine) can increase the exposure of morphine by about two-fold and increase risk of respiratory depression.

#### Use in Opioid-Tolerant Patients
A single dose of ARYMO ER greater than 60 mg, or total daily dose greater than 120 mg, is for use in opioid-tolerant patients only.

#### Product-Specific Safety Concerns
- Do not attempt to chew, crush, or dissolve. Swallow whole.
- Use with caution in patients who have difficulty in swallowing or have underlying GI disorders that may predispose them to obstruction, such as a small gastrointestinal lumen.

### Avinza

**Morphine Sulfate ER**  
Capsules, 30 mg, 45 mg, 60 mg, 75 mg, 90 mg, and 120 mg

#### Dosing Interval
Once a day

#### Key Instructions
- Initial dose in opioid non-tolerant patients is 30 mg.
- Titrate in increments of not greater than 30 mg using a minimum of 3 to 4 day intervals.
- Swallow capsule whole (do not chew, crush, or dissolve).
- May open capsule and sprinkle pellets on applesauce for patients who can reliably swallow without chewing; use immediately.
- Maximum daily dose: 1600 mg due to risk of serious renal toxicity by excipient, fumaric acid.

#### Specific Drug Interactions
- Alcoholic beverages or medications containing alcohol may result in the rapid release and absorption of a potentially fatal dose of morphine.
- P-gp inhibitors (e.g. quinidine) may increase the absorption/exposure of morphine sulfate by about two-fold.

#### Use in Opioid-Tolerant Patients
90 mg and 120 mg capsules are for use in opioid-tolerant patients only.

#### Product-Specific Safety Concerns
None

### Belbuca

**Buprenorphine Buccal Film**, 75 mcg, 150 mcg, 300 mcg, 450 mcg, 600 mcg, 750 mcg, and 900 mcg

#### Dosing Interval
Every 12 hours (or once every 24 hours for initiation in opioid naïve patients and patients taking less than 30 mg oral morphine sulfate equivalents)
## TABLE 10: Specific Drug Information for Extended-Release and Long-Acting Opioid Analgesics (ER/LA opioid analgesics)

### Key Instructions
- Opioid-naïve patients or patients taking less than 30 mg oral morphine sulfate equivalents: Initiate treatment with a 75 mcg buccal film, once daily, or if tolerated, every 12 hours.
  - Titrate to 150 mcg every 12 hours no earlier than 4 days after initiation.
  - Individual titration to a dose that provides adequate analgesia and minimizes adverse reactions should proceed in increments of 150 mcg every 12 hours, no more frequently than every 4 days.
- When converting from another opioid, first taper the current opioid to no more than 30 mg oral morphine sulfate equivalents per day prior to initiating Belbuca.
  - If prior daily dose before taper was 30 mg to 89 mg oral morphine sulfate equivalents, initiate with 150 mcg dose every 12 hours.
  - If prior daily dose before taper was 90 mg to 160 mg oral morphine sulfate equivalents, initiate with 300 mcg dose every 12 hours.
  - Titration of the dose should proceed in increments of 150 mcg every 12 hours, no more frequently than every 4 days.
- Maximum dose: 900 mcg every 12 hours due to the potential for QTc prolongation.
- Severe Hepatic Impairment: Reduce the starting and incremental dose by half that of patients with normal liver function.
- Oral Mucositis: Reduce the starting and incremental dose by half that of patients without mucositis.
- Do not use if the package seal is broken or the film is cut, damaged, or changed in any way.

### Specific Drug Interactions
- CYP3A4 inhibitors may increase buprenorphine levels.
- CYP3A4 inducers may decrease buprenorphine levels.
- Benzodiazepines may increase respiratory depression.
- Class IA and III antiarrhythmics, other potentially arrhythmogenic agents, may increase risk for QTc prolongation and torsade de pointes.

### Use in Opioid-Tolerant Patients
Belbuca 600 mcg, 750 mcg, and 900 mcg are for use following titration from lower doses of Belbuca.

### Product-Specific Safety Concerns
- QTc prolongation and torsade de pointes
- Hepatotoxic

### Relative Potency To Oral Morphine
Equipotency to oral morphine has not been established.

### Butrans
- Buprenorphine Transdermal System, 5 mcg/hr, 7.5 mcg/hr, 10 mcg/hr, 15 mcg/hr, 20 mcg/hr

### Dosing Interval
One transdermal system every 7 days
### TABLE 10: Specific Drug Information for Extended-Release and Long-Acting Opioid Analgesics (ER/LA opioid analgesics)

**Key Instructions**

- Initial dose in opioid non-tolerant patients when converting from less than 30 mg morphine equivalents, and in mild to moderate hepatic impairment - 5 mcg/hr dose.
- When converting from 30 mg to 80 mg morphine equivalents - first taper to 30 mg morphine equivalent, then initiate with 10 mcg/hr dose.
- Titrate in 5 mcg/hour or 10 mcg/hour increments by using no more than two patches of the 5 mcg/hour or 10 mcg/hour system(s) with a minimum of 72 hours between dose adjustments. The total dose from all patches should not exceed 20 mcg/hour.
- Maximum dose: 20 mcg/hr due to risk of QTc prolongation.
- Application
  - Apply only to sites indicated in the Full Prescribing Information.
  - Apply to intact/non-irritated skin.
  - Skin may be prepped by clipping hair, washing site with water only.
  - Rotate site of application a minimum of 3 weeks before reapplying to the same site.
  - Do not cut.
  - Avoid exposure to heat.
  - Dispose of used/unused patches by folding the adhesive side together and flushing down the toilet.

**Specific Drug Interactions**

- CYP3A4 Inhibitors may increase buprenorphine levels.
- CYP3A4 Inducers may decrease buprenorphine levels.
- Benzodiazepines may increase respiratory depression.
- Class IA and III anti arrhythmics, other potentially arrhythmogenic agents, may increase risk for QTc prolongation and torsade de pointe.

**Use in Opioid-Tolerant Patients**

Butrans 7.5 mcg/hr, 10 mcg/hr, 15 mcg/hr, and 20 mcg/hr transdermal systems are for use in opioid-tolerant patients only.

**Drug-Specific Safety Concerns**

- QTc prolongation and torsade de pointe.
- Hepatotoxicity
- Application site skin reactions

**Relative Potency To Oral Morphine**

 Equipotency to oral morphine has not been established.

**Dolophine**

Methadone Hydrochloride
Tablets, 5 mg and 10 mg

**Dosing Interval**

Every 8 to 12 hours

**Key Instructions**

- Initial dose in opioid non-tolerant patients: 2.5 to 10 mg.
- Conversion of opioid-tolerant patients using equianalgesic tables can result in overdose and death. Use low doses according to the table in the full prescribing information.
- Titrate slowly, with dose increases no more frequent than every 3 to 5 days. Because of high variability in methadone metabolism, some patients may require substantially longer periods between dose increases (up to 12 days).
- High inter-patient variability in absorption, metabolism, and relative analgesic potency.
- Opioid detoxification or maintenance treatment shall only be provided in a federally certified opioid (addiction) treatment program (Code of Federal Regulations, Title 42, Sec 8).
<table>
<thead>
<tr>
<th>TABLE 10: Specific Drug Information for Extended-Release and Long-Acting Opioid Analgesics (ER/LA opioid analgesics)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Specific Drug Interactions</strong></td>
</tr>
<tr>
<td>◊ Pharmacokinetic drug-drug interactions with methadone are complex.</td>
</tr>
<tr>
<td>● CYP450 inducers may decrease methadone levels.</td>
</tr>
<tr>
<td>● CYP450 inhibitors may increase methadone levels.</td>
</tr>
<tr>
<td>● Anti-retroviral agents have mixed effects on methadone levels.</td>
</tr>
<tr>
<td>◊ Potentially arrhythmogenic agents may increase risk for QTc prolongation and torsade de pointe.</td>
</tr>
<tr>
<td>◊ Benzodiazepines may increase respiratory depression</td>
</tr>
<tr>
<td><strong>Use in Opioid-Tolerant Patients</strong></td>
</tr>
<tr>
<td>Refer to full prescribing information.</td>
</tr>
<tr>
<td><strong>Product-Specific Safety Concerns</strong></td>
</tr>
<tr>
<td>● QTc prolongation and torsade de pointe.</td>
</tr>
<tr>
<td>● Peak respiratory depression occurs later and persists longer than analgesic effect.</td>
</tr>
<tr>
<td>● Clearance may increase during pregnancy.</td>
</tr>
<tr>
<td>● False positive urine drug screens possible.</td>
</tr>
<tr>
<td><strong>Relative Potency To Oral Morphine</strong></td>
</tr>
<tr>
<td>Varies depending on patient’s prior opioid experience.</td>
</tr>
<tr>
<td><strong>Duragesic</strong></td>
</tr>
<tr>
<td>Fentanyl Transdermal System, 12, 25, 37.5*, 50, 62.5*, 75, 87.5*, and 100 mcg/hr (*These strengths are available only in generic form)</td>
</tr>
<tr>
<td><strong>Dosing Interval</strong></td>
</tr>
<tr>
<td>Every 72 hours (3 days)</td>
</tr>
<tr>
<td><strong>Key Instructions</strong></td>
</tr>
<tr>
<td>◊ Use product specific information for dose conversion from prior opioid</td>
</tr>
<tr>
<td>◊ Use 50% of the dose in mild or moderate hepaticorrenal impairment, avoid use in severe hepatic or renal impairment</td>
</tr>
<tr>
<td>◊ Application</td>
</tr>
<tr>
<td>● Apply to intact/non-irritated/non-irradiated skin on a flat surface.</td>
</tr>
<tr>
<td>● Skin may be prepped by clipping hair, washing site with water only</td>
</tr>
<tr>
<td>● Rotate site of application.</td>
</tr>
<tr>
<td>● Titrate using a minimum of 72 hour intervals between dose adjustments.</td>
</tr>
<tr>
<td>● Do not cut.</td>
</tr>
<tr>
<td>◊ Avoid exposure to heat.</td>
</tr>
<tr>
<td>◊ Avoid accidental contact when holding or caring for children.</td>
</tr>
<tr>
<td>◊ Dispose of used/unused patches by folding the adhesive side together and flushing down the toilet.</td>
</tr>
<tr>
<td><strong>Specific contraindications:</strong></td>
</tr>
<tr>
<td>● Patients who are not opioid-tolerant.</td>
</tr>
<tr>
<td>● Management of acute or intermittent pain, or in patients who require opioid analgesia for a short period of time.</td>
</tr>
<tr>
<td>● Management of post-operative pain, including use after out-patient or day surgery.</td>
</tr>
<tr>
<td>● Management of mild pain.</td>
</tr>
<tr>
<td><strong>Specific Drug Interactions</strong></td>
</tr>
<tr>
<td>● CYP3A4 inhibitors may increase fentanyl exposure.</td>
</tr>
<tr>
<td>● CYP3A4 inducers may decrease fentanyl exposure.</td>
</tr>
<tr>
<td>● Discontinuation of a concomitantly used cytochrome P450 3A4 inducer may result in an increase in fentanyl plasma concentration.</td>
</tr>
<tr>
<td><strong>Use in Opioid-Tolerant Patients</strong></td>
</tr>
<tr>
<td>All doses of Duragesic are indicated for use in opioid-tolerant patients only.</td>
</tr>
<tr>
<td><strong>Product-Specific Safety Concerns</strong></td>
</tr>
<tr>
<td>● Accidental exposure due to secondary exposure to unwashed/unclothed application site.</td>
</tr>
<tr>
<td>● Increased drug exposure with increased core body temperature or fever.</td>
</tr>
<tr>
<td>● Bradycardia</td>
</tr>
<tr>
<td>● Application site skin reactions</td>
</tr>
<tr>
<td>TABLE 10: Specific Drug Information for Extended-Release and Long-Acting Opioid Analgesics (ER/LA opioid analgesics)</td>
</tr>
<tr>
<td>-------------------------------------------------</td>
</tr>
<tr>
<td>Relative Potency To Oral Morphine</td>
</tr>
<tr>
<td><strong>Embeda</strong></td>
</tr>
<tr>
<td><strong>Dosing Interval</strong></td>
</tr>
<tr>
<td><strong>Key Instructions</strong></td>
</tr>
<tr>
<td><strong>Specific Drug Interactions</strong></td>
</tr>
<tr>
<td><strong>Use in Opioid-Tolerant Patients</strong></td>
</tr>
<tr>
<td><strong>Product-Specific Safety Concerns</strong></td>
</tr>
<tr>
<td><strong>Exalgo</strong></td>
</tr>
<tr>
<td><strong>Dosing Interval</strong></td>
</tr>
<tr>
<td><strong>Key Instructions</strong></td>
</tr>
<tr>
<td><strong>Specific Drug Interactions</strong></td>
</tr>
<tr>
<td><strong>Use in Opioid-Tolerant Patients</strong></td>
</tr>
<tr>
<td><strong>Drug-Specific Adverse Reactions</strong></td>
</tr>
<tr>
<td><strong>Relative Potency To Oral Morphine</strong></td>
</tr>
<tr>
<td><strong>Hysingla ER</strong></td>
</tr>
<tr>
<td><strong>Dosing Interval</strong></td>
</tr>
</tbody>
</table>
### Key Instructions

- Opioid-naïve patients: initiate treatment with 20 mg orally once daily. During titration, adjust the dose in increments of 10 mg to 20 mg every 3 to 5 days until adequate analgesia is achieved.
- Swallow tablets whole (do not chew, crush, or dissolve).
- Consider use of an alternative analgesic in patients who have difficulty swallowing or have underlying gastrointestinal disorders that may predispose them to obstruction.
- Take one tablet at a time, with enough water to ensure complete swallowing immediately after placing in the mouth.
- Use 1/2 of the initial dose and monitor closely for adverse events, such as respiratory depression and sedation, when administering Hysingla ER to patients with severe hepatic impairment or patients with moderate to severe renal impairment.

### Specific Drug Interactions

- CYP3A4 inhibitors may increase hydrocodone exposure.
- CYP3A4 inducers may decrease hydrocodone exposure.
- Concomitant use of Hysingla ER with strong laxatives (e.g., Lactulose) that rapidly increase GI motility may decrease hydrocodone absorption and result in decreased hydrocodone plasma levels.
- The use of MAO inhibitors or tricyclic antidepressants with Hysingla ER may increase the effect of either the antidepressant or Hysingla ER.

### Use in Opioid-Tolerant Patients

A single dose of Hysingla ER greater than or equal to 80 mg is only for use in opioid tolerant patients.

### Product-Specific Safety Concerns

- Use with caution in patients with difficulty swallowing the tablet or underlying gastrointestinal disorders that may predispose patients to obstruction.
- Esophageal obstruction, dysphagia, and choking have been reported with Hysingla ER.
- In nursing mothers, discontinue nursing or discontinue drug.
- QTc prolongation has been observed with Hysingla ER following daily doses of 160 mg. Avoid use in patients with congenital long QTc syndrome. This observation should be considered in making clinical decisions regarding patient monitoring when prescribing Hysingla ER in patients with congestive heart failure, bradyarrhythmias, electrolyte abnormalities, or who are taking medications that are known to prolong the QTc interval. In patients who develop QTc prolongation, consider reducing the dose.

### Relative Potency To Oral Morphine

See individual product information for conversion recommendations from prior opioid.

### Kadian

<table>
<thead>
<tr>
<th>Morphine Sulfate Extended-Release Capsules, 10 mg, 20mg, 30 mg, 40 mg, 50 mg, 60 mg, 70 mg, 80 mg, 100 mg, 130 mg, 150 mg, and 200 mg</th>
</tr>
</thead>
</table>

**Dosing Interval**

Once a day or every 12 hours

**Key Instructions**

- Product information recommends not using as first opioid.
- Titrate using a minimum of 2-day intervals.
- Swallow capsules whole (do not chew, crush, or dissolve).
- May open capsule and sprinkle pellets on applesauce for patients who can reliably swallow without chewing, use immediately.
| Specific Drug Interactions | • Alcoholic beverages or medications containing alcohol may result in the rapid release and absorption of a potentially fatal dose of morphine.  
• P-gp inhibitors (e.g. quinidine) may increase the absorption/exposure of morphine sulfate by about two-fold. |
| Use in Opioid-Tolerant Patients | Kadian 100 mg, 130 mg, 150 mg, and 200 mg capsules are for use in opioid-tolerant patients only |
| Product-Specific Safety Concerns | None |
| **MorphaBond** | Morphine Sulfate  
Extended-release Tablets, 15 mg, 30 mg, 60 mg, 100 mg |
| Dosing Interval | Every 8 hours or every 12 hours |
| Key Instructions | For opioid-naive and opioid non-tolerant patients, initiate treatment with 15 mg tablets orally every 12 hours. Swallow tablets whole (do not cut, break, chew, crush, or dissolve). |
| Specific Drug Interactions | P-gp inhibitors (e.g. quinidine) may increase the absorption/exposure of morphine sulfate by about two-fold. |
| Use in Opioid-Tolerant Patients | MorphaBond ER 100 mg tablets, as single dose greater than 60 mg, or a total daily dose greater than 120 mg, are only for use in patients in whom tolerance to an opioid of comparable potency has been established. |
| Product-Specific Safety Concerns | None |
| **MS Contin** | Morphine Sulfate  
Extended-release Tablets, 15 mg, 30 mg, 60 mg, 100 mg, and 200 mg |
| Dosing Interval | Every 8 hours or every 12 hours |
| Key Instructions | • Product information recommends not using as first opioid.  
• Titrate using a minimum of 1 to 2-day intervals.  
• Swallow tablets whole (do not cut, break, chew, crush, or dissolve). |
| Specific Drug Interactions | P-gp inhibitors (e.g. quinidine) may increase the absorption/exposure of morphine sulfate by about two-fold. |
| Use in Opioid-Tolerant Patients | MS Contin 100 mg and 200 mg tablet strengths are for use in opioid-tolerant patients only |
| Product-Specific Safety Concerns | None |
| **Nucynta ER** | Tapentadol  
Extended-Release Tablets, 50 mg, 100 mg, 150 mg, 200 mg, and 250 mg |
| Dosing Interval | Every 12 hours |
| Key Instructions | • Use 50 mg every 12 hours as initial dose in opioid nontolerant patients.  
• Titrate by 50 mg increments using a minimum of 3-day intervals.  
• Maximum total daily dose is 500 mg  
• Swallow tablets whole (do not chew, crush, or dissolve).  
• Take one tablet at a time and with enough water to ensure complete swallowing immediately after placing in the mouth.  
• Dose once daily in moderate hepatic impairment with 100 mg per day maximum  
• Avoid use in severe hepatic and renal impairment. |
| Specific Drug Interactions | • Alcoholic beverages or medications containing alcohol may result in the rapid release and absorption of a potentially fatal dose of tapentadol.  
• Contraindicated in patients taking MAOIs. |
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Use in Opioid-Tolerant Patients</td>
<td>No product-specific considerations.</td>
</tr>
</tbody>
</table>
| Product-Specific Safety Concerns | • Risk of serotonin syndrome  
• Angioedema |
| Relative Potency To Oral Morphine | Equipotency to oral morphine has not been established. |
| **Opana ER** | **Oxymorphone Hydrochloride**  
ER Tablets, 5 mg, 7.5 mg, 10 mg, 15 mg, 20 mg, 30 mg, and 40 mg |
| Dosing Interval | Every 12h dosing, some may benefit from asymmetric (different dose given in AM than in PM) dosing. |
| Key Instructions | • Use 5 mg every 12 hours as initial dose in opioid non-tolerant patients and patients with mild hepatic impairment and renal impairment (creatinine clearance < 50 mL/min) and patients over 65 years of age  
• Swallow tablets whole (do not chew, crush, or dissolve).  
• Take one tablet at a time, with enough water to ensure complete swallowing immediately after placing in the mouth.  
• Titrate in increments of 5 to 10 mg using a minimum of 3 to 7-day intervals.  
• Contraindicated in moderate and severe hepatic impairment. |
| Specific Drug Interactions | Alcoholic beverages or medications containing alcohol may result in the absorption of a potentially fatal dose of oxymorphone. |
| Use in Opioid-Tolerant Patients | No product specific considerations. |
| Product-Specific Safety Concerns | Use with caution in patients who have difficulty in swallowing or have underlying GI disorders that may predispose them to obstruction, such as a small gastrointestinal lumen. |
| Relative Potency To Oral Morphine | Approximately 3:1 oral morphine to oxymorphone oral dose ratio |
| **OxyContin** | **Oxycodone Hydrochloride**  
Extended-release Tablets, 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg, and 80 mg |
<p>| Dosing Interval | Every 12 hours |</p>
<table>
<thead>
<tr>
<th>Key Instructions</th>
<th>◊ For Adults:</th>
<th>◊ For Pediatric patients (11 years and older):</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Initial dose in opioid-naïve and opioid non-tolerant patients is 10 mg</td>
<td>• For use only in opioid-tolerant pediatric patients already receiving and</td>
</tr>
<tr>
<td></td>
<td>every 12 hours.</td>
<td>tolerating opioids for at least 5 consecutive days with a minimum of 20</td>
</tr>
<tr>
<td></td>
<td>• If needed, adult dosage may be adjusted in 1 to 2 day intervals.</td>
<td>mg per day of oxycodone or its equivalent for at least two days immedi-</td>
</tr>
<tr>
<td></td>
<td>• When a dose increase is clinically indicated, the total daily oxycodone</td>
<td>ately preceding dosing with OxyContin.</td>
</tr>
<tr>
<td></td>
<td>dose usually can be increased by 25% to 50% of the current dose.</td>
<td>• If needed, pediatric dosage may be adjusted in 1 to 2 day intervals.</td>
</tr>
<tr>
<td></td>
<td>◊ For Pediatric patients (11 years and older):</td>
<td>• When a dose increase is clinically indicated, the total daily oxycodone</td>
</tr>
<tr>
<td></td>
<td>• Hepatic impairment: start with one third to one half the usual dosage</td>
<td>dose usually can be increased by 25% of the current total daily dose.</td>
</tr>
<tr>
<td></td>
<td>• Renal impairment (creatinine clearance &lt;60 mL/min): start with one</td>
<td>• For all patients:</td>
</tr>
<tr>
<td></td>
<td>half the usual dosage.</td>
<td>• Choking, gagging, regurgitation, tablets stuck in the throat, difficulty</td>
</tr>
<tr>
<td></td>
<td>• Consider use of other analgesics in patients who have difficulty swallow-</td>
<td>swallowing the tablet.</td>
</tr>
<tr>
<td></td>
<td>ing or have underlying GI disorders that may predispose them obstruction.</td>
<td>• Contraindicated in patients with gastrointestinal obstruction.</td>
</tr>
<tr>
<td></td>
<td>• Take one tablet at a time, with enough water to ensure complete</td>
<td>• Use with caution in patients who have difficulty in swallowing or have</td>
</tr>
<tr>
<td></td>
<td>swallowing immediately after placing in the mouth.</td>
<td>underlying GI disorders that may predispose them to obstruction, small</td>
</tr>
<tr>
<td></td>
<td>◊ For Pediatric patients (11 years and older):</td>
<td>gastrointestinal lumen.</td>
</tr>
<tr>
<td></td>
<td>• For use only in opioid-tolerant pediatric patients already receiving and</td>
<td>• If needed, pediatric dosage may be adjusted in 1 to 2 day intervals.</td>
</tr>
<tr>
<td></td>
<td>tolerating opioids for at least 5 consecutive days with a minimum of 20</td>
<td>• When a dose increase is clinically indicated, the total daily oxycodone</td>
</tr>
<tr>
<td></td>
<td>mg per day of oxycodone or its equivalent for at least two days immedi-</td>
<td>dose usually can be increased by 25% of the current total daily dose.</td>
</tr>
<tr>
<td></td>
<td>ately preceding dosing with OxyContin.</td>
<td>• For all patients:</td>
</tr>
<tr>
<td></td>
<td>• If needed, pediatric dosage may be adjusted in 1 to 2 day intervals.</td>
<td>• Choking, gagging, regurgitation, tablets stuck in the throat, difficulty</td>
</tr>
<tr>
<td></td>
<td>• When a dose increase is clinically indicated, the total daily oxycodone</td>
<td>swallowing the tablet.</td>
</tr>
<tr>
<td></td>
<td>dose usually can be increased by 25% of the current total daily dose.</td>
<td>• Contraindicated in patients with gastrointestinal obstruction.</td>
</tr>
</tbody>
</table>

| Specific Drug Interactions            | • CYP3A4 inhibitors may increase oxycodone exposure.                         |
|                                       | • CYP3A4 inducers may decrease oxycodone exposure.                           |

| Use in Opioid-Tolerant Patients       | ◊ For Adults:                                                                 | ◊ For Pediatric patients (11 years and older):                              |
|                                       | • Single dose greater than 40 mg or total daily dose greater than 80 mg     | • For use only in opioid-tolerant pediatric patients already receiving and   |
|                                       | are for use in adult patients in whom tolerance to an opioid of compara-     | tolerating opioids for at least 5 consecutive days with a minimum of 20      |
|                                       | ble potency has been established.                                           | mg per day of oxycodone or its equivalent for at least two days immedi-     |
|                                       | ◊ For Pediatric patients (11 years and older):                               | ately preceding dosing with OxyContin.                                      |
|                                       | • For use only in opioid-tolerant pediatric patients already receiving and   | • If needed, pediatric dosage may be adjusted in 1 to 2 day intervals.      |
|                                       | tolerating opioids for at least 5 consecutive days with a minimum of 20      | • When a dose increase is clinically indicated, the total daily oxycodone   |
|                                       | mg per day of oxycodone or its equivalent for at least two days immedi-     | dose usually can be increased by 25% of the current total daily dose.       |
|                                       | ately preceding dosing with OxyContin.                                      | • For all patients:                                                          |
|                                       | • If needed, pediatric dosage may be adjusted in 1 to 2 day intervals.      | • Choking, gagging, regurgitation, tablets stuck in the throat, difficulty   |
|                                       | • When a dose increase is clinically indicated, the total daily oxycodone   | swallowing the tablet.                                                      |
|                                       | dose usually can be increased by 25% of the current total daily dose.       | • Contraindicated in patients with gastrointestinal obstruction.              |

| Product-Specific Safety Concerns      | • Choking, gagging, regurgitation, tablets stuck in the throat, difficulty   |
|                                       | swallowing the tablet.                                                      |
|                                       | • Contraindicated in patients with gastrointestinal obstruction.              |

| Relative Potency To Oral Morphine     | Approximately 2:1 oral morphine to oxycodone oral dose ratio.               |

**Targiniq ER**

Oxycodone Hydrochloride / Naloxone Hydrochloride
Extended-release tablets, 10 mg/5 mg, 20 mg/10 mg, and 40 mg/20 mg

| Dosing Interval                      | Every 12 hours |
### TABLE 10: Specific Drug Information for Extended-Release and Long-Acting Opioid Analgesics (ER/LA opioid analgesics)

**Key Instructions**

- **Opioid-naïve patients:** initiate treatment with 10 mg/5 mg every 12 hours.
- **Titrate using a minimum of 1 to 2 day intervals.**
- **Do not exceed 80 mg/40 mg total daily dose (40 mg/20 mg q12) of Targiniq ER**
- **May be taken with or without food.**
- **Swallow tablets whole. Do not chew, crush, split, or dissolve, as this will release oxycodone, possibly resulting in fatal overdose, and naloxone, possibly resulting in withdrawal symptoms.**
- **Hepatic impairment: contraindicated in moderate and severe hepatic impairment. In patients with mild hepatic impairment, start with one third to one half the usual dosage.**
- **Renal impairment (creatinine clearance < 60 mL/min): start with one half the usual dosage.**

**Specific Drug Interactions**

- CYP3A4 inhibitors may increase oxycodone exposure.
- CYP3A4 inducers may decrease oxycodone exposure.

**Use in Opioid-Tolerant Patients**

Single dose greater than 40 mg/20 mg or total daily dose of 80 mg/40 mg are for use in opioid-tolerant patients only.

**Product-Specific Safety Concerns**

Contraindicated in patients with moderate to severe hepatic impairment.

**Relative Potency To Oral Morphine**

See individual product information for conversion recommendations from prior opioid.

**Troxyca ER**

Oxycodone Hydrochloride/Naltrexone Hydrochloride Extended-Release Capsules, 10 mg/1.2 mg, 20 mg/2.4 mg, 30 mg/3.6 mg, 40 mg/4.8 mg, 60 mg/7.2 mg, 80 mg/9.6 mg

**Dosing Interval**

Every 12 hours

**Key Instructions**

- **Opioid-naïve and opioid non-tolerant patients:** 10 mg/1.2 mg, every 12 hours
- **Total daily dose may be adjusted by 20 mg/2.4 mg every 2 to 3 days as needed.**
- **Swallow capsule whole (do not chew, crush, or dissolve).**
- **Crushing, chewing, or dissolving will release oxycodone, possibly resulting in fatal overdose, and naltrexone, possibly resulting in withdrawal symptoms.**
- **For patients that have difficulty swallowing, Troxyca ER, can also be taken by sprinkling the capsule contents (pellets) on applesauce and swallowing immediately without chewing.**
- **Do not administer Troxyca ER pellets through a nasogastric or gastric tube.**

**Specific Drug Interactions**

- CYP3A4 inhibitors may increase oxycodone exposure.
- CYP3A4 inducers may decrease oxycodone exposure.

**Use in Opioid-Tolerant Patients**

Single doses of greater than 40 mg/4.8 mg, or a total daily dose greater than 80 mg/9.6 mg are only for use in opioid-tolerant patients only.

**Product-Specific Safety Concerns**

None

**Relative Potency To Oral Morphine**

See individual product information for conversion recommendations from prior opioid.

**Vantrela ER**

Hydrocodone Bitartrate Extended-Release Tablets, 15 mg, 30 mg, 45 mg, 60 mg, and 90 mg

**Dosing Interval**

Every 12 hours
<table>
<thead>
<tr>
<th><strong>TABLE 10: Specific Drug Information for Extended-Release and Long-Acting Opioid Analgesics (ER/LA opioid analgesics)</strong></th>
</tr>
</thead>
</table>
| **Key Instructions** | • Opioid naïve and opioid non-tolerant patients: Initiate with 15 mg every 12 hours. Dose can be increased from the current dose to the next higher dose every 3 to 7 days as needed.  
• Swallow tablets whole (do not chew, crush, or dissolve).  
• Mild or moderate hepatic and moderate to severe renal impairment: Initiate therapy with 1/2 of the recommended initial dose in patients with either of these impairments. If a dose less than 15 mg is needed, use alternative analgesic options. |
| **Specific Drug Interactions** | • CYP3A4 inhibitors may increase hydrocodone exposure.  
• CYP3A4 inducers may decrease hydrocodone exposure. |
| **Use in Opioid-Tolerant Patients** | A 90 mg tablet, a single dose greater than 60 mg, or a total daily dose greater than 120 mg are for use in opioid-tolerant patients only. |
| **Product-Specific Safety Concerns** | None |
| **Relative Potency To Oral Morphine** | See individual product information for conversion recommendations from prior opioid. |
| **Zohydro ER** | Hydrocodone Bitartrate  
Extended-Release Capsules, 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, and 50 mg |
| **Dosing Interval** | Every 12 hours |
| **Key Instructions** | • Initial dose in opioid non-tolerant patient is 10 mg.  
• Titrate in increments of 10 mg using a minimum of 3 to 7 days as needed.  
• Swallow capsules whole (do not chew, crush, or dissolve). |
| **Specific Drug Interactions** | • CYP3A4 inhibitors may increase oxycodone exposure  
• CYP3A4 inducers may decrease oxycodone exposure |
| **Use in Opioid-Tolerant Patients** | A single dose greater than 36 mg or a total daily dose greater than 72 mg is for use in opioid-tolerant patients only. |
| **Product-Specific Safety Concerns** | None |
| **Relative Potency To Oral Morphine** | There are no established conversion ratios for conversion from other opioids to Zohydro ER defined by clinical trials |
| **Xtampza ER** | Oxycodone  
Extended-Release Capsules, 9 mg, 13.5 mg, 18 mg, 27 mg, and 36 mg (strengths equivalent to 10 mg, 15 mg, 20 mg, 30 mg, and 40 mg oxycodone hydrochloride, respectively) |
| **Dosing Interval** | Every 12 hours |
| **Key Instructions** | • Opioid naïve and opioid non-tolerant patients: Initiate with 9 mg every 12 hours.  
• Titrate using a minimum of 1 to 2 day intervals.  
• Take Xtampza ER capsules with the same amount of food in order to ensure consistent plasma levels are achieved.  
• Maximum daily dose: 288 mg (8 x 36 mg capsules) because the safety of excipients has not been established for higher doses  
• For patients that have difficulty swallowing, Xtampza ER can also be taken by sprinkling the capsule contents on soft foods or into a cup and then administering directly into the mouth and swallowing immediately. Xtampza ER may also be administered through a gastrostomy or nasogastric feeding tube.  
• Hepatic impairment: Initiate therapy at 1/3 to 1/2 the usual dosage  
• Renal impairment: (creatinine clearance <60 mL/min): Follow a conservative approach to dose initiation and adjust according to the clinical situation. |
| **Specific Drug Interactions** | • CYP3A4 inhibitors may increase oxycodone exposure  
• CYP3A4 inducers may decrease oxycodone exposure |
| **Use in Opioid-Tolerant Patients** | A single dose greater than 22.5 mg or a total daily dose greater than 45 mg is for use in opioid-tolerant patients only. |
| **Product-Specific Safety Concerns** | None |
| **Relative Potency To Oral Morphine** | See individual product information for conversion recommendations from prior opioid. |
| **Zantac ER** | Hydrocodone Bitartrate  
Extended-Release Capsules, 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, and 50 mg |
| **Dosing Interval** | Every 12 hours |
| **Key Instructions** | • Opioid naïve and opioid non-tolerant patients: Initiate with 10 mg every 12 hours.  
• Swallow tablets whole (do not chew, crush, or dissolve).  
• Titrate using a minimum of 1 to 2 day intervals. |
| **Specific Drug Interactions** | • CYP3A4 inhibitors may increase oxycodone exposure  
• CYP3A4 inducers may decrease oxycodone exposure |
| **Use in Opioid-Tolerant Patients** | A single dose greater than 22.5 mg or a total daily dose greater than 45 mg is for use in opioid-tolerant patients only. |
| **Product-Specific Safety Concerns** | None |
| **Relative Potency To Oral Morphine** | See individual product information for conversion recommendations from prior opioid. |
**TABLE 10: Specific Drug Information for Extended-Release and Long-Acting Opioid Analgesics (ER/LA opioid analgesics)**

| Specific Drug Interactions                                                                 | • Alcoholic beverages or medications containing alcohol may result in the rapid release and absorption of a potentially fatal dose of hydrocodone.  
|                                                                                           | • CYP3A4 inhibitors may increase hydrocodone exposure.  
|                                                                                           | • CYP3A4 inducers may decrease hydrocodone exposure.  
| Use in Opioid-Tolerant Patients                                                           | Single dose greater than 40 mg or total daily dose greater than 80 mg are for use in opioid-tolerant patients only.  
| Product-Specific Safety Concerns                                                          | None  
| Relative Potency To Oral Morphine                                                         | Approximately 1.5:1 oral morphine to hydrocodone oral dose ratio.  

**Source:** FDA Blueprint for Prescriber Education for Extended-Release and Long-Acting Opioid Analgesics. May, 2017.  

**TABLE 11. PATIENT COUNSELING DOCUMENT ON EXTENDED-RELEASE / LONG-ACTING OPIOID ANALGESICS**

**Patient Name:**

<table>
<thead>
<tr>
<th>The <strong>DOs</strong> and <strong>DON'Ts</strong> of Extended-Release / Long-Acting Opioid Analgesics</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>DO:</strong></td>
</tr>
<tr>
<td>• Read the Medication Guide</td>
</tr>
<tr>
<td>• Take your medicine exactly as prescribed</td>
</tr>
<tr>
<td>• Store your medicine away from children and in a safe place</td>
</tr>
<tr>
<td>• Flush unused medicine down the toilet</td>
</tr>
<tr>
<td>• Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.</td>
</tr>
<tr>
<td><strong>Call 911 or your local emergency service right away if:</strong></td>
</tr>
<tr>
<td>• You take too much medicine</td>
</tr>
<tr>
<td>• You have trouble breathing, or shortness of breath</td>
</tr>
<tr>
<td>• A child has taken this medicine</td>
</tr>
<tr>
<td><strong>Talk to your healthcare provider:</strong></td>
</tr>
<tr>
<td>• If the dose you are taking does not control your pain</td>
</tr>
<tr>
<td>• About any side effects you may be having</td>
</tr>
<tr>
<td>• About all the medicines you take, including over-the-counter medicines, vitamins, and dietary supplements</td>
</tr>
</tbody>
</table>

**DON'T:**

| **DO not** give your medicine to others  
| **DO not** take medicine unless it was prescribed for you  
| **DO not** stop taking your medicine without talking to your healthcare provider  
| **DO not** break, chew, crush, dissolve, or inject your medicine. If you cannot swallow your medicine whole, talk to your healthcare provider.  
| **DO not** drink alcohol while taking this medicine  |

For additional information on your medicine go to:  
dailymed.nlm.nih.gov

**Note:** Prescribers should counsel patients on product specific information and ensure that patients are aware that selling or sharing any controlled substance with others is against the law.
REFERENCES

American Pain Society; 1999.
64. American Pain Society Guideline for the use of chronic opioid therapy in chronic noncancer
pain. 2009. 


1. Extended-release (ER) and Long-acting (LA) formulations of opioids should typically not be used for which of the following?
   A. Treating cancer pain
   B. Treating acute pain
   C. Treating end-of-life pain
   D. Treating nociceptive pain

2. If an organic pathology cannot be found to explain a patient’s pain, what should a clinician infer?
   A. The pain is real, though unexplained
   B. The pain is psychosomatic
   C. The patient is seeking opioids for illegal use
   D. The pain is the result of a mental health condition

3. Which of the following is the appropriate use of “universal precautions” as it applies to patients with chronic pain?
   A. Exploring patients’ HIV status
   B. Having all patients submit to a screening urine toxicology test
   C. Being vigilant about the possibility of misuse or abuse with all patients
   D. Both B and C

4. The DIRE and the ORT are examples of which kind of assessment?
   A. Quantifying patients’ pain perceptions
   B. Assessing patient risk of opioid misuse or abuse
   C. Evaluating risk of physical adverse reactions to opioids
   D. Determining a reason for opioid pain medications

5. All of the following need to be documented in writing as part of an overall therapeutic approach to managing chronic pain patients EXCEPT:
   A. Informed consent
   B. Patient/provider agreements
   C. Treatment agreements
   D. Expected cost of prescribed medications

6. All of the following are possible advantages of patient/provider agreements EXCEPT:
   A. Provides a foundation for subsequent decisions about treatment termination
   B. Can help clinicians identify a patient’s level of risk for opioid abuse
   C. Can help avoid misunderstandings between provider and patient
   D. Can document informed consent

7. All of the following are examples of functional goals EXCEPT:
   A. Reduced anxiety about pain
   B. Walking around the block
   C. Increased sexual activity
   D. Returning to work

8. A fundamental part of ethical treatment for patients with chronic pain is:
   A. Assessing a patient’s risk for opioid use disorder
   B. Obtaining informed consent
   C. Proper insurance coverage
   D. Avoiding high doses of opioids

9. When opioid treatment is initiated, both the patient and clinician should view the commitment as:
   A. Short-term trial of therapy
   B. A long-term use of opioid therapy
   C. A titration of the opioid to reach optimal pain relief
   D. Continued therapy until adequate pain relief is achieved

10. It can be particularly unsafe to combine opioids with which of the following other medicines?
    A. Stimulant medications
    B. SSRI antidepressants
    C. Benzodiazepines or barbiturates
    D. Anti-hypertensive medications
11. Which class of antidepressant medications has been shown to be effective in treating some neuropathic pain conditions?
   A. SNRIs
   B. SSRIs
   C. MAOIs
   D. DNSIs

12. Combination products are those that include an opioid with which of the following elements?
   A. Non-opioid coanalgesic
   B. Non-opioid narcotic medication
   C. Opioid antagonist to prevent abuse
   D. Caffeine

13. In general, the amount of opioids prescribed for acute pain should be limited to a _____ day supply:
   A. 1
   B. 3
   C. 7
   D. 10

14. Uncomfortable or unpleasant side effects (aside from constipation) may potentially be reduced by which approach?
   A. Switching to another opioid
   B. Using adjunctive medications to treat symptoms
   C. Changing the route of administration
   D. All of the above

15. All of the following are valid reasons to pursue opioid rotation EXCEPT:
   A. Lack of efficacy
   B. Bothersome or unacceptable side effects
   C. Desire to prevent the patient from illegally diverting opioids
   D. Change in patient’s ability to absorb a medication in its present formulation

16. One reason that methadone must be prescribed with particular caution is that:
   A. Methadone is only appropriate for opioid maintenance therapy programs
   B. Methadone’s analgesic half-life is much shorter than its elimination half-life
   C. Methadone has uniquely powerful respiratory depressive effects
   D. Methadone may produce visual disturbances

17. Which of the following is not a potential benefit of urine drug testing?
   A. May deter inappropriate use
   B. Provides objective evidence of abstinence from drugs of abuse
   C. May demonstrate to regulatory authorities a clinician’s dedication to patient monitoring
   D. Can differentiate between specific opioid products that a patient may be using

18. All of the following are of particular concern when prescribing an ER/LA opioid pain medication EXCEPT:
   A. Abuse by breaking, chewing, or crushing tablets
   B. Risk of overdose if long-duration drugs are combined with short-acting medications
   C. ER/LA medications tend to be costlier than short-acting formulations
   D. Some opioids with ER/LA characteristics (i.e., methadone) may have atypical pharmacokinetics

19. In 2006, the FDA added a caution to the “black box” warning that methadone may cause which of the following serious adverse effects?
   A. Respiratory depression
   B. Cardiac conduction disturbances
   C. Myoclonus
   D. Renal failure

20. Which of the following is the APS-AAPM guideline regarding the prescription of opioids to pregnant women?
   A. Avoid prescribing opioids unless potential benefits outweigh risks
   B. Completely avoid prescribing opioids to this population
   C. Prescribe ER/LA opioids rather than short-acting opioids to avoid spike exposure to fetus
   D. Prescribe opioids as needed for maternal pain, but monitor infant after delivery for possible neonatal abstinence syndrome
TARGET AUDIENCE
This course is designed for all physicians (MD/DO) and all other health care professionals.

COURSE OBJECTIVE
The purpose of the course is to synthesize current knowledge about diagnostic error and presents recommendations on how to reduce diagnostic errors and improve diagnosis.

HOW TO RECEIVE CREDIT:
- Read the course materials
- Complete the self-assessment questions at the end. A score of 70% is required.
- Return your customer information/answer sheet, evaluation, and payment to Informed by mail, phone, fax or complete online at course website under NETPASS.

LEARNING OBJECTIVE
Completion of this course will better enable the course participant to:
1. Identify the fundamental steps in clinical reasoning and diagnosis.
2. Define “diagnostic error” and explain the ways that diagnostic error can be measured or assessed.
3. Recognize the importance of a team approach to reducing diagnostic errors.
4. Discuss the ways that clinicians can improve patient engagement in the clinical diagnostic process so as to improve diagnostic accuracy and reduce error.
5. Describe the ways that technology and healthcare information tools can be used to reduce diagnostic error.
6. Explain external environmental variables that influence diagnostic accuracy.

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Introduction

The delivery of health care has proceeded for decades with a blind spot: diagnostic errors. Inaccurate or delayed diagnoses persist throughout all settings of care and continue to harm an unacceptable number of patients. For example:

- A conservative estimate found that 5% of U.S. adults who seek outpatient care each year experience a diagnostic error.
- Postmortem examination research spanning decades has shown that diagnostic errors contribute to approximately 10% of patient deaths.
- Medical record reviews suggest that diagnostic errors account for 6 to 17% of hospital adverse events.
- Diagnostic errors are the leading type of paid medical malpractice claims, are almost twice as likely to have resulted in the patient’s death compared to other claims, and represent the highest proportion of total payments.

Most people will experience at least one diagnostic error in their lifetime, sometimes with devastating consequences. And yet, despite the pervasiveness of diagnostic errors and the risk for serious patient harm, diagnostic errors have been largely unappreciated within the quality and patient safety movements in health care. Without a dedicated focus on improving diagnosis, these errors will likely worsen as the delivery of health care and the diagnostic process continue to increase in complexity.

Getting the right diagnosis is a key aspect of health care—it provides an explanation of a patient’s health problem and informs subsequent health care decisions. Diagnostic errors stem from a wide variety of causes, including: inadequate collaboration and communication among clinicians, patients, and their families; a health care work system that is not well designed to support the diagnostic process; limited feedback to clinicians about diagnostic performance; and a culture that discourages transparency and disclosure of diagnostic errors, which impedes efforts to learn from these events and improve diagnosis.

Diagnostic errors may result in different outcomes, and as evidence accrues, these outcomes will be better characterized. For example, if there is a diagnostic error, a patient may or may not experience harm. Errors can be harmful because they can prevent or delay appropriate treatment, lead to unnecessary or harmful treatment, or result in psychological or financial repercussions. Harm may not result, for example, if a patient’s symptoms resolve even with an incorrect diagnosis.

Improving the diagnostic process is not only possible, but it also represents a moral, professional, and public health imperative. Achieving that goal will require a significant re-envisioning of the diagnostic process and a widespread commitment to change among health care professionals, health care organizations, patients and their families, researchers, and policy makers.

In addition to diagnostic errors, the public is concerned about other aspects of diagnosis, such as the value of making and communicating diagnoses at early stages in conditions such as Alzheimer’s disease and amyotrophic lateral sclerosis (Lou Gehrig’s disease) for which there is currently no known cure (Hamilton, 2015). There is also a growing concern about over-diagnosis, such as the assignment of diagnostic labels to conditions that are unlikely to affect the individual’s health and well-being (Welch et al., 2011); the focus of clinical attention on making new diagnoses in older patients while ignoring limitations to their daily living that need immediate attention (Gawande, 2014; Mechanic, 2014); and the elevation of common behavioral traits to the level of formal diagnoses, with the attendant treatment and confidentiality implications (Hazen et al., 2013; Kavan and Barone, 2014; NHS, 2013). The Institute of Medicine (IOM) report Beyond Myalgic Encephalomyelitis/Chronic Fatigue Syndrome: Redefining an Illness brought attention to the problem that individuals with debilitating but previously unrecognized symptom complexes may be given inadequate attention by clinicians or ignored altogether because a diagnosis is lacking (IOM, 2015a; Rehmeyer, 2015). Diagnoses also affect the health care that patients receive, eligibility for social security and veterans disability benefits, as well as health care research and education priorities.

The widespread challenge of diagnostic errors frequently rises to broad public attention, whether the widely reported diagnostic error of Ebola virus infection in a Dallas hospital emergency department or in the occasional report of an extraordinarily high malpractice
improving diagnosis and reducing diagnostic errors. Other factors that contribute to the limited focus on diagnostic error include a lack of awareness of the problem, attitudes and culture that encourage inaction and tolerance of errors, poorly understood characteristics of the diagnostic and clinical reasoning processes, and the need for financial and other resources to address the problem (Berenson et al., 2014; Croskerry, 2012).

Although diagnostic error has been largely under-appreciated in efforts to improve the quality and safety of health care, this issue has garnered national attention, and there is growing momentum for change (Graber et al., 2012; Schiff and Leape, 2012; Wachter, 2010). Emerging research has found new opportunities for the identification of diagnostic errors and has led to a better understanding of the epidemiology and etiology of these errors and of potential interventions to improve diagnosis (Singh et al., 2014; Tehrani et al., 2013; Trowbridge et al., 2013; Zwaan et al., 2010; Zwaan and Singh, 2015). Patients and families who have experienced diagnostic error have become increasingly vocal about their desire to share their unique insights to help identify patterns and improve the diagnostic process for future patients (Haskell, 2014; McDonald et al., 2013).

Efforts to accelerate progress toward improving diagnosis can leverage four important movements in health care—the movements to improve patient safety, increase patient engagement, foster professionalism, and encourage collaboration. Diagnostic error has even been called the next frontier in patient safety, even though the challenge of diagnostic error will have benefits beyond the realm of patient safety (Newman-Toker and Pronovost, 2009). Patient engagement and the importance of shared decision making are recognized as critical aspects of improving health care quality (IOM, 2001). The current focus on professionalism emphasizes health care professionals’ intrinsic motivation and commitment to provide patients with high-quality, patient-centered care (Berwick, 2015; Chassin and Baker, 2015; Madara and Burkhart, 2015). The growing recognition of health care as a team-based activity has led to greater collaboration among health care professionals, both intra- and inter-professionally (IOM, 2001; Josiah Macy Jr. Foundation and Carnegie Foundation for the Advancement of Teaching, 2010). These four movements have collectively transformed the way that health care is provided in the United States, and progress toward improving diagnosis and reducing diagnostic errors is a natural outgrowth of these movements.

This CME program synthesizes current knowledge about diagnostic error and presents recommendations by the Committee on Diagnostic Error in Health Care of the Institute of Medicine on how to reduce diagnostic errors and improve diagnosis.

Definition and Conceptual Model

Focusing solely on diagnostic error reduction will not achieve the extensive changes necessary; a broader focus on improving diagnosis is warranted. To provide a framework for this dual focus, the committee developed a conceptual model to articulate the diagnostic process (Figure 1), described work system factors that influence this process (Figure 2), and identified opportunities to improve the diagnostic process and outcomes (Figure 3).

The diagnostic process is a complex and collaborative activity that unfolds over time and occurs within the context of a health care work system. The diagnostic process is iterative, and as information gathering continues, the goal is to reduce diagnostic uncertainty, narrow down the diagnostic possibilities, and develop a more precise and complete understanding of a patient’s health problem.

The committee sought to develop a definition of diagnostic error that reflects the iterative and complex nature of the diagnostic process, as well as the need for a diagnosis to convey more than simply a label of a disease. The term “health problem” is used in the definition, because it is a patient-centered and inclusive term to describe a patient’s overall health condition. The committee’s definition of diagnostic error is the failure to (a) establish an accurate and timely explanation of the patient’s health problem(s) or (b) communicate that explanation to the patient.

The definition employs a patient-centered perspective because patients bear the ultimate risk of harm from diagnostic errors. Timeliness means that the diagnosis was not meaningfully delayed; however, timeliness is context-dependent. While some diagnoses may take days, weeks, or even months to establish, timely may mean quite quickly (minutes to hours) for other urgent diagnoses. A diagnosis is not accurate if it differs from the true condition a patient has (or does not have) or if it is imprecise and incomplete. The inclusion of communication is distinct from previous definitions, in recognition that communication is a key responsibility throughout the diagnostic process.
From a patient’s perspective, an accurate and timely explanation of the health problem is meaningless unless this information reaches the patient so that a patient and health care professionals can act on the explanation.

Figure 2. The work system in which the diagnostic process takes place

In addition to defining and identifying diagnostic errors in clinical practice, the report places a broader emphasis on improving the diagnostic process. Analyzing failures in the diagnostic process can provide important opportunities for learning and continued improvement. Some failures in the diagnostic process will lead to diagnostic errors; however, other failures in the diagnostic process will not ultimately lead to a diagnostic error, because subsequent steps in the process compensate for the initial failure. In this report, the committee describes “failures in the diagnostic process that do not lead to diagnostic errors” as near misses.

A related but distinct concept to diagnostic error is over-diagnosis, defined as when a condition is diagnosed that is unlikely to affect the individual’s health and well-being. While over-diagnosis represents a true challenge to health care quality, it is not a diagnostic error. Over-diagnosis is only detectable in population-based analyses—it is virtually impossible to assess whether over-diagnosis has occurred for an individual patient. However, improving the diagnostic process—such as reducing unnecessary diagnostic testing—may help avert over-diagnosis.

The Diagnostic Process

This chapter provides an overview of diagnosis in health care, including the committee’s conceptual model of the diagnostic process and a review of clinical reasoning. Diagnosis has important implications for patient care, research, and policy. Diagnosis has been described as both a process and a classification scheme, or a “pre-existing set of categories agreed upon by the medical profession to designate a specific condition” (Iutel, 2009). When a diagnosis is accurate and made in a timely manner, a patient has the best opportunity for a positive health outcome because clinical decision making will be tailored to a correct understanding of the patient’s health problem (Holmboe and Durning, 2014). In addition, public policy decisions are often influenced by diagnostic information, such as setting payment policies, resource allocation decisions, and research priorities (Iutel, 2009; Rosenberg, 2002; WHO, 2012).

The chapter describes important considerations in the diagnostic process, such as the roles of diagnostic uncertainty and time. It also highlights the mounting complexity of health care, due to the ever-increasing options for diagnostic testing and treatment, the rapidly rising levels of biomedical and clinical evidence to inform clinical practice, and the frequent comorbidities among patients due to the aging of the population (IOM, 2008, 2013b). The rising complexity of health care and the sheer volume of advances, coupled with clinician time constraints and cognitive limitations, have outstripped human capacity to apply this new knowledge. To help manage this complexity, the chapter concludes with a discussion of the role of clinical practice guidelines in informing decision making in the diagnostic process.

Figure 3. Outcomes of the diagnostic process

Because not all patients will be able to participate in the communication process, in some instances communication would be between the health care professionals and a patient’s family or designated health care proxy.
Overview of the Diagnostic Process

To help frame and organize its work, the committee developed a conceptual model to illustrate the diagnostic process. The committee concluded that the diagnostic process is a complex, patient-centered, collaborative activity that involves information gathering and clinical reasoning with the goal of determining a patient’s health problem. This process occurs over time, within the context of a larger health care work system that influences the diagnostic process. The committee’s depiction of the diagnostic process draws on an adaptation of a decision-making model that describes the cyclical process of information gathering, integration, and interpretation.

The working diagnosis may be either a list of potential diagnoses (a differential diagnosis) or a single potential diagnosis. Typically, clinicians will consider more than one diagnostic hypothesis or possibility as an explanation of the patient’s symptoms and will refine this list as further information is obtained in the diagnostic process. The working diagnosis should be shared with the patient, including an explanation of the degree of uncertainty associated with a working diagnosis. Each time there is a revision to the working diagnosis, the process of information gathering, information integration and interpretation, and developing a working diagnosis continues. When the diagnostic team members judge that they have arrived at an accurate and timely explanation of the patient’s health problem, they communicate that explanation to the patient as the diagnosis.

It is important to note that clinicians do not need to obtain diagnostic certainty prior to initiating treatment; the goal of information gathering in the diagnostic process is to reduce diagnostic uncertainty enough to make optimal decisions for subsequent care (Kassirer, 1989). In addition, the process of information gathering, information integration and interpretation, and providing a working diagnosis (Parasuraman et al., 2000; Sarter, 2014).

The diagnostic process proceeds as follows: first, a patient experiences a health problem. The patient is likely the first person to consider his or her symptoms and may choose at this point to engage with the health care system. Once a patient seeks health care, there is an iterative process of information gathering, information integration and interpretation, and determining a working diagnosis. Performing a clinical history and interview, conducting a physical exam, performing diagnostic testing, and referring or consulting with other clinicians are all ways of accumulating information that may be relevant to understanding a patient’s health problem. The information gathering approaches can be employed at different times, and diagnostic information can be obtained in different orders. The continuous process of information gathering, integration, and interpretation involves hypothesis generation and updating prior probabilities as more information is learned. Communication among health care professionals, the patient, and the patient’s family members is critical in this cycle of information gathering, integration, and interpretation.

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Case Study

Sue’s son, Cal, was born healthy in a large hospital, but jaundice appeared soon afterwards. Cal’s father, Pat, and Sue were informed that treatment for such newborn jaundice isn’t usually necessary. (Because of an incorrect entry of the family blood types into Cal’s medical record, the hospital’s clinicians had not recognized that a common blood incompatibility existed and could lead to serious elevations in Cal’s bilirubin levels.)

Within 36 hours, Cal’s jaundice had deepened and spread from head to toe. Nevertheless, without measuring his bilirubin level, the hospital discharged Cal to home and provided Pat and Sue with reassuring information about jaundice, never mentioning that high levels of bilirubin in the blood can cause damage to the brain.

Four days later, Cal was more yellow, lethargic, and feeding poorly. His parents took him to a pediatrician, who noted the jaundice, still did not do a bilirubin test, and advised them to wait 24 more hours to see if Cal improved.

The next day, at the request of his parents, Cal was admitted to the hospital, and a blood test showed that the bilirubin level in Cal’s blood was dangerously high. Over the next few days while Cal was in the hospital, Pat and Sue reported to staff that he was exhibiting worrisome new behaviors, such as a high-pitched cry, respiratory distress, increased muscle tone, and arching of the neck and back. They were told not to worry.

Later it became clear that Cal was experiencing kernicterus, a preventable form of brain damage caused by high bilirubin levels in the blood of newborns. As a result, at age 20, Cal now has significant cerebral palsy, with spasticity of his trunk and limbs, marked impairment of his speech, difficulty aligning his eyes, and other difficulties.
interview of the patient, when a clinician compiles a patient’s medical history or verifies that the details of the patient’s history already contained in the patient’s medical record are accurate. A patient’s clinical history includes documentation of the current concern, past medical history, family history, social history, and other relevant information such as current medications (prescription and over-the-counter) and dietary supplements.

The process of acquiring a clinical history and interviewing a patient requires effective communication, active listening skills, and tailoring communication to the patient based on the patient’s needs, values, and preferences. The National Institute on Aging, in guidance for conducting a history and interview, suggests that clinicians should avoid interrupting, demonstrate empathy, and establish a rapport with patients (NIA, 2008). Clinicians need to know when to ask more detailed questions and how to create a safe environment for patients to share sensitive information about their health and symptoms.

Obtaining a history can be challenging in some cases, for example, in working with older adults with memory loss, with children, or with individuals whose health problems limit communication or reliable self-reporting. In these cases it may be necessary to include family members or caregivers in the history-taking process. The time pressures often involved in clinical appointments also contribute to challenges in the clinical history and interview. Limited time for clinical visits, partially attributed to payment policies, may lead to an incomplete picture of a patient’s relevant history and current signs and symptoms.

There are growing concerns that traditional “bedside evaluation” skills (history, interview, and physical exam) have received less attention due to the large growth in diagnostic testing in medicine. Verghese and colleagues noted that these methods were once the primary tools for diagnosis and clinical evaluation, but “the recent explosion of imaging and laboratory testing has inverted the diagnostic paradigm. [Clinicians] often bypass the bedside evaluation for immediate testing” (Verghese et al., 2011, p. 550). The interview has been called a clinician’s most versatile diagnostic and therapeutic tool, and the clinical history provides direction for subsequent information gathering activities in the diagnostic process (Lichstein, 1990). An accurate history facilitates a more productive and efficient physical exam and the appropriate utilization of diagnostic testing (Lichstein, 1990).

Indeed, Kassirer concluded: “Diagnosis remains fundamentally dependent on a personal interaction of a [clinician] with a patient, the sufficiency of communication between them, the accuracy of the patient’s history and physical examination, and the cognitive energy necessary to synthesize a vast array of information” (Kassirer, 2014, p. 12).

### Physical Exam

The physical exam is a hands-on observational examination of the patient. First, a clinician observes a patient’s demeanor, complexion, posture, level of distress, and other signs that may contribute to an understanding of the health problem (Davies and Rees, 2010). If the clinician has seen the patient before, these observations can be weighed against previous interactions with the patient. A physical exam may include an analysis of many parts of the body, not just those suspected to be involved in the patient’s current complaint. A careful physical exam can help a clinician refine the next steps in the diagnostic process, can prevent unnecessary diagnostic testing, and can aid in building trust with the patient (Verghese, 2011).

There is no universally agreed upon physical examination checklist; myriad versions exist online and in textbooks. Due to the growing emphasis on diagnostic testing, there are concerns that physical exam skills have been underemphasized in current health care professional education and training (Kassirer, 2014; Kugler and Verghese, 2010). For example, Kugler and Verghese have asserted that there is a high degree of variability in the way that trainees elicit physical signs and that residency programs have not done enough to evaluate and improve physical exam techniques. Physicians at Stanford have developed the “Stanford 25,” a list of physical diagnostic maneuvers that are very technique-dependent (Verghese and Horwitz, 2009). Educators observe students and residents performing these 25 maneuvers to ensure that trainees are able to elicit the physical signs reliably (Stanford Medicine 25 Team, 2015).

### Diagnostic Testing

Over the past 100 years, diagnostic testing has become a critical feature of standard medical practice (Berger, 1999; European Society of Radiology, 2010). Diagnostic testing may occur in successive rounds of information gathering, integration, and interpretation, as each round of information refines the working diagnosis. In many cases, diagnostic testing can identify a condition before it is clinically apparent; for example, coronary artery disease can be identified by an imaging study indicating the presence of coronary artery blockage even in the absence of symptoms. The primary emphasis of this section focuses on laboratory medicine, anatomic pathology, and medical imaging. There are, however, many important forms of diagnostic testing that extend beyond these fields, and the committee’s conceptual model is intended to be broadly applicable. Additional forms of diagnostic testing include, for example, screening tools used in making mental health diagnoses (SAMHSA and HRSA, 2015), sleep apnea testing, neurocognitive assessment, and vision and hearing testing.

Although it was developed specifically for laboratory medicine, the brain-to-brain loop model is useful for describing the general process of diagnostic testing (Lundberg, 1981; Plebani et al., 2011). The model includes nine steps: test selection and ordering, sample collection, patient identification, sample transportation, sample preparation, sample analysis, result reporting, result interpretation, and clinical action (Lundberg, 1981). These steps occur during five phases of diagnostic testing: pre-pre-analytic, pre-analytic, analytic, post-analytic, and post-post-analytic phases. Errors related to diagnostic testing can occur in any of these five phases, but the analytic phase is the least susceptible to errors (Eichbaum et al., 2012; Epner et al., 2013; Laposata, 2010; Nichols and Rauch, 2013; Stratton, 2011).

The pre-pre-analytic phase, which involves clinician test selection and ordering, has been identified as a key point of vulnerability in the work process due to the large number and variety of available tests, which makes it difficult for non-specialist clinicians to accurately select the correct test or series of tests (Hickner et al., 2014; Laposata and Dighe, 2007). The pre-analytic phase involves sample collection, patient identification, sample transportation, and sample preparation. During the analytic phase, the specimen is tested, examined, or both. Adequate performance in this phase depends on the correct execution of a chemical analysis or morphological examination (Hollensead et al., 2004), and the contribution to diagnostic errors at this step is small. The post-analytic phase includes the generation of results, reporting, interpretation, and follow-up. Ensuring timely and accurate reporting from the laboratory to the ordering clinician and patient is central to this phase. During the post-post-analytic phase, the ordering clinician, sometimes in consultation with pathologists, incorporates the test results into the patient’s clinical context, considers the probability of a particular diagnosis in light of the test results, and considers the harms and benefits of future tests and treatments, given the newly acquired information. Possible factors contributing to failure in this phase include an incorrect interpretation of the test result by the ordering clinician or pathologist and the failure by the ordering clinician to act on the test results—e.g., not ordering a follow-up test or not providing treatment consistent with the test results (Hickner et al., 2014; Laposata and Dighe, 2007; Plebani and Lippi, 2011).

The medical imaging work process parallels the work process described for pathology. There is a pre-pre-analytic phase (the selection and ordering of medical imaging), a pre-analytic phase (preparing the patient for imaging), an analytic phase (image acquisition and analysis), a post-analytic phase (the imaging results are interpreted and reported to the ordering clinician or the patient), and a post-post-analytic phase (the integration of results into the
screening test for a low-risk patient as indicative of HIV infection (Gigerenzer, 2013; Kleinman et al., 1998). In addition, test performance may only be characterized in a limited patient population, leading to challenges with generalizability (Whiting et al., 2004).

**Medical Imaging**

Medical imaging plays a critical role in establishing the diagnoses for innumerable conditions and it is used routinely in nearly every branch of medicine. The advancement of imaging technologies has improved the ability of clinicians to detect, diagnose, and treat conditions while also allowing patients to avoid more invasive procedures (European Society of Radiology, 2010; Gunderman, 2005). For many conditions (e.g., brain tumors), imaging is the only non-invasive diagnostic method available. The appropriate choice of imaging modality depends on the disease, organ, and specific clinical questions to be addressed. Computed tomography (CT) and magnetic resonance imaging (MRI) are first-line methods for assessing conditions of the central and peripheral nervous system, while for musculoskeletal and a variety of other conditions, X-ray and ultrasound are often employed first because of their relatively low cost and ready availability, with CT and MRI being reserved as problem-solving modalities. CT procedures are frequently used to assess and diagnose cancer, circulatory system diseases and conditions, inflammatory diseases, and head and internal organ injuries. A majority of MRI procedures are performed on the spine, brain, and musculoskeletal system, although usage for the breast, prostate, abdominal, and pelvic regions is rising (IMV, 2014).

Medical imaging is characterized not just by the increasingly precise anatomical detail it offers, but also by an increasing capacity to illuminate biology. For example, magnetic resonance spectroscopic imaging has allowed the assessment of metabolism, and a growing number of other MRI sequences are offering information about functional characteristics, such as blood perfusion or water diffusion. In addition, several new tracers for molecular imaging with PET (typically as PET/CT) have recently been approved for clinical use, and more are undergoing clinical trials, while PET/MRI was recently introduced to the clinical setting. Functional and molecular imaging data may be assessed qualitatively, quantitatively, or both.

Although other forms of diagnostic testing can identify a wide array of molecular markers, molecular imaging is unique in its capacity to non-invasively show the locations of molecular processes in patients, and it is expected to play a critical role in advancing precision medicine, particularly for cancers, which often demonstrate both intra- and inter-tumoral biological heterogeneity (Hricak, 2011).

The growing body of medical knowledge, the variety of imaging options available, and the regular increases in the amounts and kinds of data that can be captured with imaging present tremendous challenges for radiologists, as no individual can be expected to achieve competency in all of the imaging modalities. General radiologists continue to be essential in certain clinical settings, but extended training and sub-specialization are often necessary for optimal, clinically relevant image interpretation, as is involvement in multidisciplinary disease management teams. Furthermore, the use of structured reporting templates tailored to specific examinations can help to increase the clarity, thoroughness, and clinical relevance of image interpretation (Schwartz et al., 2011). Like other forms of diagnostic testing, medical imaging has limitations. Some studies have found that between 20 and 50 percent of all advanced imaging results fail to provide information that improves patient outcome, although these studies do not account for the value of negative imaging results in influencing decisions about patient management (Hendee et al., 2010). Imaging may fail to provide useful information because of modality sensitivity and specificity parameters; for example, the spatial resolution of an MRI may not be high enough to detect very small abnormalities. Inadequate patient education and preparation for an imaging test can also lead to suboptimal imaging quality that results in diagnostic error.

Perceptual or cognitive errors made by radiologists are at times a source of diagnostic error (Berlin, 2014; Krupinski et al., 2012). In addition, incomplete or incorrect patient information, as well as insufficient sharing of patient information, may lead to the use of an inadequate imaging protocol, an incorrect interpretation of imaging results, or the selection of an inappropriate imaging test by a referring clinician. Referring clinicians often struggle with selecting the appropriate imaging test, in part because of the large number of available imaging options and gaps in the teaching of radiology in medical schools. Although consensus-based guidelines (e.g., the various “appropriateness criteria” published by the American College of Radiology [ACR]) are available to help select imaging tests for many conditions, these guidelines are often not followed.

The use of clinical decision support systems at the point of care as well as direct consultations with radiologists have been proposed by the ACR as methods for improving imaging test selection (Allen and Thorwarth, 2014). There are several mechanisms for ensuring the quality of medical imaging. The Mammography Quality Standards Act (MQSA)—overseen by the Food and Drug Administration—was the first government-mandated accreditation program for any type of medical facility; it was focused on X-ray imaging for
breast cancer. MQSA provides a general framework for ensuring national quality standards in facilities that perform screening mammography (IOM, 2005). MQSA requires all personnel at facilities to meet initial qualifications, to demonstrate continued experience, and to complete continuing education. MQSA addresses protocol selection, image acquisition, interpretation and report generation, the communication of results, and recommendations. In addition, it provides facilities with data on diagnostic performance that can be used for benchmarking, self-monitoring, and improvement.

MQSA has decreased the variability in mammography performed across the United States and improved the quality of care (Allen and Thorwarth, 2014). However, the ACR noted that MQSA is complex and specified in great detail, which makes it inflexible, leading to administrative burdens and the need for extensive training of staff for implementation (Allen and Thorwarth, 2014). It also focuses on only one medical imaging modality in one disease area; thus it does not address some of the new screening technologies (IOM, 2005).

The Medicare Improvements for Patients and Providers Act (MIPPA) requires that private outpatient facilities that perform CT, MRI, breast MRI, nuclear medicine, and PET exams be accredited. The requirements include personnel qualifications, image quality, equipment performance, safety standards, and quality assurance and quality control (ACR, 2015a). There are four CMS-designated accreditation organizations for medical imaging: ACR, The Joint Commission, the Intersocietal Accreditation Commission, and RadSite (CMS, 2015a). MIPPA also mandated that, beginning in 2017, ordering clinicians will be required to consult appropriateness criteria to order advanced medical imaging procedures, and the act called for a demonstration project evaluating clinician compliance with appropriateness criteria (Timbie et al., 2014). In addition to these mandated activities, societies such as ACR and the Radiological Society of North America (RSNA) provide quality improvement programs and resources (ACR, 2015b; RSNA, 2015).

**Referral and Consultation**

Clinicians may refer to or consult with other clinicians (formally or informally) to seek additional expertise about a patient’s health problem. The consultation may help to confirm or reject the working diagnosis or may provide information on potential treatment options. If a patient’s health problem is outside a clinician’s area of expertise, he or she can refer the patient to a clinician who holds more suitable expertise. Clinicians can also recommend that the patient seek a second opinion from another clinician to verify their impressions of an uncertain diagnosis or if they believe that this would be helpful to the patient.

Many groups raise awareness that patients can obtain a second opinion on their own (AMA, 1996; CMS, 2015c; PAF, 2012). Diagnostic consultations can also be arranged through the use of integrated practice units (IPUs) or diagnostic management teams (DMTs).

IPUs are groups charged with providing care for a specific medical condition or a closely related set of conditions (Porter, 2010). DMTs serve as a model for more closely involving pathologists and radiologists in the diagnostic process. DMTs can provide consultations on diagnostic testing, such as selecting the appropriate test or image and understanding these results (Gover, 2013).

**Important Considerations In The Diagnostic Process**

The committee elaborated on several aspects of the diagnostic process:

- Diagnostic uncertainty
- Time
- Population trends
- Language, health literacy, and culture
- Mental health

**Diagnostic Uncertainty**

One of the complexities in the diagnostic process is the inherent uncertainty in diagnosis. As noted in the committee’s conceptual model of the diagnostic process, an overarching question throughout the process is whether sufficient information has been collected to make a diagnosis. This does not mean that a diagnosis needs to be absolutely certain in order to initiate treatment. Kassirer concluded that: “Absolute certainty in diagnosis is unattainable, no matter how much information we gather, how many observations we make, or how many tests we perform. A diagnosis is a hypothesis about the nature of a patient’s illness, one that is derived from observations by the use of inference. As the inferential process unfolds, our confidence as [clinicians] in a given diagnosis is enhanced by the gathering of data that either favor it or argue against competing hypotheses. Our task is not to attain certainty, but rather to reduce the level of diagnostic uncertainty enough to make optimal therapeutic decisions” (Kassirer, 1989, p. 1489).

Thus, the probability of disease does not have to be equal to one (diagnostic certainty) in order for treatment to be justified (Pauker and Kassirer, 1980). The decision to begin treatment based on a working diagnosis is informed by: (1) the degree of certainty about the diagnosis, (2) the harms and benefits of treatment; and (3) the harms and benefits of further information gathering activities, including the impact of delaying treatment. The risks associated with diagnostic testing are important considerations when conducting information gathering activities in the diagnostic process. While underuse of diagnostic testing has been a long-standing concern, overly aggressive diagnostic strategies have recently been recognized for their risks (Zhi et al., 2013).

Overuse of diagnostic testing has been partially attributed to clinicians’ fear of missing something important and intolerance of diagnostic uncertainty: “I am far more concerned about doing too little than doing too much. It’s the scan, the test, the operation that I should have done that sticks with me—sometimes for years…By contrast, I can’t remember anyone I sent for an unnecessary CT scan or operated on for questionable reasons a decade ago” (Gawande, 2015). However, there is growing recognition that overly aggressive diagnostic pursuits are putting patients at greater risk for harm, and they are not improving diagnostic certainty (Kassirer, 1989; Welch, 2015).

When considering diagnostic testing options, the harm from the procedure itself needs to be weighed against the potential information that could be gained. For some patients, the risk of invasive diagnostic testing may be inappropriate due to the risk of mortality or morbidity from the test itself (such as cardiac catheterization or invasive biopsies). In addition, the risk for harm needs to take into account the cascade of diagnostic testing and treatment decisions that could stem from a diagnostic test result. Included in these assessments are the potential for false positives and ambiguous or slightly abnormal test results that lead to further diagnostic testing or unnecessary treatment.

There are some cases in which treatment is initiated even though there is limited certainty in a working diagnosis. For example, an individual who has been exposed to a tick bite or HIV may be treated with prophylactic antibiotics or antivirals, because the risk of treatment may be felt to be smaller than the risk of harm from tick-borne diseases or HIV infection. Clinicians sometimes employ empiric treatment strategies—or the provision of treatment with a very uncertain diagnosis—and use a patient’s response to treatment as an information gathering activity to help arrive at a working diagnosis. However, it is important to note that response rates to treatment can be highly variable, and the failure to respond to treatment does not necessarily reflect that a diagnosis is incorrect. Nor does improvement in treatment over a decade ago” (Gawande, 2015). However, there is growing recognition that overly aggressive diagnostic pursuits are putting patients at greater risk for harm, and they are not improving diagnostic certainty (Kassirer, 1989; Welch, 2015).

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diagnostic procedure and the likelihood of disease is sufficiently high that significant therapy has been given empirically. Moroff and Pauker (1983) described a decision analysis in which a 90 year old practicing lawyer with a new 1.5 cm lung nodule was deemed to have a sufficiently high risk for mortality from lung biopsy and high likelihood of malignancy that the radiation oncologists felt comfortable treating the patient empirically for suspected lung cancer.

**Time**

Most diseases evolve over time, and there can be a delay between the onset of disease and the onset of a patient’s symptoms; time can also elapse before a patient’s symptoms are recognized as a specific diagnosis (Zwaan and Singh, 2015). Some diagnoses can be determined in a very short time-frame, while months may elapse before other diagnoses can be made. This is partially due to the growing recognition of the variability and complexity of disease presentation. Similar symptoms may be related to a number of different diagnoses, and symptoms may evolve in different ways as a disease progresses, e.g., a disease affecting multiple organs may initially involve symptoms or signs from a single organ. The thousands of different diseases and health conditions do not present in thousands of unique ways; there are only a finite number of symptoms with which a patient may present. At the outset, it can be very difficult to determine which particular diagnosis is indicated by a particular combination of symptoms, especially if symptoms are nonspecific, such as fatigue.

Diseases may also present atypically, with an unusual and unexpected constellation of symptoms (Emmett, 1998). Adding to the complexity of the time-dependent nature of diagnosis are the numerous settings of care in which diagnosis occurs and the potential involvement of multiple settings of care within a single diagnostic process. Henriksen and Brady noted that this process—for patients, their families, and clinicians alike—can often feel like “a disjointed journey across confusing terrain, aided or impeded by different agents, with no destination in sight and few landmarks along the way” (Henriksen and Brady, 2013, p. ii2).

Some diagnoses may be more important to establish immediately than others. These include diagnoses that can lead to significant patient harm, if not recognized, diagnosed, and treated early, such as anthrax, aortic dissection, and pulmonary embolism. Sometimes making a timely diagnosis relies on the fast recognition of symptoms outside of the health care setting (for example, public awareness of stroke symptoms can help improve the speed of receiving medical help and increase the chances of a better recovery) (National Stroke Association, 2015). In these cases, the benefit of treating the disease promptly greatly exceeds the potential harm from unnecessary treatment. Consequently, the threshold for ordering diagnostic testing or for initiating treatment becomes quite low for such disorders (Pauker and Kassirer, 1975, 1980). In other cases, the potential harm from rapidly and unnecessarily treating a diagnosed condition can lead to a more conservative (or higher-threshold) approach in the diagnostic process.

**Population Trends**

Population trends, such as the aging of the population, are adding significant complexity to the diagnostic process and require clinicians to consider complicating factors in diagnosis, such as comorbidity, polypharmacy and attendant medication side effects, as well as disease and medication interactions (IOM, 2008, 2013b). Diagnosis can be especially challenging in older patients because classic presentations of disease are less common in older adults (Jarrett et al., 1995). For example, infections such as pneumonia or urinary tract infections often do not present in older patients with fever, cough, and pain but rather with symptoms such as lethargy, incontinence, loss of appetite, or disruption of cognitive function (Mouton et al., 2001). Acute myocardial infarction (MI) may present with fatigue and confusion rather than with typical symptoms such as chest pain or radiating arm pain (Bayer et al., 1986; Qureshi et al., 2000; Rich, 2006). Sensory limitations in older adults, such as hearing and vision impairments, can also contribute to challenges in making diagnoses (Campbell et al., 1999).

Physical illnesses often present with a change in cognitive status in older individuals without dementia (Mouton et al., 2001). In older adults with mild to moderate dementia, such illnesses can manifest with worsening cognition. Older patients who have multiple comorbidities, medications, or cognitive and functional impairments are more likely to have atypical disease presentations, which may increase the risk of experiencing diagnostic errors (Gray-Miceli, 2008).

**Language, Health Literacy, and Culture**

Communicating with diverse populations can also contribute to the complexity of the diagnostic process. Language, health literacy, and cultural barriers can all affect clinician–patient encounters and increase the potential for challenges in the diagnostic process (Flores, 2006; IOM, 2003; The Joint Commission, 2007). There are indications that biases influence diagnosis; one well-known example is the differential referral of patients for cardiac catheterization by race and gender (Schulman et al., 1999). In addition, women are more likely than men to experience a missed diagnosis of heart attack, a situation that has been partly attributed to real and perceived gender biases, but which may also be the result of physiologic differences, as women have a higher likelihood of presenting with atypical symptoms, including abdominal pain, shortness of breath, and congestive heart failure (Pope et al., 2000).

**Mental Health**

Mental health diagnoses can be particularly challenging. Mental health diagnoses rely on the Diagnostic and Statistical Manual of Mental Disorders (DSM); each diagnosis in the DSM includes a set of diagnostic criteria that indicate the type and duration of symptoms that need to be present, as well as the symptoms, disorders, and conditions that cannot be present, in order to be considered for a particular diagnosis (APA, 2015). Compared to physical diagnoses, many mental health diagnoses rely on patient reports and observation; few biological tests are used in such diagnoses (Pincus, 2014). A key challenge can be distinguishing physical diagnoses from mental health diagnoses; sometimes physical conditions manifest as psychiatric ones, and vice versa (Croskerry, 2003a; Hope et al., 2014; Pincus, 2014; Reeves et al., 2010).

In addition, there are concerns about missing psychiatric diagnoses, as well as overtreatment concerns (Bor, 2015; Meyer and Meyer, 2009; Pincus, 2014). For example, clinician biases toward older adults can contribute to missed diagnoses of depression, because it may be perceived that older adults are likely to be depressed, lethargic, or have little interest in interactions. Patients with mental health-related symptoms may also be more vulnerable to diagnostic errors, a situation that is attributed partly to clinician biases; for example, clinicians may disregard symptoms in patients with previous diagnoses of mental illness or substance abuse and attribute new physical symptoms to a psychological cause (Croskerry, 2003a). Individuals with health problems that are difficult to diagnose or those who have chronic pain may also be more likely to receive psychiatric diagnoses erroneously.

**Clinical Reasoning and Diagnosis**

Timely, accurate, and patient-centered diagnosis relies on proficiency in clinical reasoning, which is often regarded as the clinician’s quintessential competency. Clinical reasoning is the “the cognitive process that is necessary to evaluate and manage a patient’s medical problems” (Barrows, 1980, p. 19). Understanding the clinical reasoning process and the factors that can impact it are important to improving diagnosis, given that clinical reasoning processes contribute to diagnostic errors (Croskerry, 2003a; Graber, 2005). Health care professionals involved in the diagnostic process have an obligation and ethical responsibility to employ clinical reasoning skills:
Clinical reasoning occurs within clinicians' minds (facilitated or impeded by the work system) and involves judgment under uncertainty, with a consideration of possible diagnoses that might explain symptoms and signs, the harms and benefits of diagnostic testing and treatment for each of those diagnoses, and patient preferences and values. The current understanding of clinical reasoning is based on the dual process theory, a widely accepted paradigm of decision making. The dual process theory integrates analytical and non-analytical models of decision making. Analytical models (slow system 2) involve a conscious, deliberate process guided by critical thinking (Kahneman, 2011). Nonanalytical models (fast system 1) involve unconscious, intuitive, and automatic pattern recognition (Kahneman, 2011).

Fast system 1 (non-analytical, intuitive) automatic processes require very little working memory capacity. They are often triggered by stimuli or result from overlearned associations or implicitly learned activities. Examples of such system 1 processes include the ability to recognize human faces (Canwisher and Yovel, 2006), the diagnosis of Lyme disease from a bull's-eye rash, or decisions based on heuristics (mental shortcuts), intuition, or repeated experiences. In contrast, slow system 2 (reflective, analytical) processing places a heavy load on working memory and involves hypothetical and counterfactual reasoning (Evans and Stanovich, 2013; Stanovich and Toplak, 2012).

System 2 processing requires individuals to generate mental models of what should or should not happen in particular situations, in order to test possible actions or to explore alternative causes of events (Stanovich, 2009). Hypothetical thinking occurs when one reasons about what should occur or be observable if some condition held—e.g., if this patient has diabetes, then the blood sugar level should exceed 126 mg/dl after an 8-hour fast, or if prescribed a diabetes medication, the sugar level should improve. Counterfactual reasoning occurs when one reasons about what should occur or be evident if the situation differed from how it actually is. The deliberate, conscious, and reflective nature of both hypothetical and counterfactual reasoning illustrates the analytical nature of system 2.

Heuristics—cognitive strategies or mental shortcuts that are automatically and unconsciously employed—are particularly important for decision making (Gigerenzer and Goldstein, 1996). Heuristics can facilitate decision making but can also lead to errors (Cosmides and Tooby, 1996; Gigerenzer, 2000; Kahneman, 2011; Klein, 1998; Lipshitz et al., 2001; McDonald, 1996). When a heuristic fails, it is referred to as a cognitive bias. Cognitive biases, or predispositions to think in a way that leads to failures in judgment, can also be caused by affect and motivation (Kahneman, 2011). Prolonged learning in a regular and predictable environment increases the effectiveness of heuristics, whereas uncertain and unpredictable environments are a chief cause of heuristic failure (Kahneman, 2011; Kahneman and Klein, 2009).

There are many heuristics and biases that affect clinical reasoning and decision making. Additional examples of heuristics and biases that affect decision making and the potential for diagnostic errors are described below (Croskerry, 2003b):

1. The representativeness heuristic answers the question, “how likely is it that this patient has a particular disease?” by assessing how typical the patient’s symptoms are for that disease. If the symptoms are highly typical (e.g., fever and nausea after contact with an individual from West Africa with Ebola virus), then it is likely the patient will be diagnosed as having that condition (e.g., Ebola virus infection). The representativeness bias refers to the tendency to make decisions based on a typical case, even when this may lead to an incorrect judgment. The representativeness bias helps to explain why an incorrect diagnosis (e.g., a patient diagnosed as not having Ebola virus infection) is made when presenting symptoms are atypical (e.g., no fever or nausea after contact with a person from West Africa).

2. Base-rate neglect describes the tendency to ignore the prevalence of a disease in determining a diagnosis. For example, a clinician may think the diagnosis is acid reflux because it is a prevalent condition, even though it is actually an MI, which can present with similar symptoms (e.g., chest pain), but is less likely.

3. The overconfidence bias reflects the universal tendency to believe that we know more than we do. This bias encourages individuals to diagnose a disease based on incomplete information; too much faith is placed in one’s opinion, rather than on carefully gathering evidence. This bias is especially likely to develop if clinicians do not have feedback on their diagnostic performance.

4. Psych-out errors describe the increased susceptibility of people with mental illnesses to clinician biases and heuristics, due to their mental health conditions. Patients with mental health issues may have new physical symptoms that are not considered seriously because their clinicians attribute them to their mental health issues. Patients with physical symptoms that mimic mental illnesses (hypoxia, delirium, metabolic abnormalities, central nervous infections, and head injuries) may also be susceptible to these errors and experience diagnostic errors.

Although the use of heuristics often leads to the correct diagnosis, it can fail, especially when patients present with atypical symptoms. In addition to cognitive biases, research suggests that fallacies in reasoning, ethical violations, and financial and non-financial conflicts of interest can influence medical decision making (Seshia et al., 2014a, 2014b). These factors, collectively referred to as “cognitive biases plus,” have been identified as potentially undermining the evidence that informs clinical decision making (Seshia et al., 2014a, 2014b).

The interaction between fast system 1 and slow system 2 remains controversial. Some hold that these processes are constantly occurring in parallel and that any conflicts are resolved as they arise. Others have argued that system 1 processes generate an individual’s default response and that system 2 processes may or may not intervene and override system 1 processing (Evans and Stanovich, 2013; Kahneman, 2011). When system 2 overrides system 1, this can lead to improved decision making, because engaging in analytical reasoning may correct for inaccuracies. It is important to note that slow system 2 processing does not guarantee correct decision making. For instance, clinicians with an inadequate knowledge base may not have the information necessary to make a correct decision. There are some instances when system 1 processing is correct, and the override from system 2 can contribute to incorrect decision making.

However, when system 1 overrides system 2 processing, this can also result in irrational decision making. Intervention by system 2 is likely to occur in novel situations when the task at hand is difficult, when an individual has minimal knowledge or experience (Evans and Stanovich, 2013; Kahneman, 2011), or when an individual deliberately employs strategies to overcome known biases (Croskerry et al., 2013). Monitoring and intervention by system 2 on system 1 is unlikely to catch every failure because it is inefficient and would require sustained vigilance, given that system 1 processing often leads to correct solutions (Kahneman, 2011). Factors that affect working memory can impede the ability of system 2 to monitor and, when necessary, intervene on system 1 processes. For example, if clinicians are tired or distracted by elements in the work system, they may fail to recognize when a decision provided by system 1 processing needs to be reconsidered (Croskerry, 2009b).
Bayesian reasoning is most often considered in the decision making process. Feedback mechanisms—both in the educational settings and in learning health care systems—allow clinicians to compare their patients’ ultimate diagnoses with the diagnoses that they provided to those patients. Through calibration, clinicians can assess their diagnostic accuracy and improve their future performance. Work system factors influence diagnostic reasoning, including diagnostic team members and tasks, technologies and tools, organizational characteristics, the physical environment, and the external environment.

Figure 4. Calibration in the diagnostic process

Favorable or unfavorable outcomes provide good feedback and improve clinician calibration. When outcomes are unknown, they will be treated as favorable and lead to poor calibration.

Probabilistic (Bayesian) Reasoning

As described above, the diagnostic process involves initial information gathering that leads to a working diagnosis or differential diagnosis. The process of ruling in or ruling out a diagnosis involves probabilistic reasoning as findings are integrated and interpreted. Probabilistic, or Bayesian, reasoning provides a formal method to avoid some cognitive biases, such as base rate neglect or anchoring, when integrating and interpreting information. For instance, when patients present with typical symptoms but the disease is rare (e.g., the classic triad of headache, sweating, and rapid heart rate for pheochromocytoma), base rate neglect and the representativeness bias may lead clinicians to overestimate the likelihood of pheochromocytoma among patients presenting with high blood pressure. Using Bayesian reasoning and formally revising probabilities of the various diseases under consideration helps clinicians avoid these errors. Clinicians can then decide whether to pursue additional information gathering or treatment based on an accurate estimate of the likelihood of disease, the harms and benefits of treatment, and patient preferences (Kassirer et al., 2010; Pauker and Kassirer, 1980).

Bayesian reasoning is most often considered in the context of diagnostic testing, but the presence or absence of specific symptoms and signs can also help to rule in or rule out diseases. The likelihood of a positive finding (the presence of symptoms or signs or a positive test) when disease is present is referred to as sensitivity. The likelihood of a negative finding (the absence of symptoms, signs, or a negative test) when a disease is absent is referred to as specificity. If a symptom, sign, or test is always positive in the presence of a particular disease (100 percent sensitivity), then the absence of that symptom, sign, or test rules out disease (e.g., absence of pain or stiffness means the patient does not have polymyalgia rheumatica). If a symptom, sign, or test is always negative in the absence of a particular disease (100 percent specificity), then the presence of that symptom, sign, or test rules in disease (e.g., all patients with Kayser–Fleischer rings have Wilson’s disease; all patients with Koplik’s spots have measles).

However, nearly all signs, symptoms, or test results are neither 100 percent sensitive nor specific. For example, studies suggest exceptions for findings such as Kayser–Fleischer rings with other causes of liver disease (Frommer et al., 1977; Lipman and Deutsch, 1990) or Koplik’s spots with parvovirus B19 or echovirus (Suringa et al., 1970) and even for Reed-Sternberg cells for Hodgkin’s lymphoma (Azar, 1975).

Bayes’ theorem provides a framework for clinicians to revise the probability of disease, given disease prevalence, as well as the presence or absence of clinical findings or positive or negative test results (Grimes and Schulz, 2005; Griner et al., 1981; Kassirer et al., 2010; Pauker and Kassirer, 1980). Bayesian calculators are available to facilitate these probability revision analyses (Simel and Rennie, 2008). While most clinicians will not formally calculate probabilities, the logical principles behind Bayesian reasoning can help clinicians consider the trade-offs involved in further information gathering, decisions about treatment, or evaluating clinically ambiguous cases (Kassirer et al., 2010). The committee’s recommendation on improving diagnostic competencies includes a focus on diagnostic test ordering and subsequent decision making, which relies on the principles of probabilistic reasoning.

OVERVIEW OF DIAGNOSTIC ERROR IN HEALTH CARE

Definition of Diagnostic Error

The Institute of Medicine (IOM) has defined quality of care as “the degree to which
health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge” (IOM, 1990, p. 5). The IOM’s report Crossing the Quality Chasm elaborated on high-quality care by identifying six aims of quality: “[H] ealth care should be (1) safe—avoiding injuries to patients from the care that is intended to help them; (2) effective—providing services based on scientific knowledge to all who could benefit and refraining from providing services to those not likely to benefit; (3) patient-centered—providing care that is respectful of and responsive to individual preferences, needs, and values, and ensuring that patient values guide all clinical decisions; (4) timely—reducing waits and sometimes harmful delays for both those who receive and those who give care; (5) efficient—avoiding waste, including waste of equipment, supplies, ideas, and human resources; and (6) equitable—providing care that does not vary in quality because of personal characteristics, such as gender, ethnicity, geography, and socioeconomic status” (IOM, 2001, p. 6).

Communicating accurate and timely diagnoses to patients is an important component of providing high-quality care; conversely, errors in diagnosis are a major threat to achieving high-quality care. The IOM defines an error in medicine to be the “failure of a planned action to be completed as intended (i.e., error of execution) and the use of a wrong plan to achieve an aim (i.e., error of planning) [commission]” (IOM, 2004, p. 30). The definition also recognizes the failure of an unplanned action that should have been completed (omission) as an error (IOM, 2004). The IOM report To Err Is Human: Building A Safer Health System distinguished among four types of error: diagnostic, treatment, preventive, and other. An adverse event is “an event that results in unintended harm to the patient by an act of commission or omission rather than by the underlying disease or condition of the patient” (IOM, 2004, p. 32).

The committee’s deliberations were informed by a number of existing definitions and definitional frameworks on diagnostic error. For instance, Graber and colleagues used a classification of error from the Australian Patient Safety Foundation to define diagnostic error as a “diagnosis that was unintentionally delayed (sufficient information was available earlier), wrong (another diagnosis was made before the correct one), or missed (no diagnosis was ever made), as judged from the eventual appreciation of more definitive information” (Graber et al., 2005, p. 1493). They further divided diagnostic error into three main categories: no-fault errors, system-related errors, and cognitive errors. No-fault errors, which were originally described by Kassirer and Kopelman (1989), stem from factors outside the control of the clinician or the health care system, including atypical disease presentation or patient-related factors such as providing misleading information. The second category, system-related errors, can include technical or organizational barriers, such as problems with communication and care coordination; inefficient processes; technical failures; and equipment problems. Finally, there are cognitive errors that clinicians may make. The causes of these can include inadequate knowledge, poor critical thinking skills, a lack of competency, problems in data gathering, and failing to synthesize information (Chimowitz et al., 1990).

Each of these errors can occur in isolation, but they often interact with one another; for instance, system factors can lead to cognitive errors. Schiff and colleagues (2009, p. 1882) defined diagnostic error as “any mistake or failure in the diagnostic process leading to a misdiagnosis, a missed diagnosis, or a delayed diagnosis.” Schiff and colleagues (2005) divide the diagnostic process into seven stages: (1) access and presentation, (2) history taking/collection, (3) the physical exam, (4) testing, (5) assessment, (6) referral, and (7) follow-up. A diagnostic error can occur at any stage in the diagnostic process, and there is a spectrum of patient consequences related to these errors ranging from no harm to severe harm. Schiff and colleagues noted that not all diagnostic process errors will lead to a missed, delayed, or wrong diagnosis, and not all errors (either in the diagnostic process or related to misdiagnosis) will result in patient harm. Relating this model to Donabedian’s structure-process-outcome framework, Schiff and colleagues consider diagnosis to be an intermediate outcome of the diagnostic process, and any resulting adverse patient harm would be considered true patient outcomes (Schiff et al., 2009; Schiff et al., 2005; Schiff and Leape, 2012).

In describing diagnostic error, Singh focused on defining missed opportunities, where a missed opportunity “implies that something different could have been done to make the correct diagnosis earlier… Evidence of omission (failure to do the right thing) or commission (doing something wrong) exists at the particular point in time at which the ‘error’ occurred” (Singh, 2014, p. 99). Singh’s definition of a missed opportunity takes into account the evolving nature of a diagnosis, making the determination of a missed opportunity dependent on the temporal or sequential context of events. It also assumes that missed opportunities could be caused by individual clinicians, the care team, the system, or patients. Singh focused on preventable diagnostic harm, or when a missed opportunity results in harm from delayed or wrong treatment or test, as being the best opportunity to intervene.

Newman-Toker (2014a, b) developed a conceptual model of diagnostic error that attempted to harmonize the current definitional frameworks. His framing distinguished between diagnostic process failures and diagnostic labeling failures. Diagnostic process failures include problems in the diagnostic workup, and may include both cognitive and system errors. Diagnosis label failures occur when the diagnosis that a patient receives is incorrect or when there is no attempt to provide a diagnosis label. Newman-Toker identified preventable diagnostic error as the overlap between a diagnostic process failure and a diagnostic label failure, and noted that this is similar to Singh’s conceptualization of a missed opportunity (Singh, 2014). A preventable diagnostic error differs from a near-miss process problem, which is a failure in the diagnostic process without a diagnostic labeling failure. Newman-Toker also identifies unavoidable misdiagnosis, which is a diagnostic labeling failure that may occur in the absence of a diagnostic process failure and corresponds to the no-fault category described earlier. Furthermore, his model illustrates that harm may—or may not—result from diagnostic process failures and diagnostic labeling failures.

In reviewing the diagnostic error literature, the committee concluded that there are varying definitions and terminology currently in use to describe diagnostic error. For example, there is disagreement about exactly what constitutes a diagnostic error as well as about the precise meanings of a delayed diagnosis, a missed diagnosis, and a misdiagnosis (Newman-Toker, 2014b). Some treat the terms “diagnostic error” and “misdiagnosis” as synonyms (Newman-Toker and Pronovost, 2009; Newman-Toker, 2014b). There are some who prefer the term “diagnosis error” rather than “diagnostic error” because they conclude that diagnostic error should refer to the process of arriving at a diagnosis, whereas diagnosis error should refer to the final multifactorial outcome, of which the diagnostic process is only one factor (Berenson et al., 2014). Some use the term “missed diagnosis” solely for situations in which the diagnosis was found upon autopsy (Graber et al., 2005; Newman-Toker, 2014b). While some definitions of diagnostic error include unavoidable errors, others conceptualize diagnostic error as something that stems from a failure in the diagnostic process (Graber et al., 2005; Newman-Toker, 2014b; Schiff et al., 2009). In part, the various definitions that have arisen reflect the intrinsic dualistic nature of the term “diagnosis,” which has been used to refer both to a process and to the result of that process. Definitions of diagnostic error can also vary by stakeholder; for example, a patient’s definition of a diagnostic error may be different from a clinician or research-oriented definition of diagnostic error. Other terms used in the diagnostic error literature include diagnostic accuracy (Wachter, 2014),
misdiagnosis-related harm (Newman-Toker and Pronovost, 2009), and preventable diagnostic errors (Newman-Toker, 2014b).

Because of this lack of agreement, the committee decided to formulate a new definition of diagnostic error. The committee’s patient-centered definition of diagnostic error is:

**The failure to (a) establish an accurate and timely explanation of the patient’s health problem(s) or (b) communicate that explanation to the patient.**

The definition frames a diagnostic error from the patient’s perspective, in recognition that a patient bears the ultimate risk of harm from a diagnostic error. The committee’s definition is two-pronged—if there is a failure in either part of the definition, a diagnostic error results. It also conveys that each arm of the definition may be evaluated separately for measurement purposes.

The first part of the committee’s definition focuses on two major characteristics of diagnosis: timeliness and accuracy. Timeliness means that the diagnosis was not meaningfully delayed. However, the committee did not specify a time period that would reflect “timely” because this is likely to depend on the nature of a patient’s condition as well as on a realistic expectation of the length of time needed to make a diagnosis. Thus, the term “timely” will need to be operationalized for different health problems. Depending on the circumstances, some diagnoses may take days, weeks, or even months to establish, while timely may mean quite quickly (minutes to hours) for other urgent diagnoses. The other characteristic the committee highlighted was accuracy. A diagnosis is not accurate if it differs from the true condition a patient has (or does not have) or if it is imprecise and incomplete (lacking in sufficient detail). It is important to note that a working diagnosis, described in Chapter 2, may lack precision or completeness, but is not necessarily a diagnostic error. The nature of the diagnostic process is iterative, and as information gathering continues, the goal is to reduce diagnostic uncertainty, narrow down the diagnostic possibilities, and develop a more precise and complete diagnosis.

The second part of the committee’s definition focuses on communication. A fundamental conclusion from the committee’s deliberations was that communication is a key responsibility in the diagnostic process. From a patient’s perspective, an accurate and timely explanation of the health problem is meaningless unless this information reaches the patient so that a patient and health care professionals can act on the explanation. The phrase “explanation of the patient’s health problem” was chosen because it was meant to describe the health problem (or problems) involved as well as the manner in which the information is conveyed to a patient. The explanation needs to align with a patient’s level of health literacy and to be conveyed in a way that facilitates patient understanding. Because not all patients will be able to participate in the communication process, there will be some situations where the explanation of the health problem may not be feasible to convey or be fully appreciated by the patient (for example, pediatric patients or patients whose health problems limit or prevent communication). In these circumstances, the communication of the health problem would be between the health care professionals and a patient’s family or designated health care proxy.

There may also be urgent, life-threatening situations in which a patient’s health problem will need to be communicated following treatment. However, even in these urgent situations, patients and their families need to be informed about new developments, so that decision making reflects a patient’s values, preferences, and needs. Timely communication is also context-dependent: with some health problems, providing an explanation to a patient can take weeks or months to establish. However, throughout this time clinicians can communicate the working diagnosis, or the current explanation of the patient’s health problem, as well as the degree of certainty associated with this explanation.

The phrase “failure to establish” is included in the definition because it recognizes that determining a diagnosis is a process that involves both the passage of time and the collaboration of health care professionals, patients, and their families to reach an explanation. The committee chose the term “health problem” because it is more inclusive than the term “diagnosis” and often reflects a more patient-centered approach to understanding a patient’s overall health condition. For example, a health problem could include a predisposition to developing a condition, such as a genetic risk for disease. In addition, there are circumstances when it is important to focus on resolving the symptoms that are interfering with a patient’s basic functioning, described as “activities of daily living,” rather than focusing exclusively on identifying and following up on all of a patient’s potential diagnoses (Gawande, 2007). Individual patient preferences for possible health outcomes can vary substantially, and with the growing prevalence of chronic disease, patients often have comorbidities or competing causes of mortality that need to be taken into consideration when defining a patient’s health problem and subsequent plan for care (Gawande, 2014; Liss et al., 2013; Mulley et al., 2012).

There could be situations in which clinicians and health care organizations, practicing conscientiously (e.g., following clinical practice guidelines or established standards of care), may be unable to establish a definitive diagnosis. Sometimes a health care professional will need to acknowledge an inability to establish a diagnosis and will need to refer the patient to other specialists for further assessment to continue the diagnostic process. However, in some cases, this iterative process may still not lead to a firm diagnosis. For example, individuals may have signs and symptoms that have not been recognized universally by the medical community as a specific disease. From the patient’s perspective, this could be a diagnostic error, but medicine is not an exact science, and documenting and examining such instances could provide an opportunity to advance medical knowledge and ultimately improve the diagnostic process.

The committee’s definition reflects the six aims of high-quality care identified by the IOM (2001). It specifically refers to effectiveness and efficiency (i.e., accuracy), timeliness, and patient-centeredness as important aspects of diagnosis, while assuming safety and equity throughout the diagnostic process. Patients and their families play a key role in the diagnostic process, but a patient’s care team is ultimately responsible for facilitating the diagnostic process and the communication of a diagnosis.

The committee’s definition of diagnostic error differs from previous definitions in that it focuses on the outcome from the diagnostic process (the explanation of the patient’s health problem provided to the patient). Other definitions of diagnostic error focus on determining whether or not process-related factors resulted in the diagnostic error. For example, Singh’s definition focuses on whether there was a missed opportunity to make a diagnosis earlier (Singh, 2014). Likewise, Schiff and colleagues’ (2009) definition of diagnostic error requires a determination that there was a mistake or failure in the diagnostic process. The committee’s focus on the outcome from the diagnostic process is important, because it reflects what matters most to patients—the communication of an accurate, timely explanation of their health problem.

However, identifying failures in the diagnostic process is also critically important, which is reflected in the committee’s dual focus on improving the diagnostic process and reducing diagnostic errors. The committee’s discussion of measurement includes an emphasis on understanding where failures in the diagnostic process can occur and the work system factors that contribute to these failures.

Analyzing failures in the diagnostic process provides important information for learning how to improve the work system and the diagnostic process. Some failures in the diagnostic process will lead to diagnostic errors; however, other failures in the diagnostic process will not ultimately lead to a diagnostic error. In this report, the committee describes “failures in the diagnostic process that do not lead to diagnostic errors” as near misses.
In other words, a near miss is a diagnosis that was almost erroneous. For example, it would be considered a near miss if a radiologist reported no significant findings from a chest x-ray, but a primary care clinician reviewing the image identified something that required further follow up (Newman-Toker, 2014b). While there may have been a failure in the diagnostic process, the patient nonetheless received an accurate and timely explanation of the health problem. Examining near misses can help identify vulnerabilities in the diagnostic process as well as strengths in the diagnostic process that compensate for these vulnerabilities.

Likewise, several of the committee’s recommendations focus on identifying both diagnostic errors and near misses, because they both serve as learning opportunities to improve diagnosis. The diagnostic process can lead to a number of outcomes. An accurate, timely diagnosis that is communicated to a patient presents the best opportunity for a positive health outcome, because clinical decision making will be tailored to a correct understanding of the patient’s health problem. Diagnostic errors and near misses can stem from a wide variety of causes and result in multiple outcomes, and as evidence accrues, a more nuanced picture of diagnostic errors and near misses will develop. For example, further research can be directed at better understanding the causes of diagnostic errors and vulnerabilities in the diagnostic process. Some of the reasons diagnostic errors and near misses occur may be more remediable to interventions than others. In addition, determining which types of diagnostic errors are priorities to address, as well as which interventions could be targeted at preventing/mitigating specific types of diagnostic errors, will be informative in improving the quality of care.

A better understanding of the outcomes resulting from diagnostic errors and near misses will also be helpful. For example, if there is a diagnostic error, a patient may or may not experience harm. The potential harm from diagnostic errors could range from no harm to significant harm, including morbidity or death. Errors can be harmful because they can prevent or delay appropriate treatment, lead to unnecessary or harmful treatment, or result in psychological or financial repercussions. Harm may not result, for example, if a patient’s symptoms resolve even with an incorrect diagnosis. Diagnostic errors and near misses may also lead to inefficiency in health care organizations (e.g., the provision of unnecessary treatments) and increase system costs unnecessarily (covering the costs of otherwise unnecessary care or medical liability expenses). Diagnostic errors and near misses influence both the morale of individuals participating in the diagnostic process and public trust in the health care system. Correct diagnoses, diagnostic errors, and near misses can be used as opportunities to learn how to improve the work system and the diagnostic process (Klein, 2011, 2014).

**Overuse In The Diagnostic Process and Over-Diagnosis**

There is growing recognition that over-diagnosis is a serious problem in health care today, contributing to increased health care costs, over-treatment, and the associated risks and harms from this treatment (Welch and Black, 2010; Welch, 2015). Over-diagnosis has been described as “when a condition is diagnosed that would otherwise not go on to cause symptoms or death” (Welch and Black, 2010, p. 605). Chiolero and colleagues note that advances in prevention and diagnosis “have changed the diagnostic process, expanding the possibilities of interventions across asymptomatic individuals and blurring the boundaries between health, risk, and disease” (Chiolero et al., 2015, p. w14060). Over-diagnosis has been attributed to the increased sensitivity of diagnostic testing (e.g., improved radiographic resolution), the identification of incidental findings, the widening boundaries or lowered thresholds for defining what is abnormal (e.g., hypertension, diabetes, or cholesterol levels), clinicians’ concerns about missing diagnoses and subsequent medical liability risks (Chiolero et al., 2015; Gawande, 2015; Moynihan et al., 2012).

Recent discussions in the diagnostic error community have drawn attention to the issue of over-diagnosis and whether over-diagnosis should be defined and classified as an error (Berenson et al., 2014; Newman-Toker, 2014b; Zwaan and Singh, 2015). Although over-diagnosis is a complex and controversial topic, it is distinct from diagnostic error. For example, Chiolero and colleagues (2015, p. w14060) state: “Over-diagnosis is … neither a misdiagnosis (diagnostic error), nor a false positive result (positive test in the absence of a real abnormality).” Similarly, Gawande makes the distinction between over-diagnosis and diagnostic error: “Over-testing has also created a new, unanticipated problem: over-diagnosis. This isn’t misdiagnosis—the erroneous diagnosis of a disease. This is the correct diagnosis of a disease that is never going to bother you in your lifetime” (Gawande, 2015). Challenges in terminology and the blurry distinctions between diagnosis and treatment add to the confusion between over-diagnosis and diagnostic error. Recent reports in the literature have used the term “over-diagnosis” broadly to incorporate the concept of over-medicalization, including over-detection, over-diagnosis, over-treatment, and over-utilization (Carter et al., 2015).

For example, widening the criteria used to define a disease may raise important concerns about over-medicalization, but if a diagnosis is consistent with consensus guidelines for medical practice, it would not constitute a diagnostic error as defined by the IOM committee.

A major reason over-diagnosis is not characterized as an error is because it is found primarily with population-based estimates—it is virtually impossible to assess whether over-diagnosis has occurred for an individual patient (Welch and Black, 2010). Our understanding of biology and disease progression is often not advanced enough to determine which individuals are going to be harmed by their health condition, versus the health conditions that are never going to lead to patient harm (e.g., thyroid, breast, and prostate cancers). Thus, clinicians are treating patients based on uncertain prognoses, and many more people are treated compared to those who actually benefit from treatment. Likewise, screening guidelines are intended to identify populations that will most likely benefit from screening, but not all individuals who undergo screening will benefit. For example, screening mammography—like many interventions—is an imperfect test with associated harms and benefits; some breast cancers will be missed, some women will die from breast cancer regardless of being screened, and some cancers that are identified will never lead to harm (Pace and Keating, 2014). Because current diagnostic testing technologies often cannot distinguish the cancers that are likely to progress and lead to patient harm from those that will not, inevitably clinicians treat some patients with breast cancer who will not benefit from the treatment (Esserman et al., 2009).

It would be incorrect (and largely impossible) to classify these cases as errors because clinicians are basing screening and treatment decisions on the best available medical knowledge, and the assessment of over-diagnosis is dependent on population-based analysis. For example, once diagnosed and treated for cancer, it is impossible to know whether the patient’s outcome would have been different if the tumor (which may have been indolent rather than life-threatening) had never been diagnosed. However, over-diagnosis represents a true challenge to health care quality, and further efforts are warranted to prevent over-diagnosis and associated over-treatment concerns. Reducing over-diagnosis will likely require improved understanding of disease biology and progression, as well as increased awareness of its occurrence among health care professionals, patients, and their families (Chiolero, 2015). In addition, an important strategy that has been suggested for preventing over-diagnosis and associated over-treatment is avoiding unnecessary and untargeted diagnostic testing (Chiolero, 2015).

Based on the committee’s definition of diagnostic error, which focuses on the outcomes for patients, over-utilization of diagnostic testing is not necessarily a diagnostic error. Based on the committee’s conceptual model, over-utilization of diagnostic testing would be considered a failure in the diagnostic process (failure in information...
gathering). Over-utilization is a serious concern, and efforts to improve diagnosis need to focus on preventing inappropriate over-utilization of diagnostic testing (Newman-Toker et al., 2014a).

Improving diagnosis should not imply the adoption of overly aggressive diagnostic strategies. The goal of diagnostic testing is not to reduce diagnostic uncertainty to zero (an impossible task), but rather to optimize decision making by judicious use of diagnostic testing (Newman-Toker et al., 2013; Kassirer, 1989). This is also why the committee highlighted iterative information gathering and the role of time in the diagnostic process; oftentimes it is not appropriate to test for everything at the outset—further information gathering activities can be informed by test results, time, and a patient’s response to treatment.

The committee makes a number of recommendations that are targeted at preventing over-utilization in the diagnostic process throughout the report, including improved collaboration and communication among treating clinicians and pathologists, radiologists, and other diagnostic testing health care professionals, as well as increased emphasis on diagnostic testing in health care professional education.

### Measurement and Assessment of Diagnostic Error

For a variety of reasons, diagnostic errors have been more challenging to measure than other quality or safety concepts. Singh and Sittig (2015, p. 103) note that “compared with other safety concerns, there are also fewer sources of valid and reliable data that could enable measurement” of diagnostic errors. Studies that have evaluated diagnostic errors have employed different definitions, and the use of varying definitions can lead to challenges in drawing comparisons across studies or synthesizing the available information on measurement (Berenson et al., 2014; Schiff and Leape, 2012; Singh, 2014). Even when there is agreement on the definition of diagnostic error, there can be genuine disagreement over whether a diagnostic error actually occurred, and there are often blurry boundaries between different types of errors (treatment or diagnostic) (Singh et al., 2012a; Singh and Sittig, 2015).

The complexity of the diagnostic process itself, as well as the inherent uncertainty underlying clinical decision making, makes measurement challenging (Singh, 2014; Singh and Sittig, 2015). The committee’s conceptual model illustrates the complex, time-dependent, and team-based nature of the diagnostic process as well as all of the potential work system factors that can contribute to the occurrence of diagnostic error. The temporal component of the diagnostic process can complicate measurement since the signs and symptoms of a health condition may evolve over time, and there can be disagreement about what an acceptable time-frame is in which to make a timely diagnosis (Singh, 2014; Zwaan and Singh, 2015). Clinical reasoning plays a role in diagnostic errors, but clinical reasoning processes are difficult to assess because they occur in clinicians’ minds and are not typically documented (Croskerry, 2012; Wachter, 2010). Similarly, some measurement approaches, such as medical record reviews, may not identify diagnostic errors because information related to diagnosis may not be documented (Singh et al., 2012a). Furthermore, many people recover from their health conditions regardless of the treatment or diagnosis they receive, so a diagnostic error may never be recognized (Croskerry, 2012).

#### The Purposes of Measurement

There are a variety of ways that measurement can be used in the context of the diagnostic process and in assessing the occurrence of diagnostic errors. The committee identified five primary purposes for measuring diagnostic errors: establishing the magnitude and nature of the problem of diagnostic error, determining the causes and risks of diagnostic error, evaluating interventions to improve diagnosis and reduce diagnostic errors, as well as for educational and training purposes and for accountability purposes (e.g., performance measurement). Each of these purposes is described in greater detail below.

1. **Establish the incidence and nature of the problem of diagnostic error.** Today this task is primarily the province of research and is likely to remain that way for the foreseeable future. Researchers have used a variety of methods to assess diagnostic errors. Attention to harmonizing these approaches and recognizing what each method contributes to the overall understanding of diagnostic error may better characterize the size and dimensionality of the problem and may facilitate assessment of diagnostic error rates over time.

2. **Determine the causes and risks of diagnostic error.** This use of measurement and assessment is also primarily undertaken in research settings, and this is also likely to continue. Previous research has provided numerous insights into causes and risks, but moving from these insights to constructing approaches to prevent or detect problems more rapidly will require additional work.

3. **Evaluate interventions.** This report should stimulate the development of programs designed to prevent, detect, and correct diagnostic errors across the spectrum, but these programs will require appropriate measurement tools (both quantitative and qualitative) to allow a rigorous assessment of whether the interventions worked. This will be particularly challenging for measuring prevention, as is always the case in medical care. Research needs to focus on the required attributes of these measurement tools for this application.

4. **Education and training.** Given the importance of lifelong learning in health care, it will be useful to have measurement tools that can assess the initial training of health care professionals, the outcomes of ongoing education, and the competency of health care professionals. For this application, these tools need to provide an opportunity for feedback and perhaps decision support assistance in identifying potential high risk areas. In this instance, the measurement tools need to include both the assessment of whether an event occurred or is at risk for occurring, and also effective methods for feeding back information for learning.

5. **Accountability.** In today’s environment, significant pressure exists to push toward accountability through public reporting and payment for every area in which a potential problem has been identified in health care. As an aspiration, the committee recognizes that transparency and public reporting are worthy goals for helping patients identify and receive high-quality care. However, current pushes for accountability neglect diagnostic performance, and this is a major limitation of these approaches. The committee’s assessment suggests that it would be premature either to adopt an accountability framework or to assume that the traditional accountability frameworks for public reporting and payment will be effective in reducing diagnostic error. A primary focus on intrinsic motivation—unleashing the desire on the part of nearly all health care professionals to do the right thing—may be more effective at improving diagnostic performance than programs focused on public reporting and payment. Public awareness may also be a key leverage point, but at this point measurement approaches that reveal weak spots in the diagnostic process and identify errors reliably are lacking.

For both health care professionals and for patients, it is critical to develop measurement approaches that engage all parties in improving diagnostic performance. With this in mind, the following discussion elaborates on three of the purposes of measurement: establishing the incidence and nature of diagnostic error, determining the causes and risks of diagnostic error, and evaluating interventions. This section summarizes the approaches to measurement that are best matched to each purpose. All of the data sources and methods that were identified have some limitations.
for the committee-defined purposes of measurement. Because the committee determined that it is premature to consider diagnostic error from an accountability framework, measurement for the purpose of accountability is not described further in this chapter.

**Establishing the Incidence and Nature of Diagnostic Error**

A number of data sources and methods have been used to understand the incidence and nature of diagnostic error, including postmortem examinations (autopsy), medical record reviews, malpractice claims, health insurance claims, diagnostic testing studies, patient and clinician surveys, among others (Berner and Graber, 2008; Graber, 2013; Singh and Sittig, 2015). Before reviewing each of these approaches, the committee sought to identify or construct a summary, population-based estimate of the frequency with which diagnostic errors occur. Such a number can underscore the importance of the problem and, over time, be used to evaluate whether progress is being made. To arrive at such a number, the committee considered the necessary measurement requirements to establish the incidence and nature of diagnostic errors. First, one would need an estimate of the number of opportunities to make a diagnosis each year (denominator) and the number of times the diagnosis (health problem) is not made in a timely and accurate manner or is not communicated to the patient. This formulation takes into consideration the fact that patients may experience multiple health problems for which a diagnosis is required during any given year; each represents an opportunity for the health care system to deliver a timely and accurate explanation of that health problem.

About one-third of ambulatory visits are for a new health problem (CDC, 2015). The formulation also reflects the fact that the final product (the explanation of the patient’s health problem) needs to be free of defects; that is, it needs to meet all elements of a correct diagnosis (timeliness, accuracy, and communication).

<table>
<thead>
<tr>
<th>Data Source</th>
<th>Key Features of the Data Source</th>
<th>Method(s) for Selecting Cases for Review (Denominator)</th>
<th>Method for Determining if Error Occurred (Numerator)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Postmortem examination (Autopsy)</td>
<td>Deaths only&lt;br&gt;Limited number of reviews&lt;br&gt;Selection bias (typically focused on unexpected deaths)&lt;br&gt;Limited workforce</td>
<td>Consecutive series with criteria&lt;br&gt;Convenience samples&lt;br&gt;Pre-specified criteria&lt;br&gt;Requests (from clinicians)</td>
<td>Comparison to another data source (medical record, interview, location/circumstance of death)&lt;br&gt;Cause of death determination&lt;br&gt;Effects or indication of disease</td>
</tr>
<tr>
<td>Medical records</td>
<td>Rely on documentation (what was recorded, such as clinical history and interview, physical exam, and diagnostic testing)</td>
<td>Pre-specified criteria (e.g., trigger tool)&lt;br&gt;Random sample</td>
<td>Implicit review/expert assessment&lt;br&gt;Explicit criteria</td>
</tr>
<tr>
<td>Malpractice claims</td>
<td>Requires claim to be filed; more likely for negligent care&lt;br&gt;Most studies done on closed claims</td>
<td>Classification criteria (typically based on claim made in suit)</td>
<td>Claims adjudication process (including courts)</td>
</tr>
<tr>
<td>Health insurance claims</td>
<td>Requires a billable event&lt;br&gt;Relies on documentation necessary for payment</td>
<td>Criteria-based algorithm (selected)&lt;br&gt;Universe of claims</td>
<td>Criteria-based algorithm</td>
</tr>
<tr>
<td>Diagnostic testing</td>
<td>Source data available for review&lt;br&gt;Applies only to diagnoses for which diagnostic testing data are a key factor&lt;br&gt;Focus on interpretation</td>
<td>Random sample&lt;br&gt;Pre-specified criteria</td>
<td>Expert assessment compared to original</td>
</tr>
<tr>
<td>Medical imaging</td>
<td>Source data available for review&lt;br&gt;Applies only to diagnoses for which medical imaging data are a key factor&lt;br&gt;Focus on interpretation</td>
<td>Random sample&lt;br&gt;Pre-specified criteria</td>
<td>Expert assessment compared to original</td>
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<tr>
<td>Surveys of clinicians</td>
<td>Subject to non-response bias&lt;br&gt;May be difficult to validate</td>
<td>Sample receiving survey</td>
<td>Descriptive statistics on self report</td>
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<tr>
<td>Surveys of patients</td>
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<td>Descriptive statistics on self report</td>
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The committee recognized that, perhaps not surprisingly, the available research estimates were not adequate to extrapolate a specific estimate or range of the incidence of diagnostic errors in clinical practice today. Even less information is available to assess the severity of harm caused by diagnostic errors. Part of the challenge in gathering such data is the variety of settings in which these errors can occur; these settings include hospitals, emergency departments, a variety of outpatient settings (such as primary and specialty care settings and retail clinics), and long term-care settings (such as nursing homes and rehabilitation centers). A second part of the challenge is the complexity of the diagnostic process itself.

Although there are data available to examine diagnostic errors in some of these settings, there are wide gaps and much variability in the amount and quality of information available. In addition, a number of problems arise when aggregating data across the various research methods (such as postmortem examinations, medical record reviews, and malpractice claims). Each method captures information about different subgroups in the population, different dimensions of the problem, and different insights into the frequency and causes of diagnostic error. Taken together, however, the committee concluded that the evidence suggests that diagnostic errors are a significant and common challenge in health care and that most people will experience at least one diagnostic error in their lifetime. The committee based this observation on its collective assessment of the available evidence describing the epidemiology of diagnostic errors. In each data source that the committee evaluated, diagnostic errors were a consistent quality and safety challenge.

The committee anticipates that its definition of diagnostic error will inform measurement activities. The two components of the definition—(a) timeliness and accuracy and (b) communication—will likely have to be accounted for separately. For example, it is often difficult to determine from a medical record review whether the diagnosis has been communicated to the patient. Other data sources, such as patient surveys, may be helpful in making this determination. Alternatively, medical record charting practices could be improved to emphasize communication, because of its importance in improving diagnosis and subsequent care. Measuring each arm of the definition is also consistent with the committee’s approach to identifying failures in the diagnostic process; the committee specifies that each step in the diagnostic process can be evaluated for its susceptibility to failures. To better understand both the challenges and the opportunities associated with the various measurement methods, for each of the data sources the committee examined (1) the mechanism by which eligible patients were identified for assessment (denominator) and (2) the way that diagnostic errors were identified (numerator). The results are summarized in Table 1.

### Diagnostic Team Members and Tasks: Improving Patient Engagement and Health Care Professional Education and Training in Diagnosis

This chapter describes the team-based nature of the diagnostic process, the importance of clinicians partnering with patients and their families throughout the process, and the preparation that health care professionals need to participate effectively in the diagnostic process. Making accurate and timely diagnoses requires team work among health care professionals, patients, and their family members. In terms of the committee’s conceptual model of the diagnostic process, the focus of this chapter is on two of the elements of the work system: diagnostic team members (health care professionals, patients, and their families) and the tasks that they perform in the diagnostic process.

### The Diagnostic Process as a Team Endeavor

Too often the diagnostic process is characterized as a solitary activity, taking place exclusively within an individual physician’s mind. While the task of integrating relevant information and communicating a diagnosis to a patient is often the responsibility of an individual clinician, the diagnostic process ideally involves collaboration among multiple health care professionals, the patient, and the patient’s family. Patients and their families play a pivotal role in the diagnostic process. Thus, arriving at timely and accurate diagnoses, even those made by an individual clinician working with a single patient, involves teamwork. The number of health care professionals involved in the diagnostic process can vary substantially, depending on the nature of the patient’s health problem: for example, McDonald (2014) noted that a diagnostic process could involve a single clinician if the suspected diagnosis is considered straightforward, such as a common cold. However, at the other end of the spectrum, the diagnostic process could be quite complex and involve a broad array of health care professionals, such as primary care clinicians, diagnostic testing health care professionals, multiple specialists if different organ systems are suspected to be involved, nurses, pharmacists, and others.

Even though some diagnoses continue to be made by individual clinicians working independently, this solitary approach to the diagnostic process is likely to be insufficient given the changing nature of health care. The mounting complexity of health care, including ever-increasing options for diagnostic testing and treatment and the movement toward precision medicine, the rapidly rising levels of biomedical and clinical evidence to inform clinical practice, and the frequent co-morbidities among patients due to the aging population will require greater reliance on team-based diagnosis (IOM, 2008, 2013b). To manage the increasing complexity in health care and medicine, clinicians will need to collaborate effectively and draw upon the knowledge and expertise of other health care professionals, as well as patients and families, throughout the diagnostic process. The committee recognizes that reframing the diagnostic process as a team-based activity may require changing norms of health care professional roles and responsibilities and that these changes may take some time and may meet some resistance. Nevertheless, the committee concluded that improving diagnosis will require a team-based approach to the diagnostic process, in which all individuals collaborate toward the goal of timely and accurate diagnoses. Consistent with the committee’s conclusion, recent reports in the literature make the case that the diagnostic process is a team-based endeavor (Grady and Grady, 2014; Haskell, 2014; Henriksen and Brady, 2013; McDonald, 2014). For example, Schiff noted that the new paradigm for diagnosis is that it is carried out by a well-coordinated team of people working together through reliable processes; in this view, diagnosis is the collective work of the team of health care professionals and the patient and his or her family (Schiff, 2014b).

In health care, teamwork has been described as a “dynamic process involving two or more professionals with complementary backgrounds and skills, sharing common health goals and exercising concerted physical and mental effort in assessing, planning, or evaluating patient care. This is accomplished through interdependent collaboration, open communication and shared decision-making” (Xyrichis and Ream, 2008, p. 238). Five principles of team-based care have been identified by the Institute of Medicine (IOM): shared goals, clear roles, mutual trust, effective communication, and measurable processes and outcomes. Research by a number of organizations, including the IOM, has highlighted the important role that teamwork plays in health care (Borrill et al., 2000; Boul et al., 2009; IOM, 2001, 2013a, 2013b; Naylor, 2010; Josiah Macy Jr. Foundation and Carnegie Foundation for the Advancement of Teaching, 2010; WHO, 2010).

A report commissioned by the Robert Wood Johnson Foundation identified several factors that are important to fostering and sustaining interprofessional collaboration: patient-centeredness, leadership commitment, effective communication, awareness of roles and responsibilities, and an organizational structure that integrates interprofessional practice (CFAR et al., 2015). A review by the United Kingdom’s National Health Service found that teamwork has “been reported to reduce hospitalization time and costs, improve service
provision, [and] enhance patient satisfaction, staff motivation and team innovation” (Borrill et al., 2000, p. 14). One study found that a “culture of collaboration” is a key feature shared by academic medical centers considered to be top-performers in quality and safety (Keroack et al., 2007), and a literature review found moderate evidence for an association between teamwork and positive patient outcomes, with the most consistent evidence from the intensive care unit setting (Sorbero et al., 2008). Another study found that surgical teams that did not engage in teamwork had worse patient outcomes, including a higher likelihood of death or serious complications (Mazzocco et al., 2009). These findings are consistent with those from other sectors. For example, in aviation and in the nuclear power industry teamwork and training in team-based skills have been found to improve performance and reduce errors related to communication and coordination problems (Leonard et al., 2004; Salas et al., 2008; Weaver et al., 2014).

Compared to teamwork in other areas of health care, teamwork in the diagnostic process has not received nearly as much attention. Teamwork in diagnosis is likely to be somewhat distinct from the teamwork that occurs after a diagnosis is made, in part due to the fluid, or unstable, collection of health care professionals involved in the diagnostic process. Fluid team membership has been recognized as a strategy to deal with fast-paced, complex tasks such as diagnosis where pre-planned coordination may not be possible and where communication and coordination are a necessity (Bushe and Chu, 2011; Edmondson, 2012; Vashdi et al., 2013). Fluid team membership can introduce new challenges, such as a reduced sense of belonging to the team and a decrease in team efficacy (Bushe and Chu, 2011; Dineen and Noe, 2003; Shumate et al., 2010). A number of strategies have been identified to lessen the negative impacts of fluid teams, including standardizing roles and skills, reducing task interdependence, and increasing health care professionals’ understanding of others’ roles (Bushe and Chu, 2011).

Although teams focused on patient treatment may also exhibit fluidity, the uncertainty and complexity of the diagnostic process make unstable team membership more likely in the diagnostic process.

The committee concluded that literature on the role of teams in diagnosis is limited and that lessons from teamwork in other settings, including the treatment setting, are applicable to the diagnostic process. In testimony to the committee, Eduardo Salas of the University of Central Florida said that teamwork was likely to improve diagnosis and reduce diagnostic errors because teamwork has been found to mitigate communication and coordination challenges in other areas of health care. These same challenges have been found to have an impact on diagnostic performance (Gandhi, 2014; IOM, 2013b; Schiff, 2014a; Singh, 2014; Sutcliffe et al., 2004; The Joint Commission, 2014). Emerging research also suggests that teamwork will improve the diagnostic process; one study found that medical students working in teams made fewer diagnostic errors than those working individually, and other research has found that collaboration among treating clinicians and clinical pathology teams resulted in better diagnostic test selection (Hautz et al., 2015; Seegmiller et al., 2013).

Diagnosis depends on health care professionals with differing educational and training backgrounds working together and practicing to the full extent of their education and training (IOM, 2001, 2012c). Having clear roles and responsibilities leaves “those with greater training or responsibility free to perform tasks or to solve problems for which they are uniquely equipped” (Baldwin and Tsukuda, 1984, p. 427), while other tasks in the diagnostic process can be distributed to health care professionals within their own scope of practice (Baldwin and Tsukuda, 1984; IOM, 2011a). Improving diagnostic performance requires participating individuals to recognize the importance of teamwork as well as the contributions of other health care professionals to the diagnostic process.

In recognition that the diagnostic process is a dynamic team-based activity, health care organizations should ensure that health care professionals have the appropriate knowledge, skills, resources, and support to engage in teamwork in the diagnostic process. Ensuring that individuals participating in the diagnostic process have the appropriate resources and support extends beyond the purview of this chapter and requires a systems approach to diagnosis, including consideration of health information technology (health IT) resources, an organizational culture and work system that supports teamwork, and payment and care delivery models that promote teamwork. This chapter focuses on describing the individuals involved in the diagnostic process, identifying opportunities to facilitate patient engagement and intra- and inter-professional collaboration in the diagnostic process, and ensuring that team members have and maintain appropriate competencies in the diagnostic process.

**Participants in the Diagnostic Process**

The committee described diagnostic teamwork as the collaboration of interrelated individuals working toward the goal of establishing and communicating an accurate and timely explanation of a patient’s health problem (Salas et al., 2008). Teamwork in the diagnostic process involves the collaboration of patients and their families; diagnosticians, such as physicians, physician assistants (PAs), and advanced practice nurses (APNs); and health care professionals who support the diagnostic process, such as nurses, pharmacists, laboratory scientists, radiology technologists, medical assistants, and patient navigators.

Patients and their family members are at the center of the process because the ultimate goal of the diagnostic process is to explain a patient’s health problem and to inform subsequent decision making about a patient’s care. Surrounding patients and their families are diagnosticians, health care professionals whose tasks include making diagnoses. Encircling the diagnosticians are health care professionals who support the diagnostic process. Although a distinction is sometimes made between diagnosticians and health care professionals who support the diagnostic process, this distinction may be less clear in practice. For example, triage—a complex cognitive nursing task designed to identify patients needing immediate medical care—has not typically been included as a component in the diagnostic process, but it can often play a de facto role, since a nurse may identify a suspected diagnosis during this process (Soni and Dhalwal, 2012). Similarly, incorrect triage decisions can also introduce cognitive biases (such as framing or anchoring effects) that can contribute to diagnostic errors. The overlapping nature of the diagnostic team members reflects the importance of effective communication and collaboration among all individuals in the diagnostic process.

**Patients and Their Family Members**

The goal of patient engagement in diagnosis is to improve patient care and outcomes by enabling patients and their families to contribute valuable input that will facilitate an accurate and timely diagnosis and improve shared decision-making about the path of care. Because patients are a heterogeneous population with varying needs, values, and preferences, their roles in diagnosis need to be individually tailored. Patients hold critical knowledge that informs the diagnostic process, such as knowledge of their health history, their symptoms, their exposure to individuals or environmental factors, the course of their condition, the medications they are taking, as well as knowledge gained from information searches that they conducted in advance of their appointment. In addition, patients and their families may also maintain more complete version of their own medical records, and they can help ensure that test results are received and facilitate communication among their clinicians (Gruman, 2013).

**Diagnosticians**

Diagnosticians are health care professionals (physicians, PAs, APNs, and others) who are educated and licensed to provide patients with diagnoses. Although a diagnostician is defined
as any health care professional with diagnosis in his or her scope of work, in general physicians are expected to deal with a greater complexity of diagnostic tasks than other diagnosticians. In addition to diagnosing patients’ health problems, diagnosticians often participate in a variety of other health care tasks, such as the provision of preventive care and the management of patients’ chronic and acute health conditions. Diagnosticians work in all health care settings and include both general and specialist practitioners. Their clinical reasoning skills come into play as they collect and integrate information from a patient’s clinical history, interview, physical exam, diagnostic testing, and consultations with or referrals to other health care professionals.

Pathologists and radiologists are diagnosticians who provide information and consultations that are critical to diagnosing patients’ health problems, such as advising on the appropriate diagnostic testing for a particular patient and conveying the implications of the test results to treating health care professionals. Despite the important roles that laboratory medicine, anatomic pathology, and medical imaging play in a diagnosis, pathologists and radiologists have sometimes been treated as ancillary or support services.

Expert testimony to the committee found that many pathologists and radiologists have not been adequately engaged in the diagnostic process and that better collaboration among all diagnostic team members is necessary (Allen and Thorwart, 2014; Kroft, 2014). The committee concluded that a culture perpetuating the notion of anatomic pathology, laboratory medicine, and medical imaging as ancillary health care services will inhibit efforts to improve diagnosis. Thus, the committee recommends health care organizations should facilitate and support collaboration among pathologists, radiologists, other diagnosticians, and treating health care professionals to improve diagnostic testing processes. This includes collaboration throughout the testing process, including the ordering of appropriate tests or images, analysis and interpretation, the reporting and communication of results, and subsequent decision making. Depending on a patient’s health problem, treating clinicians may also need to work collaboratively with other diagnosticians, such as sleep specialists, cardiologists, and others. Education and training of health care professionals also needs to ensure that they are prepared to work in this manner.

Health Care Professionals Who Support the Diagnostic Process

In addition to diagnosticians, the diagnostic process may involve an array of health care professionals, including nurses, medical assistants, radiology technologists, laboratory scientists, pharmacists, patient navigators, social workers, therapists, nutritionists, and many others. These health care professionals play a crucial role by facilitating the diagnostic process through the performance of their tasks.

Nurses in particular play a key role in the diagnostic process. Nurses may ensure communication and care coordination among diagnostic team members, monitor a patient over time to see if the patient’s course is consistent with a working diagnosis, and identify potential diagnostic errors. Nurses facilitate patient engagement in the diagnostic process by communicating with patients about their history, actively listening to patients’ descriptions of their reasons for a visit, documenting patients’ symptoms, assessing vital signs, and conveying this information to other clinicians. Nurses need to be full and active members of the diagnostic team, with opportunities to present their observations and conclusions to other team members. The committee’s understanding of nurses as crucial contributors to the diagnostic process builds on the recommendations of the IOM report The Future of Nursing: Leading Change, Advancing Health (IOM, 2011a). This report provided a roadmap for transforming nursing practice in the United States. To achieve the necessary changes, the report offered four key recommendations (IOM, 2011a):

- Nurses should achieve higher levels of education and training through an improved education system that promotes seamless academic progression.
- Nurses should be full partners, with physicians and other health professionals, in redesigning health care in the United States.
- Effective workforce planning and policy making require better data collection and an improved information infrastructure.

In the five years since the report’s release, there has been increased awareness of and growing support for these recommendations in nursing schools, health care professional societies, and health care organizations. For example, AARP and the Robert Wood Johnson Foundation recently launched the “Future of Nursing: Campaign for Action,” an initiative designed to drive implementation of the report’s recommendations. Despite these efforts, progress in the implementation of these recommendations has been uneven. Re-envisioning the roles that nurses play in the diagnostic process is one component of these larger efforts to transform the practice of nursing in the United States.

Radiology technologists and laboratory scientists also play important roles in the diagnostic process. In some cases radiology technologists take images and make decisions, such as how many and what type of images to take. For example, ultrasound technologists will capture images of normal structures and take additional images of any abnormalities they find. If the radiology technologist does not notice an abnormality, important information may not be conveyed to the radiologist, which may negatively impact the diagnostic process. Laboratory scientists are tasked with procuring samples, preparing samples for analysis, performing analyses, and ensuring that the testing tools are functioning properly. In some cases these scientists may detect a specimen abnormality during the analysis process that suggests an unsuspected diagnosis or necessitates further investigation.

Pharmacists can make important contributions to the diagnostic process, especially in
identifying and averting health problems that stem from drug side effects and interactions (Hines and Murphy, 2011; Malone et al., 2005). Pharmacists and treating clinicians can collaborate to identify whether a patient’s symptoms may be due to the side effects of a particular drug or the interaction of multiple medications. Because clinicians may not be aware of all possible drug side effects or interactions, pharmacists may also provide input in the selection of medications for a patient’s health problem.

**Facilitating Teamwork In Clinical Practice**

Health care organizations play a critical role in ensuring effective teamwork. Thus, the committee recommends that health care organizations should facilitate and support inter-professional and intra-professional teamwork in the diagnostic process. There are a number of strategies that health care organizations can employ to improve teamwork in the diagnostic process. Creating a culture that encourages intra- and inter-professional collaboration is critical, as is designing a work system that is supportive of effective teamwork, including the use of results reporting tools that convey important information to the diagnostic team members. For example, the use health IT and telemedicine may help facilitate communication and collaboration among team members, especially when geographically distant health care professionals are involved in the diagnostic process. The following section describes several opportunities for improving collaboration, such as care delivery reforms, treatment planning conferences, diagnostic management teams, integrated practice units, morbidity and mortality conferences, and multidisciplinary rounds.

**Care Delivery Reforms**

Two care delivery reforms—patient-centered medical homes (PCMHs) and accountable care organizations (ACOs)—have recently been implemented across the country as a means to improve patient care coordination and increase communication among health care professionals. PCMHs are designed to improve the quality of primary care by fostering a sense of partnership among patients and clinicians and by designating a particular health care practice as being accountable for a patient’s care (Health Affairs, 2010; Schoen et al., 2007). PCMHs can improve team-based care by acting as the nexus of coordination and communication for a patient and their health care professionals; recent evidence suggests that attempts to improve primary care by enhancing its role in coordination have shown some success in improving patient and staff experiences and reducing hospitalization (AHRQ, 2010a). Some PCMH demonstrations are still under evaluation, and other PCMHs are trying new formats; for example, Maryland Blue Cross Blue Shield is offering incentives for physicians to form virtual panels that serve as de facto PCMHs (CMS, 2013; Dentzer, 2012). Barriers to PCMHs include the high up-front costs associated with implementing the health IT infrastructure necessary for improved communication and collaboration and also difficulties in incentivizing outside clinicians to work with those in the PCMH (Crabtree et al., 2010; Rittenhouse et al., 2009).

ACOs are organized groups of health care professionals, practices, or hospitals that work together to assume responsibility for and provide cost effective care to a defined population of beneficiaries. The Affordable Care Act created ACOs to address delivery system fragmentation and to align incentives to improve communication and collaboration among health care professionals (Berwick, 2011). Although the evidence needed to evaluate the impact of ACOs on improved communication and care coordination is still being collected, there are early indications that ACOs can improve patient care. For example, the Medicare Physician Group Practice, the predecessor to ACOs, demonstrated achievement of 29 of 32 quality measures (Iglehart, 2011), and an early study shows that some Pioneer ACOs were able to reduce overall costs (CMS, 2013). As with PCMHs, high initial costs associated with IT implementation are a barrier to the implementation of ACOs (Kern, 2014).
Treatment Planning Conferences

Treatment planning conferences (also referred to as tumor boards) are a form of case review in which a multidisciplinary team of health care professionals “review and discuss the medical condition and treatment options of a patient” (NCI, 2015). Treatment planning conferences are often held for specific types of cancers, and their participants may include surgeons, medical oncologists, radiologists, radiation oncologists, pathologists, nurses, and other collaborating health care professionals. These boards generally serve two purposes—to help diagnose complex cases involving cancer and to consider treatment options for patients with a cancer diagnosis. An advantage of this approach is that it provides a collaborative environment where an intra- and inter-professional team of clinicians can collaborate and share information and opinions. The evidence on whether treatment planning conferences improve patient outcomes is inconclusive; although a number of studies have found that a small percentage of initial cancer diagnoses changed after review in a treatment planning conference (Chang et al., 2001; Newman et al., 2006; Pawlik et al., 2008; Cohen et al., 2009; Santoso et al., 2004), a multi-site study found that treatment planning conferences did not significantly improve the quality of care of patients (Keating et al., 2012). Despite the mixed evidence, treatment planning conferences may help to identify and avoid potential diagnostic errors by bringing multiple perspectives to challenging diagnoses. This approach could also be applied to diagnoses other than cancer, especially ones with serious health consequences or complex symptom presentations.

Diagnostic Management Teams

Health care organizations can support teamwork among pathologists, radiologists, other diagnosticians, and treating health care professionals by forming diagnostic management teams (DMTs). For example, Vanderbilt University’s DMT is designed to improve diagnosis through improved communication and access to diagnostic specialists; it offers participating health care professionals assistance in selecting appropriate diagnostic tests and interpreting diagnostic test results (Gover, 2013). DMT consultations consider a patient’s clinical information to provide a context for the test result, and they ensure that a clinically valuable interpretation is included in the test result report. Clinicians who participate in this process report a favorable view of DMTs, and although perceived high initial costs are a potential barrier, there is some evidence that DMTs can lower overall costs (Seegmiller et al., 2013).

Integrated Practice Units

Integrated practice units (IPUs) have been proposed as a way to improve the value of health care and to address the communication problems that result from system fragmentation (Porter, 2010; Porter and Lee, 2013). An IPU is a group of clinicians and non-clinicians who are responsible for the comprehensive care of a specific medical condition and the associated complications or for a set of closely related conditions (Porter and Lee, 2013). The members of an IPU have expertise in the relevant condition and work together as a team to provide total care for patients, including inpatient care, outpatient care, and health care education. The IPU model, which has been applied to such conditions as breast cancer and joint replacement, has been shown to improve patient outcomes. For example, patients treated by a spinal care IPU were found to miss fewer days of work, require fewer physical therapy visits, and fewer magnetic resonance images to evaluate their back problems (Porter and Lee, 2013).

Morbidity and Mortality Conferences

Morbidity and mortality conferences (M&M conferences) are forums that bring clinicians together to review cases involving medical errors and adverse events that have occurred. M&M conferences have been used to better understand how errors occur and to help health care organizations identify work system failures an develop interventions to address these failures (AHRQ, 2008b). These conferences have been used to elucidate the causes of diagnostic error and to help improve diagnostic performance (Cifra et al., 2014; Cifra et al., 2015).

Multidisciplinary Rounds

Multidisciplinary rounds (also referred to as interdisciplinary rounds) bring health care professionals from different disciplines together to consider the diagnosis and treatment of specific patients. These rounds may involve interacting with patients, or may be part of a lecture with a patient-actor. They provide an opportunity for health care professionals to learn how other health care professionals approach medical issues and to interact with health care professionals from different disciplines. Multidisciplinary rounds have been associated with improvements in care quality, shortened length of stays, and enhancements in resident education (O’Mahony et al., 2007).

Patient Engagement in Diagnosis

The IOM report Crossing the Quality Chasm: A New Health System for the 21st Century highlighted patient-centeredness as a core aim of the health care system and defined it as “providing care that is respectful of and responsive to individual patient preferences, needs, and values and ensuring that patient values guide all clinical decisions” (IOM, 2001, p. 6). A critical feature of patient-centeredness is the active engagement and shared decision making of patients and their families in the patients’ health care. Patient engagement has been defined as “actions [people] take to support their health and benefit from health care” (CFAH, 2015) and has been shown to increase patient satisfaction with care and to improve health outcomes (Boulding et al., 2011; Etchegary et al., 2014; Glickman et al., 2010; Lucian Leape Institute, 2014; Safran et al., 1998; Sequist et al., 2008; Weingart, 2013). The goal of patient engagement in diagnosis is to improve patient care and outcomes by enabling patients and their families to contribute valuable input that will facilitate an accurate and timely diagnosis and improve shared decision-making about the path of care. There are a variety of factors that present challenges to patient engagement in diagnosis, and the committee makes one recommendation to improve patient and family engagement in the diagnostic process.

Challenges to Patient Engagement in Diagnosis

Patients and their families may not be effectively engaged in the diagnostic process for a variety of reasons, including both patient-related factors and health care professional and system factors.

Patient-Related Factors

The patient-related factors that prevent active engagement in the diagnostic process can include unfamiliarity with and poor access to the health care system; difficulty with communication due to language, health literacy, and cultural barriers; and a patient’s lack of comfort in taking an active role in diagnosis. Patients are a heterogeneous population, and their needs, values, preferences, and ability to engage in the diagnostic process vary considerably.

Some patients may fear asserting themselves in the diagnostic process because they do not want to appear to be difficult and risk alienating their clinician, which could affect the quality of their care (Frosch et al., 2012). In one study involving cancer patients who thought there had been a serious breakdown in their care, 87% did not formally report their concern to the health care organization (Mazor et al., 2012). A patient may also feel uncomfortable asking for a referral to seek a second opinion or asking to see a more experienced clinician (Entwistle et al., 2010). The stress that patients feel related to their health, to navigating the health care system, to missing work, or to dealing with insurance issues can make them less likely to participate in their own care (Evans, 2013).

A patient’s symptoms and severity of illness can also prevent active engagement in the diagnostic process.
Challenges to Effective Patient and Family Engagement in the Diagnostic Process

Patients and families may:
- Fear complaining and being seen as difficult
- Feel a lack of control or vulnerability for many reasons (sick, scared, social status)
- Not always take their own problems seriously enough
- Lack understanding of the health care system or opportunities to become involved
- Encounter inexperienced health care professionals
- Have language and health literacy barriers
- Be unsure how to seek resolution to a problem when issues are not resolved at the point of care

Health care professionals may:
- Dismiss patients’ complaints and knowledge
- Act on implicit or explicit biases and stereotypes
- Incorrectly assume that a patient does not want to be involved in his or her care

Health care systems may exhibit:
- Disjointed care through a lack of coordination and teamwork
- Breakdowns in communication among health care professionals
- Failure to transmit information to patients
- Failure to adequately review or follow up on diagnostic testing results
- Lack of disclosure or apology after diagnostic errors

Events in health care (Joint Commission, 2007). These barriers have also been associated with diagnostic errors (Flores, 2006; Marcus, 2003; Price-Wise, 2008). To meet the needs of patients with limited English proficiency, some health care organizations have instituted policies to ensure that language services, such as those provided by interpreters, are available and that educational literature is provided in languages other than English (HHS, 2015). Despite these steps, a study found that even when hospitals have a policy regarding language services, they often do not provide staff with the training necessary to access language services, assess the competency of interpreters, and there is little oversight of the quality of the translated literature (Wilson-Stronks, 2007).

Even if a patient speaks the same language as his or her clinicians, there can be...
communication challenges if the patient has limited health literacy or if clinicians use unfamiliar medical terminology. In the United States more than 80 million adults have a poor level of health literacy, which has been defined as “the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions” (AHRQ, 2011, pp.ES-1). Health literacy requires applying a complex set of skills involving reading, listening, analysis, and decision making to health settings (NNLM, 2013). Patients lacking health literacy skills may be limited in their ability to participate in the diagnostic process and in decision making about the planned path of care (Peters et al., 2007). A recent study indicated that a group of medical trainees including PA and MD students lacked confidence in their ability to communicate effectively with low-health-literacy patients (Ali et al., 2014).

There is a tremendous amount of information and resources available on the Internet and mobile apps to help patients identify potential diagnoses and to plan for health care appointments. A 2013 Pew Research Center study found that 35 percent of American adults have used online resources to diagnose a condition in themselves or someone else (Fox and Duggan, 2013). These resources have varying levels of accuracy, and patients may have difficulty assessing the quality of the information available to them (NLm, 2012b; Semigran et al., 2015). Clinicians may also react negatively to patients’ use of this information in clinical visits (Julavits, 2014).

Patients’ level of comfort with actively engaging in care decisions, such as asking questions, stating preferences, or seeking alternative opinions, may differ considerably from one patient to another. Some patients may prefer to be actively involved in all aspects of the decision-making process, while others would rather defer to their clinicians’ judgment (Fowler, 2011). In a national survey, the majority of respondents reported that they would like clinicians to effectively engage them in health care decision making by talking about their diagnosis and explaining the options available, including the risks and their impact on quality of life and the costs associated with them (IOM, 2012b). Another survey found that 96 percent of respondents desired to be asked questions and to be given choices regarding their care, and approximately half preferred to have their clinicians make the final decisions (Levinson et al., 2005). Clinicians may not be aware of—or they may misjudge—the role that a patient desires to play in decision making, and as a result they may make decisions that are misaligned with patient preferences, a phenomenon that has been referred to as a preference misdiagnosis (Mulley et al., 2012). Factors such as age, gender, medical history, familiarity with the health care system, socioeconomic status, and cultural issues can factor in to patients’ preferences regarding engagement and shared decision making (Boyer et al., 2001; Cox et al., 2012; Lipson et al., 2003; Longtin et al., 2010). Several studies have found that female patients who are younger and have more education tend to prefer a more active role in decisions regarding their health (Arora and McHorney, 2000; Deber et al., 2007; Say et al., 2006). A survey of low-income patients faced with major medical decisions found that 75% wanted to be very involved in the decision-making process (BSCF, 2014). Clinical visits (Julavits, 2014). As clinicians may not be aware of—health care professionals may differ considerably from one patient to another. Some patients may prefer to be actively involved in the diagnostic process and in decision making about the planned path of care (Peters et al., 2007). A recent study indicated that a group of medical trainees including PA and MD students lacked confidence in their ability to communicate effectively with low-health-literacy patients (Ali et al., 2014).

Health Care Professional and System Factors

A major concern cited by health care professionals is a lack of time to truly engage patients in the diagnostic process (Anderson and Funnell, 2005; Sarkar et al., 2012, 2014; Stevenson, 2003). Compared to more procedure-oriented tasks, fee-for-service payment does not incentivize the time spent on evaluation and management services that reflect the cognitive expertise and skills that clinicians employ in the diagnostic process (National Commission on Physician Payment Reform, 2013). This creates an environment in which communication, such as the clinical history and interview, may be rushed and patients may not have time to thoroughly discuss their symptoms and health concerns, although new models of payment and care delivery may make this a higher priority (AHRQ, 2014c; Cosgrove et al., 2013; Roades, 2013). Time pressures may also lead to an over-reliance on diagnostic testing in place of patient engagement, even when these may be inappropriate (Newman-Toker et al., 2013; Rao and Levin, 2012; Zhi et al., 2013). The use of EHRs may also lead to problems with patient engagement, as health care professionals may be distracted from communicating with patients as they enter information in the EHR (O’Malley et al., 2010; Spain, 2014).

Although many clinicians are positive about engaging with their patients (Stevenson, 2003), there are indications that some may be resistant to active patient involvement (Graedon and Graedon, 2014; Haskell, 2014; IOM, 2013a; Julavits, 2014). In interactions with patients, certain clinician behaviors can discourage open communication and patient engagement, including being dismissive of a patient’s complaints and their knowledge of their symptoms, not listening, or interrupting frequently (Dyche and Swiderski, 2005; Marvel et al., 1999; McDonald et al., 2013). For example, one study found that after a clinician entered the room, patients spoke uninterrupted for an average of only 12 seconds; the clinicians frequently interrupted the patients before they had finished speaking (Rhoades et al., 2001). Clinicians’ vulnerability to cognitive and affective biases may also contribute to behaviors that hinder patient engagement and contribute to diagnostic errors (Croskerry, 2013; Klein, 2005). Clinicians may exhibit biases in regard to gender, race, ethnicity, sexual orientation, age, obesity, a patient’s health problem (e.g., chronic pain, mental health) or other factors (IOM, 2003b, 2011b, 2011c, 2012e; Puhl and Brownell, 2001; Schwartz et al., 2003). For example, clinicians may be judgmental or blame patients for their illnesses, and this could affect a patient’s willingness to participate in the diagnostic process (Croskerry, 2003). Patients may fear disclosing sensitive information to their clinicians, such as their sexual orientation, due to a fear that such disclosure could negatively affect their care (IOM, 2011b; Durso and Meyer, 2013; Foglia and Fredriksen-Goldsen, 2014). If this information is not disclosed, Foglia and Fredriksen-Goldsen (2014) note that it could result in diagnostic error, such as a delay in diagnosing a serious health problem. The Unequal Treatment report found that “bias, stereotyping, prejudice, and clinical uncertainty on the part of health care providers may contribute to racial and ethnic disparities in healthcare” (IOM, 2003b, p. 12). For example, one study found that a patient’s race and gender independently influenced how physicians managed chest pain; physicians were significantly more likely to refer white men exhibiting signs of coronary artery disease for cardiac catheterization than to refer black women with the same symptoms (Schulman et al., 1999). Clinicians may also disregard symptoms in patients with previous diagnoses of mental illness or substance abuse and may attribute new physical symptoms to a psychological cause without a proper evaluation. Alternatively, clinicians may incorrectly diagnose or assume psychiatric, alcohol, or drug abuse diagnoses for serious medical conditions, such as hypoxia, delirium, metabolic abnormalities, or head injuries, a mistake known as a “psych-out error” (Croskerry, 2003).

Fragmentation of health care organizations and poor coordination of care hinder patient engagement and can contribute to errors in diagnosis (CFPAH, 2014c; Gandhi et al., 2006; Gandhi and Lee, 2010; IOM, 2013a; Schiff, 2008; Starfield, 2000). In cases where there is poor care coordination and communication among a patient’s clinicians, patients and their families may need to convey their information among their health care professionals. For example, one survey reported that approximately 25 percent of patients reported that a test had to be repeated because the results had not been shared with other health care professionals involved in a patient’s care (Stremikis, 2011). Limited interoperability among EHRs and laboratory and medical informatics systems also prevents the flow of information among clinicians and health care settings.
Improving Patient Engagement in the Diagnostic Process

Patients and their families play a crucial role in the diagnostic process, and the ultimate responsibility for supporting and enabling patient and family engagement in the diagnostic process rests with health care professionals and organizations. Thus, the committee recommends that health care professionals and organizations should partner with patients and their families as diagnostic team members and facilitate patient and family engagement in the diagnostic process, aligned with their needs, values, and preferences. Health care professionals need to embrace patients and their families as essential partners in the diagnostic process, with valuable contributions that can improve diagnosis and avert diagnostic errors.

Learning About the Diagnostic Process

To facilitate patient and family engagement, the committee recommends that health care professionals and organizations provide patients with opportunities to learn about the diagnostic process. One of the challenges that patients and their families face with diagnosis is their unfamiliarity with the process; thus, informing patients and their families about it has the potential to improve engagement and reduce diagnostic errors. Patients may be unfamiliar with the terminology related to the diagnostic process, such as a “differential diagnosis” or a “working diagnosis,” and also with the role of time in the process. For example, a health care professional may propose a working diagnosis if there is some uncertainty in the diagnosis, and this may change with new information. For some health problems, watchful waiting is appropriate, and patients need to be informed that time can give clinicians a better understanding of their health problem. It is also important that patients understand when and who to contact if their symptoms do not resolve or if they experience new symptoms that do not seem to fit with a working diagnosis. Providing information explaining the roles and tasks of the various individuals involved in diagnosis could also facilitate more active engagement in the diagnostic process.

A number of groups have developed information and resources to help patients become more actively involved in their health care, including the diagnostic process (CFAH, 2014c; Lucian Leape Institute, 2014; Josiah Macy Jr. Foundation, 2014). The Center for Advancing Health has developed a variety of resources to help patients gain maximum benefit from their health care, including information about communicating with clinicians, organizing health care, seeking knowledge about health, and other topics (CFAH, 2014a, 2014b). The Speak Up™ Program offers materials to help patients become more actively involved in their care and avoid errors (Joint Commission, 2015). The National Patient Safety Foundation, the Society to Improve Diagnosis in Medicine, and Kaiser Permanente have developed resources to help patients get the right diagnosis (Kaiser Permanente, 2012; NPSF and SIDM, 2014). The actions suggested in the checklists include having a thorough knowledge of medical history, formulating notes about symptoms and questions to bring to appointments, and maintaining a list of medications (such as prescriptions, over the counter medications, dietary supplements, and complementary and alternative medicines). Health care professionals and organizations can also inform patients and families about the reliability and accuracy of online resources and direct them to reputable sources (FamilyDoctor.org, 2014; Mayo Clinic, 2015; NLM, 2012a, 2012b; Semigran et al., 2015).

Health Care Environments that are Supportive of Patient and Family Engagement

Health care professionals and the organizations in which they practice can facilitate patient engagement in the diagnostic process by improving communication and shared decision making and by addressing health literacy barriers. Thus, the committee recommends that health care professionals and organizations should create environments in which patients and their families are comfortable engaging in the diagnostic process and sharing feedback and concerns about diagnostic errors and near misses. Health care organizations will need to carefully consider whether their care delivery systems and processes fully support patient engagement and work to improve systems and processes that are oriented primarily toward meeting the needs of health care professionals rather than patients. One of the most important actions that health care professionals can take to implement this recommendation is to improve their communication skills because effective patient–clinician communication is critical to making accurate diagnoses and to averting diagnostic errors. Several organizations offer communication training courses for clinicians, including the Institute for Healthcare Communication and the American Academy on Communication in Healthcare (AACH, 2015; ICH, 2015).

There are several techniques and strategies that clinicians can use to improve communication and patient engagement. One of the most well-known methods is teach-back, which involves a clinician explaining a concept and then asking the patient to repeat in his or her own words what was said (Nouri and Rudd, 2015; Schillinger et al., 2003). The clinician can then evaluate whether the patient has a good understanding and, if the patient does not, can explain the concept further using a different approach in order to improve the patient’s comprehension. Patient–clinician communication can also be improved by using clear and simple language, encouraging questions, listening actively, allowing the patient to speak without interruption, and responding to the patient’s emotions. Such techniques may also help some patients overcome their fear of discussing their concerns and become more likely to share sensitive information that could provide valuable input to the diagnostic process. If patients are upset or anxious, they may be less likely to give a thorough and accurate account of their symptoms and health concerns. Inclusion of a patient’s family in a patient’s care may also facilitate engagement and comprehension.

Supportive health care environments are places where patients and families feel comfortable sharing their concerns about diagnostic errors, near misses, and providing feedback on their experiences with diagnosis. As discussed in the education section of this chapter, providing feedback to health care professionals about the accuracy of their diagnoses can help improve their diagnostic performance. However, health care professionals often do not have opportunities to hear from patients about their diagnostic performance (Berner and Graber, 2008; Schiff, 2008). For example, a patient discharged from the emergency department may then see a primary care clinician, and the emergency department clinician may never hear whether the diagnosis on discharge was correct. To improve diagnostic performance, health care professionals and organizations should encourage patients and their families to follow up with their health care professionals to let them know about their experiences. Health care organizations can facilitate feedback from patients and their families by, for example, implementing procedures to follow up with patients after their visits. This feedback could also be used as a routine part of assessing patient satisfaction with clinicians and the health care organization.

In order to establish environments where patients and families can share their concerns, clinicians need to be ready to communicate with patients about the occurrence of diagnostic errors. A study involving 13 focus groups found that patients who have experienced a medical error wanted clinicians to disclose all harmful errors (Gallagher et al., 2003). These patients sought information about what happened, why the error happened, how to mitigate the consequences of the error, and how clinicians would prevent recurrences (Gallagher et al., 2003). Clinicians have been reluctant to disclose medical errors to patients and their families because of the fear of litigation as well as anxiety over communicating these errors; however, disclosing errors has been broadly recognized as the right thing to do (AHRQ, 2014a). There is evidence that disclosure improves patient outcomes and may reduce malpractice claims and costs (AHRQ, 2014a; Hendrich et al., 2014; Kachalia et al., 2003; Mello et al., 2014).
Fostering shared decision making, which is defined as “a collaborative process that allows patients and their providers to make health care decisions together, taking into account the best scientific evidence available, as well as the patient’s values and preferences” (IMDF, 2014), can also improve patient and family engagement in the diagnostic process. Tools to promote shared decision making are decision aids, which provide objective, evidence-based information on options that patients may have so that they can make informed decisions (IMDF, 2014; MedPAC, 2010). Although many decision aids are focused on treatment and screening decisions, some have been developed for diagnostic situations, such as an evaluation for low back pain or whether to do imaging studies for chest discomfort (Ronda et al., 2014; SCAI, 2014).

Addressing health literacy barriers may also improve patient and family engagement in the diagnostic process. Acknowledging that the health care system can place unreasonably high health literacy demands on patients and families, an IOM discussion paper identified 10 attributes of health-literate health care organizations, summarized in (IOM, 2012a). For example, health care organizations can encourage the use of tools—such as Speak Up, Ask Me Three, Getting the Right Diagnosis, and Smart Partners About Your Health—in order to improve communication among patients and their clinicians. If health care organizations make it easier for patients and families to navigate, understand, and use health care services, then patients and their families can become more engaged in the diagnostic process. In addition, health care professionals and organizations can ensure that health care environments reflect cultural and language competencies (AHRQ, 2012). The IOM recommended the broader use of interpretation services where community need exists (IOM, 2003b), and the U.S. Department of Health and Human Services (HHS) has established national standards for culturally and linguistically appropriate care (HHS, 2015). Many health care professional schools offer cultural competency courses, and there are continuing education programs designed to increase cultural competency and sensitivity. Some health care organizations have instituted policies to ensure that language services, such as those provided by interpreters, are available and that educational literature is provided in languages other than English. Though there is evidence that improving cultural competency can improve patient satisfaction with care (Castro and Ruiz, 2009; Paez et al., 2009), the evidence connecting cultural competency with improvements in patient outcomes is limited (Beach et al., 2005; Lie et al., 2011).

Health care organizations can also facilitate patients’ re-engagement with the health care system for unresolved symptoms or in other instances (such as a missed follow-up appointment). For example, Kaiser Permanente’s SureNet Program identifies people who have inadvertent lapses in care and uses electronic surveillance and staff to follow up with these patients (Kanter, 2014). Closed-loop communication systems that require all information from referrals and consultations to be relayed to the referring clinician may also help ensure that patients re-engage the health care system when necessary (Gandhi, 2014; Schiff, 2014a).

### Patient Access to Their Electronic Health Information

Another opportunity to encourage patient engagement in the diagnostic process is to make a patient’s health information more accessible and transparent. One way to accomplish this is through open medical records, or records that “patients, and others authorized by them, are allowed to read...When used properly, they let patients see themselves through the eyes of their caregivers and give them insight into diagnoses and treatment options. Having access to such information permits patients to take a more active role in decisions about their care” (Frampton et al., 2009, p.59). Thus, the committee recommends that health care professionals and organizations should ensure patient access to EHRs, including clinical notes and diagnostic testing results, to facilitate patient engagement in the diagnostic process and patient review of health records for accuracy. The Office of the National Coordinator for Health Information Technology’s Meaningful Use 2 requirements include patient access to their electronic health information (such as medication lists, diagnostic test results, allergies, and clinical problem lists), and organizations have begun to employ patient portals in order to enable patient access to this information (Adler-Milstein et al., 2014; Bruno et al., 2014; Furukawa et al., 2014; HealthIT.gov, 2015).

Unfortunately, many organizations are having trouble meeting the Meaningful Use 2 requirement that five percent of patients “view, download, or transmit their health information” (Adler-Milstein, 2015).

OpenNotes initiative, available to almost five million patients, has promoted even greater transparency of patients’ health information by inviting patients to view the notes recorded by health care professionals during a clinical visit (OpenNotes, 2015a). In an analysis of patients who were invited to read their notes over the course of a year, approximately 70 to 80 percent surveyed said that they read their notes, understood their care plan better, and were better prepared for visits (Delbanco et al., 2012; Bell et al., 2014). Clinicians report that implementing OpenNotes results in few, if any, disruptions to their practice (Bell et al., 2014; Walker et al., 2014).

### Attributes of Health Literate Health Care Organizations

1. A health literate organization:  
   - Has leadership that makes health literacy integral to its mission, structure, and operations  
2. Integrates health literacy into planning, evaluation measures, patient safety, and quality improvement  
3. Prepares the workforce to be health literate and monitors progress  
4. Includes populations served in the design, implementation, and evaluation of health information and services  
5. Meets the needs of populations with a range of health literacy skills while avoiding stigmatization  
6. Uses health literacy strategies in interpersonal communications and confirms understanding at all points of contact  
7. Provides easy access to health information and services and navigation assistance  
8. Designs and distributes print, audiovisual, and social media content that is easy to understand and act on  
9. Addresses health literacy in high-risk situations, including care transition and communications about medicines  
10. Communicates clearly what health plans will cover and what individuals will have to pay for services  

The OpenNotes developers suggested that initiatives like OpenNotes have the potential to reduce diagnostic errors by enabling patients and families to catch errors within clinician notes, by encouraging patients to speak up, and by preventing diagnostic delay by helping patients better remember recommendations for tests and procedures. In addition, the developers cited transparency as a means to help patients better understand their clinicians’ thought processes, to enhance trust, and to engage family caregivers. In a pilot study, the developers found that patients with access to their medical information were more likely than those without such access to have questions,
to identify inaccuracies, and to offer additional information regarding the data in their health records (NORC, 2014).

Direct patient access to diagnostic testing results is also important to patient engagement because diagnostic errors commonly occur within the testing steps of the diagnostic process (Gandhi et al., 2006; Schiff et al., 2009). In 2014, HHS strengthened patients’ rights to directly access their laboratory test results (HHS, 2014). Prior to the implementation of this regulation, an analysis found that only 3 in 10 laboratories allowed patients or their legal representatives access to their clinical test results (Swain and Patel, 2014). Similarly, the Mammography Quality Standards Act mandated the direct reporting of mammography results to patients with a summary of the report written in easily understood terms. A study found that direct reporting improved patient satisfaction with mammography and the timeliness of the results reporting, although it did not significantly reduce patient anxiety or improve patient adherence to the recommendations (Priyanath et al., 2002). Although there is some concern that providing patients direct access to diagnostic testing results before they consult with their clinician may not be appropriate in all cases (for example, for worrisome test results or for test results that patients may have difficulty in interpreting), there are a number of advantages to direct patient access, including reducing the likelihood that patients do not receive a test result and improving subsequent decision making and treatment (ASCP, 2014). Some organizations have implemented time delays to enable clinicians to communicate directly with patients before the patients access their diagnostic testing results electronically (Butcher, 2014).

Involvement of Patients and Families in Efforts to Improve Diagnosis

Patients and their families have unique insights into the diagnostic process, their health outcomes, and the occurrence of diagnostic errors (Etchegaray et al., 2014; Gertler et al., 2014; Schiff et al., 2014). Their perspectives are critical to identifying errors and near misses, especially ones that health care professionals may not be aware of, and they can also inform efforts to improve the diagnostic process (Gertler et al., 2014; Weingart et al., 2005). Thus, the committee recommends that health care professionals and organizations should identify opportunities to include patients and their families in efforts to improve the diagnostic process by learning from diagnostic errors and near misses. Some of the opportunities for learning include participation in root cause analyses and M&M conferences (Gertler et al., 2014; Zimmerman and Amori, 2007; Schiff et al., 2014; NSPF, 2015b).

For example, patients and family members may have information that is unavailable to health care professionals that can be used during a root cause analysis to identify contributors to a diagnostic error (Etchegaray et al., 2014). Participation in these events may also be satisfying to patients and their families, because they have an opportunity to help improve safety and reduce the chance of future errors (Zimmerman and Amori, 2007). However, it is important for health care organizations to tailor patient and family involvement according to individual needs and preferences and to be aware of the legal constraints to involving patients and families in these efforts.

Health care organizations can also create patient and family advisory councils and use their input to design more patient-centered diagnostic processes. Patient and family advisory councils may be involved in the development, implementation, or evaluation of new programs, the design of materials or tools to improve patient–clinician relationships, and other activities (AHRQ, 2014b). These councils can involve patients and families in the design of care and can leverage their experiences in order to implement patient-centered changes, including changes that may reduce diagnostic errors (Coulter et al., 2008; IOM, 2013a). For example, a patient and family advisory council at Inova Health System played a role in designing a shift-change procedure for nursing staff that could reduce the potential for errors related to care transitions (Friesen et al., 2013).

Health Care Professional Education & Training

There are indications that health care professionals may not receive adequate preparation to function optimally in the diagnostic process (Brush, 2014; Cate, 2014; Dhalliwal, 2014; Durning, 2014; Richardson, 2007; Trowbridge et al., 2013). Education and training-related challenges include methods that have not kept pace with advances in the learning sciences and an insufficient focus on areas critical to the diagnostic process, such as clinical reasoning, teamwork, communication, and the use of diagnostic testing and health IT. Because there is limited research on how education and training can affect diagnosis, the committee drew from a broader literature that included research on the impact of education and training in other areas of health care, in other industries, as well as submitted expert input to the committee. Education and training across the career trajectory plays an important role in improving the diagnostic process and reducing diagnostic errors and near misses. This section describes the challenges to health care professional education and training and presents the committee’s recommendation. Though the focus is on leveraging changes in education and training to improve diagnosis, recommended actions could also have broader impact on clinical practice. For example, ensuring that clinicians have clinical reasoning skills may also improve clinicians’ abilities to treat and manage patients’ health problems. Although this section’s emphasis is on diagnosticians, the challenges and solutions are relevant to many health care professionals who participate in the diagnostic process.

Educational Approaches

The learning sciences are an interdisciplinary field that studies learning methods and principles in an effort to understand how to optimize learning (Torre et al., 2006). The findings from this field—including the importance of developing deep conceptual understandings, participative learning, building on prior knowledge, the use of reflection, and appropriate learning environments—are relevant to health care professional education and training (Sawyer, 2006). For example, students often gain deeper knowledge when their learning involves activities that mimic those of professionals engaged in the relevant discipline, a learning style that has been described as “authentic practice” (Sawyer, 2008). The learning sciences have also found that some learning styles are better suited for some individuals than others (Dunn et al., 2002; Lujan and DiCarlo, 2006).

Health care professional education programs may not be adequately informed by advances in the learning sciences (Cooke et al., 2010; Rolfe and Sanson–Fisher, 2002). For example, programs may continue to emphasize memorization without helping students develop the deeper conceptual understandings that are needed to apply knowledge in novel, practice-based situations (Myers, 2013). This may result in them having difficulty diagnosing conditions in non-standard contexts, such as cases involving atypical presentations or comorbidities. Educational experts have asserted that there is a tendency to focus learning on prototypical and representational cases of disease, rather than on real-life presentations (AHRQ, 2010b; Papa, 2014). While this may be appropriate for the early stages of learning, students need exposure to actual patient cases, including atypical cases, in order to be prepared to diagnose disease in practice (Dhalliwal, 2014). Programs that delay student interaction with patients until the later stages of education also miss opportunities to provide students with authentic practice (Cate, 2014). Given the mismatch of training and practice environments, it may be challenging to provide students with authentic practice; for example, a majority of graduate medical education (GME) training occurs in inpatient settings, even though many physicians will work in outpatient settings (ACGME, 2015; Cooke et al., 2010; IOM, 2014; Josiah Macy Jr. Foundation, 2011). Some health care professional education programs may not be providing learners adequate opportunities to achieve expertise in diagnosis. For example, educators may attempt to teach students
Experts who provided input to the committee focused on the use of feedback to improve diagnostic performance and promote self-reflection (Schiff, 2014a; Singh, 2014; Trowbridge, 2014). Feedback is an integral part of continuous learning and can help health care professionals understand how well they are performing (Croskerry, 2000b). However, there are indications that current educational settings are not providing sufficient opportunities for learners to receive timely feedback, and students often perceive that they receive inadequate feedback (Hekelman et al., 1993; Milan et al., 2011; Nutter, 2001). Insufficient time for feedback, teacher reluctance to provide feedback, a lack of continuity in the learner–teacher relationship, and a lack of observation time necessary for feedback may all contribute to an inadequate focus on providing feedback (Bernard et al., 2011; Schiff, 2008).

A recent IOM report concluded that continuing education is also disconnected from theories of how adults learn and from the delivery of patient care (IOM, 2010). Many continuing education requirements and evaluations focus on achieving credit hours instead of on educational outcomes and competencies (IOM, 2009). The result is a continuing education system that does not meet the needs of health care professionals in practice; for example, didactic activities such as lectures are large components of continuing education, even though participatory learning opportunities may be more appropriate (Hager et al., 2008).

In light of these findings, the committee concluded that health care professional education and training needs to better reflect findings from the learning sciences. Thus, the committee recommends that educators should ensure that curricula and training programs across the career trajectory employ educational approaches that are aligned with evidence from the learning sciences. Given the heterogeneity of learners and the variety of educational objectives, it is important that educational programs consider the spectrum of learning sciences approaches when developing curricula and training opportunities. Although it is beyond the committee’s charge to recommend specific changes that should be made in health care professional education, the committee identified a number of opportunities for educators to consider. For example, programs may need to accommodate different learning styles, to include mechanisms to provide immediate feedback to learners (both positive and negative), to use CBE to assess performance, to increase the time allotted for clinical experience and patient interaction, and to place a larger emphasis on self-directed learning (Cooke et al., 2010; Hirsh et al., 2014; McLaughlin et al., 2014; Trowbridge, 2014).

It may also be necessary to develop more effective forms of instruction and instructional media (Mayer, 2010), including the use of simulation-based exercises (McGaghie et al., 2011; Patel et al., 2009a). Employing deliberate practice approaches that focus on “frequent practice, rapid feedback to understand and correct errors, and raising bars with new attempts” may also be helpful (Cate, 2014; Durning, 2014). Changes to GME could include replacing traditional discipline-specific block rotations with longitudinal integrated clerkships in order to improve relationship building skills, both interprofessionally and among patients and clinicians (Cate, 2014; Teherani et al., 2013; Thibault, 2013). In addition, the IOM report The Future of Nursing: Leading Change, Advancing Health recommended the development and implementation of nursing residency programs to facilitate nurses’ transition to practice and to ensure that nurses develop the knowledge and skills to deliver safe, high-quality care (IOM, 2011a). This report also emphasized the importance of developing an expectation for lifelong learning.

A number of academic institutions have implemented changes in their health professional programs, including a major shift toward incorporating more authentic practice. For example, most medical schools have introduced clinical practice experience much earlier in their curriculum, rather than delaying this experience until after students have completed the basic sciences training. Programs are also experimenting with innovative ways to help students develop a deeper conceptual understanding of human biology and disease, including an increased emphasis on individualized learning, self-teaching and assessment, and an exposure to more and varied cases of disease (OHSU, 2014). Northwestern University’s Feinberg School of Medicine is adopting CBE, removing time requirements for degree completion, and moving from lecture-based instruction to small group and practice-based learning (Feinberg School of Medicine, 2015).

There is a growing recognition of the need to better align training and practice environments. For example, the Health Resources and Services Administration’s Teaching Health Center Graduate Medical Education program is providing more opportunities for authentic practice by funding community-based primary care residency programs (HRSA, 2015). The IOM report Graduate Medical Education that Meets the Nation’s Health Needs concluded that the Medicare GME payment system discourages physician training outside of the hospital setting and may not provide graduates the skills necessary for office-based practice, even though most are likely to practice in community settings (IOM, 2014). In addition, The Future of Nursing report highlighted the need to develop nursing expertise outside of hospital-based care settings. Because of the aging of the population...

The evaluation of students may need to be better aligned with best practices from the learning sciences. Some health care professional schools rely on training time as a means of evaluating student performance, but it has been suggested that competency-based evaluation (CBE), which evaluates students based on their competency in certain areas, may be a better method because it is a better predictor of future performance (Holmboe et al., 2010). CBE is still in development, however, and there is some disagreement about using it exclusively to assess learners’ abilities. There is limited evidence connecting CBE to improvements in student learning, and it is difficult to assess certain characteristics, such as professionalism, through a competency-based approach (Jarvis–Selinger et al., 2012; Lurie, 2012; Morcke et al., 2013).

A number of methods to assess competency have been proposed, including written and computerized testing, performance appraisals, medical record reviews, and simulations; some methods may be better suited for assessing specific competencies than others (Kak et al., 2001). Psychometric testing methods such as multiple choice and vignette based exams have been used to evaluate clinicians’ medical knowledge, though they often do not capture key aspects of clinical reasoning that contribute to diagnostic expertise (Holmboe and Durning, 2014). Given the importance of clinical reasoning to practice, there is now a growing movement to develop assessment methods that are better able to evaluate clinical reasoning competencies (ABIM, 2014; Holmboe and Durning, 2014). For example, the American Board of Internal Medicine’s Assessment 2020 Initiative is focused on improving cognitive assessment in internal medicine. It is evaluating the role of computer-based clinical simulations, in which a simulated patient’s condition changes as clinicians make decisions in the diagnostic and treatment processes (ABIM, 2015). Oral exams, such as chart stimulated recall and case-based discussions, as well as audio and video reviews of actual clinical encounters have also been suggested as assessment methods for clinical reasoning (Holmboe and Durning, 2014). Simulation exercises have been used to assess teamwork skills and communication competencies (Scalese et al., 2008).

Experts who provided input to the
and the shift from hospital-based to community-based care settings, there is a greater “need for nursing expertise in chronic illness management, care of older adults in home settings, and transitional services” (IOM, 2011a, p. 121).

Though many programs are beginning to initiate changes that better align with current knowledge about health care professional education, a larger focus on aligning education with the learning sciences is warranted across the career trajectory. This includes a focus on continuing education to ensure that individuals maintain and continue to develop the competencies necessary for the diagnostic process. Models of continuing education that are competency based or that focus on quality improvement have been proposed and may improve the effectiveness of continuing education (Campbell et al., 2010; Sho詹ia et al., 2012).

The Diagnostic Process

Improving the content of health care professional education can improve diagnostic performance and reduce the potential for diagnostic errors and near misses. Thus, the committee recommends that educators should ensure that curricula and training programs across the career trajectory address performance in the diagnostic process. The committee identified a number of areas of performance that could be improved. These are:

- Clinical reasoning
- Teamwork
- Communication with patients, their families, and other health care professionals
- Appropriate use of diagnostic tests and the application of these results on subsequent decision-making
- Use of health IT

Clinical Reasoning

Clinical reasoning, including diagnostic decision-making, is underemphasized in current health care professional education and training (Cate, 2014; Graber et al., 2012; IOM, 2011a; Richardson, 2014; Stark and Fins, 2014; Trowbridge et al., 2013). This lack of focus on clinical reasoning and on the development of critical thinking skills throughout the education process is a contributor to diagnostic error (Brush, 2014; Cate, 2014; Durning, 2014; Richardson, 2007). A recent study found that a majority of the academic difficulties that medical students face “are of a cognitive nature and include difficulties in clinical reasoning” (Audétat et al., 2012, p. 217). Poor performance in clinical reasoning is generally discovered during later stages of training, which makes remediation more difficult (Audétat et al., 2012; Hauer et al., 2007).

In recognition of the importance of clinical reasoning in health care professional education, the Medical College Aptitude Test (MCAT) recently added a critical analysis and reasoning skills section (AAMC, 2015a).

Health care professionals have an ethical responsibility to improve clinical reasoning skills in order to improve diagnostic performance and avert diagnostic errors (Stark and Fins, 2014). Thus, educators need to ensure that students receive education and training opportunities that develop these skills—both “fast” system 1 processes and “slow” system 2 processes (Brush, 2014; Cate, 2014; Durning, 2014; Richardson, 2014). The development of clinical reasoning includes critical thinking skills such as analysis, evidence evaluation, and interpretation (Papp et al., 2014). Opportunities to improve clinical reasoning include instruction and practice on how to develop and refine a differential diagnosis and a focus on developing probabilistic reasoning skills and also an understanding of likelihood ratios (Brush, 2014). Students also need feedback and training in self-assessment and cognitive reflection in order to identify mistakes in their clinical reasoning and to assess their diagnostic performance. Without this, they may have trouble with calibration, or the development of an accurate sense of one’s diagnostic abilities. Poor calibration contributes to clinician overconfidence and diagnostic errors (Berner and Graber, 2008; Croskerry and Norman, 2008; Yang et al., 2012; Meyer et al., 2013).

The success of diagnostic reasoning often depends on one’s knowledge base of disease and the accompanying illness scripts (Cate, 2014; Durning, 2014; Norman et al, 2014). Students need this wide knowledge base, especially to develop “fast” system 1 processes that rely on pattern recognition. However, there are concerns that the exposure that students receive to disease cases, actual or simulated, is inadequate to develop effective diagnostic decision making based on pattern recognition (Cate, 2014; Dhaliwal, 2014; Eva, 2005; Norman et al, 2014; Trowbridge et al., 2013). Early clinical experience, either through simulations or with patients, as well as an exposure to a variety of cases, including atypical cases, can help develop this knowledge base (Cate, 2014; Papa, 2014b; Richardson, 2014).

Equally important, students need to understand and become comfortable with the uncertainty that is inherent in the diagnostic process (Durning, 2014; Kassirer, 1989). Developing a better sense of and comfort with uncertainty may help clinicians avoid diagnostic errors related to premature closure as well as inappropriate use of diagnostic testing. Improved understanding of diagnostic uncertainty can help clinicians make decisions about whether further diagnostic testing or treatment is warranted. This could also facilitate improved collaboration with other health care professionals and better communication with patients and their families about the nature of a working diagnosis.

Case Study

Carolyn came to the ED with chest pain, nausea, sweating and radiating pain through her left arm, which are often considered classic symptoms of a heart attack. The ED clinicians ordered an EKG, blood tests, a chest X-ray, and a treadmill stress test; all of these tests came back normal. Her ED clinician diagnosed her as having acid reflux, noting she was in the right demographic for this condition. When she asked the ED doctor about the pain in her arm, he was dismissive of the symptom. Privately, a nurse in the ED asked Carolyn to stop asking questions of the doctor, noting that he was a very good doctor and didn’t like to be questioned.

Carolyn was released from the hospital less than 5 hours after the onset of her symptoms, feeling embarrassed about making a “big fuss” over a relatively common condition. Over the next 2 weeks, she developed increasingly debilitating symptoms, which prompted her return to the ED where she received a diagnosis of significant heart disease. Carolyn had a myocardial infarction caused by 99 percent blocked artery—what clinicians still call the “widow maker” heart attack.

Students also need exposure to easy-to-miss diagnoses and common causes of diagnostic error (Graber et al., 2012). This includes a focus on the work system factors that can contribute to diagnostic errors, such as communication and collaboration challenges among diagnostic team members; health IT tools that are not supportive of clinical reasoning activities; cultural, organizational, and physical environmental factors; and the impact of reporting, medical liability, and payment.

In addition, there also needs to be a focus on heuristics (mental shortcuts) and biases, which play a role in clinical reasoning and present a major challenge to diagnosis (Croskerry, 2003a, 2009, 2014; Eva and Norman, 2005; Kahneman, 2011; Klein, 1993). Education and training that focuses on the cognitive heuristics and biases that can affect diagnosis and on how to counteract their effects are particularly important. Debiasing strategies, such as engaging in metacognition (i.e., critically thinking about one’s thinking, reasoning, and decision-making) have been proposed as a means to address the negative effect that heuristics can have on
reasoning skills as a lifelong competency. There are educational strategies that could receive more attention include decision making. A number of debiasing strategies have been proposed, including considering the opposite, debiasing through awareness of bias, becoming aware of what one does not know, and others (Hirt and Markman, 1995; Hodges et al., 2001; Mummia and Steven, 1995; Mussweiler et al., 2000; Redelmeier, 2005). There is some debate about the effectiveness and feasibility of debiasing strategies (Cate, 2014; Norman et al., 2014); for example, monitoring every decision to ensure that no bias has occurred would be inefficient since heuristics work most of the time. However, because heuristics tend to fail in predictable ways, it is possible to determine the types of situations in which some heuristics are likely to lead to error. For example, heuristic failure is likely to occur in the emergency medicine setting, given that this environment is highly complex, inconstant, and uncertain, and that emergency clinicians often work under time constraints that force them to rely heavily on heuristics (Croskerry, 2000a, 2002a). Given the susceptibility of this environment to heuristics failure, several proposed solutions focus on the use of debiasing strategies in emergency medicine (Croskerry, 2000a, 2002; Pines, 2006). Additional strategies to reduce errors related to heuristics and biases include a greater focus on the development of expertise, offering clinicians more realistic training settings, providing decision support tools, and ensuring that the work system in which the diagnostic process occurs better supports decision making (Eva and Norman, 2005; Gigerenzer, 2000; Gigerenzer and Goldstein, 1996; Marewski and Gigerenzer, 2012; Wegwarth et al., 2009; Weed and Weed, 2014). Because there is uncertainty regarding which strategies are best at reducing the impact of bias on diagnostic decision-making, it is an area that needs further research (Croskerry et al., 2013a, 2013b).

Several medical programs have begun offering clinical reasoning courses. For example, Dalhousie University offers a critical thinking course for medical students that teaches how decision making occurs, discusses cognitive biases and potential debiasing strategies, and provides students with tools for improved self-assessment and critical thinking development (Dalhousie University, 2015). Dalhousie also offers an online faculty development course to improve the education and training that medical students receive. Developing clinical reasoning skills is important for practicing health care professionals who are beyond formal education and training settings. Continuing health care professional education can be leveraged to develop clinical reasoning skills as a lifelong competency. There are several continuing education opportunities available that focus on clinical reasoning and diagnosis, but a greater focus on them is needed (Cruet al., 2009).

**Teamwork and Communication**

Despite widespread attention to the importance of teamwork skills, health care professionals are not adequately prepared to employ these skills in practice (IOM, 2014; Patel et al., 2009a; Pecukonis et al., 2008; Schmitt et al., 2011). The focus in this report on improving education and training in teamwork skills builds upon earlier IOM work. For example, the study on continuing education concluded that professional development activities should ensure that health care professionals are proficient in the collaborative skills required for team-based care (IOM, 2010), and another study highlighted the need for transforming nursing education in order to prepare nurses to engage other health care professionals in a collaborative manner (IOM, 2011a). In addition, the IOM recently highlighted the importance of evaluating inter-professional education approaches, and made recommendations on generating evidence to better identify successful inter-professional education practices (IOM, 2015).

Several leading organizations have concluded that inter-professional and teamwork training opportunities have been slow to materialize (Josiah Macy Jr. Foundation and Carnegie Foundation for the Advancement of Teaching, 2010). Barriers to teamwork and team-based education include “logistical challenges inherent in coordinating between two or more autonomous health professions schools, deep-rooted cultural differences between the health professions, differences in the educational curricula and pathways of the various health professions, and issues around program sustainability and funding” (Josiah Macy Jr. Foundation and Carnegie Foundation for the Advancement of Teaching, 2010, p. 3).

Academic institutions and training programs are beginning to offer more opportunities for health care professionals to improve their teamwork skills. As of 2012, 76 percent of medical schools required students to participate in inter-professional education (AAMC, 2015b). The goals of the inter-professional education programs varied, but most aimed to familiarize students with the roles of other health care professionals (89 percent) and to teach students teamwork skills (76 percent) (AAMC, 2015b). Educational settings also varied, with schools offering training in classroom programs (77 percent), simulation center programs (60 percent), and clinical practice settings (44 percent) (AAMC, 2015b).

For example, the University of Virginia’s Center for Academic and Strategic Partnerships for Inter-professional Research and Education offers workshops and clinical programs to improve teamwork skills and provides workshops for clinician-educators. Other programs offer courses taught jointly with students from both nursing and medical schools, provide interdisciplinary team-based training for the care of individuals with advanced illness, and use interactive interdisciplinary Web-based learning modules (Josiah Macy Jr. Foundation and Carnegie Foundation for the Advancement of Teaching, 2010). Academic centers have also been implementing simulation-based team training opportunities, which have shown promise in improving team performance and in the development of teamwork skills (Patel et al., 2009b). Although these efforts are encouraging, the committee concluded that a much greater emphasis on developing teamwork skills is needed. Rather than each program developing its own curriculum on an ad hoc basis, health care professional educators could collaborate in the development of curricula and training opportunities in teamwork.

An important teamwork skill in diagnosis is communication with patients, their families, and other health care professionals. Communication failures between health care professionals are recognized as a leading cause of patient harm and error, while poor communication between clinicians and patients is recognized as a barrier to accurate and timely diagnoses (AHRQ, 2008a; IHC, 2011). Although interpersonal communication skills are listed as a competency by the Accreditation Council for Graduate Medical Education (ACGME) and most medical specialty boards recognize communication as a core competency for practice, these skills may not be taught to students in a focused and standardized manner (Rider and Keefer, 2006). Health care professionals need to receive training in interpersonal communication skills to ensure that they can function effectively in teamwork settings. For example, one study found that students receiving communication training exhibited improved communication skills, such as relationship building and shared decision-making (Yedidia et al., 2003). Effective communication training programs tend to last at least a day, to involve feedback, and to include role play and small group discussions (Berhorn et al., 2011). Tools to improve communication among health care professionals, such as the Situation-Background-Assessment-Recommendation Tool, help clinicians convey the most important information in an organized manner (Haig et al., 2006; Leonard et al., 2004).

Health care professionals also need training in how to communicate openly and effectively with patients and their families. This training may include an emphasis on basic communication skills and also on topics such as communication with patients who are perceived as difficult, culturally and linguistically appropriate communication, interviewing techniques, history-taking skills, and delivering difficult diagnoses (Smith and Longo, 2012; AHRQ, 2015b). Other relevant strategies that could receive more attention include...
the teach-back method described in the patient engagement section of this chapter, encouraging questionsfrom patients, and responding to patient emotions. In recognition of the importance of patient–clinician communication, a number of schools have implemented curricula designed to improve this communication (Georgetown University, 2015; University of Pittsburgh, 2015). Outside of formal education settings, health care organizations can play a role in improving teamwork performance through team-based training practices (Salas et al., 2008). For example, a recent literature review found “moderate-to-high-quality evidence suggesting team-training can positively impact healthcare team processes and, in turn, clinical processes and patient outcomes” (Weaver et al., 2014, p. 369). A training program designed by the Department of Defense and the Agency for Healthcare Research and Quality (AHRQ), Team Strategies and Tools to Enhance Performance and Patient Safety (TeamSTEPPS), has been used to improve teamwork in health care environments by increasing team awareness, clarifying roles and responsibilities, improving information sharing, and building efficient teams that optimize people and information to provide high quality care (AHRQ, 2015a; Straus et al., 2014). The system is at various stages of implementation in numerous facilities throughout the Military Health System (King et al., 2008). In recent years, AHRQ has launched a nationwide implementation program that trains master trainers to work with health care organizations interested in implementing TeamSTEPPS.

**Diagnostic Testing**

Diagnostic testing has become an integral component of the diagnostic process, yet medical school curricula have not kept pace with the advances in diagnostic testing and with how these advances affect diagnosis (Hallworth, 2011; Laposata and Dighe, 2007; Smith et al., 2010). A 2009 report from the Centers for Disease Control and Prevention on laboratory medicine noted that there is inadequate attention and emphasis on laboratory testing in the medical school curriculum, even though it plays a central role in medical practice (CDC, 2009). Another survey detailed the lack of emphasis on laboratory medicine within medical training programs: Although approximately 78 percent of medical schools require coursework in laboratory medicine, the median time dedicated to this topic is 12.5 hours, not including exposure to laboratory medicine gained through clinical rotations. However, training during clinical rotations is problematic because it is not standardized and may rely on clinician–educators who do not have an adequate background in laboratory medicine (Smith et al., 2010). Many of the processes within laboratory medicine—such as ordering the correct tests, understanding test performance characteristics (sensitivity and specificity), and interpreting test results and, subsequently, making decisions—cannot be addressed using the teaching methods that many programs employ (Wilson, 2010).

The shortcomings in laboratory medicine education are well recognized by clinicians. According to several surveys, clinicians and students report feeling uncertain about which tests to order because of naming conventions, unfamiliarity with the available tests, and the rapid development of new diagnostic tests (Hickner et al., 2014; Laposata and Dighe, 2007). One of the largest sources of error in the test-ordering phase is health care professionals requesting an incorrect test (Laposata and Dighe, 2007). Clinicians order laboratory tests in 31.4 percent of primary care visits, however, they report uncertainty when ordering tests 14.7 percent of the time and confusion about interpreting results in 8.3 percent of the cases where they ordered tests (Hickner et al., 2014). There is also uncertainty among clinicians about applying test results to subsequent decision making, such as refining or expanding a differential diagnosis, determining the likelihood that a patient has a specific diagnosis on the basis of a positive or negative test result, deciding whether retesting or ordering new tests is appropriate, and beginning appropriate treatment. There are indications that students and practicing clinicians struggle with concepts like sensitivity and specificity and lack an understanding of how disease prevalence contributes to making decisions about a patient’s diagnosis (Kroenke, 2013; Manrai et al., 2014; Ross, 2014). In a small survey of health care professionals, three-quarters of respondents failed to correctly calculate the positive predictive value of a test result for a specific disorder (Manrai et al., 2014). Similar surveys completed several decades ago found that many health care professionals had trouble applying statistical methods and understanding statistical concepts, suggesting that this may be a longstanding gap in health care professional education (Casscells et al., 1978; Berwick et al., 1981). Another study found that medical students are generally able to describe Bayes theorem but are subsequently unable to apply this theorem to clinical practice (Bergus et al., 2004). These educational gaps negatively affect a clinician’s ability to appropriately assign and update diagnostic probabilities in light of test findings.

In addition, there are concerns about an inadequate focus on anatomic pathology in medical education (Magid and Cambor, 2012). While aspects of anatomic pathology are covered in the medical school curriculum, the amount has decreased significantly over the years, particularly as medical schools have adopted integrated curricula (Talbert et al., 2009; Taylor et al., 2008). An inadequate understanding of anatomic pathology may negatively affect clinical decision making and the diagnostic process. For example, inadequate understanding of the mechanisms underlying inflammation might affect the ability to recognize diseases or disease processes and the selection of appropriate treatment to address inflammation. In addition, students may not understand the limitations of certain anatomic pathology tests (e.g., the limited sensitivity of Pap smears) and how to collect, prepare, and transport specimens (Magid and Cambor, 2011).

The use of medical imaging as a diagnostic tool has also increased substantially, and for many symptoms, medical imaging has become an integral part of the diagnostic process. Although many clinicians request medical imaging for their patients, the ordering of this imaging and the application of medical imaging interpretations to subsequent decision making are not emphasized in the medical school curriculum and subsequent training (Kondo and Swerdlow, 2013; Rubin and Blackham, 2015). Errors in imaging can occur during all phases of the process, from the ordering and selection of medical imaging to the interpretation of results and subsequent decision making. The majority of allopathic and osteopathic medical schools do not have a focused course on medical imaging, and medical imaging rotations are required in only 29 percent of medical schools (Rubin and Blackham, 2015). Typically, for most medical students medical imaging instruction is integrated into other coursework or clinical rotations in a very limited fashion (Kondo and Swerdlow, 2013; Rubin and Blackham, 2015). The teaching of important concepts in medical imaging, such as the scientific principles of imaging techniques, radiation safety, modality differences, and the use of contrast materials, is limited (Rubin and Blackham, 2015). A recent survey of fourth-year medical school students noted that the majority of students underestimated the risks associated with medical imaging techniques and were not informed about the American College of Radiology Appropriateness Criteria (Prezzia et al., 2013; Rubin and Blackham, 2015). Many medical schools do not follow the radiology-dedicated curriculum designed by the Alliance of Medical School Educators in Radiology (Rubin and Blackham, 2015).

Thus, health care professionals need improved education and training on the appropriate use of diagnostic tests and the application of these results to subsequent decision making. The committee recognizes that, given the growing number and complexity of the options available, it is not feasible to expect that clinicians will be familiarized with every available diagnostic test procedure. Therefore, in addition to improved education in diagnostic testing, improved collaboration among treating clinicians and pathologists and radiologists is warranted. Education and training
focused on how to most effectively convey findings from pathologists and radiologists to treating clinicians may alleviate some of the challenges clinicians face with respect to understanding results and subsequent decision making.

Health Information Technology

Health IT is an important component of the diagnostic process, including the involvement of EHRs, laboratory and medical imaging information systems, and decision support tools. As health IT becomes increasingly integrated into all aspects of health care, clinicians will likely rely more on it to facilitate diagnostic decision making and communication and collaboration among health care professionals and patients (Thibault, 2013). Thus, clinicians need to develop competencies in the use of health IT tools; however, many health care professionals do not receive adequate education and training in the use of health IT (Graber et al., 2012; McGowan et al., 2007). Individuals who lack competencies in health IT use will be unable to take advantage of these opportunities to improve diagnosis and reduce diagnostic error. Training health care professionals to work with health IT has been found to be a major challenge (NIST, 2010). In an effort to address this, the Office of the National Coordinator has been working with licensing bodies and medical societies to better integrate health IT into the medical education curriculum (Buntin et al., 2010). The Patient Protection and Affordable Care Act includes provisions to incorporate health IT training into the education of primary care clinicians (Buntin et al., 2010). The IOM report Health IT and Patient Safety also emphasized the importance of improving workforce education and training on safe health IT use, using mechanisms such as formal education and postgraduate training as well as health care organization-facilitated training (IOM, 2012d).

Ensuring Competency in the Diagnostic Process

In addition to improving the content and teaching methods for health care professional education and training, oversight processes can help ensure that individuals achieve and maintain competency in the diagnostic process, including clinical reasoning, teamwork, communication, and the use of diagnostic testing and health IT. Health care professional oversight processes include education and training program accreditation, licensure, and certification. These oversight processes act as levers to induce change in the health care system: “Educational accreditation serves as a leverage point for the inclusion of particular educational content in a curriculum. Licensure assesses that a student has understood and mastered formal curricula. Certification ensures that a practitioner maintains competence in a given area over time” (IOM, 2003a, p. 5). The committee received input suggesting that accreditation, licensure, and certification processes can be introduced to help ensure that health care professionals possess diagnostic competencies throughout the career trajectory (Brush, 2014; Papa, 2014a, 2014b).

Organizations that accredit health care professional education and training programs can use their accreditation requirements as a mechanism to ensure that these programs include appropriate curricular content to prepare students in the areas of the diagnostic process that the committee has articulated. Accreditation organizations for all levels of health care professional education and training—i.e., undergraduate, graduate, and continuing education—need to address diagnostic competencies. Many accreditation organizations already include skills important for diagnostic performance in their accreditation requirements, but these organizations can make competencies in the diagnostic process a larger priority within their requirements. For example, the IOM report The Future of Nursing: Leading Change, Advancing Health recommended that the “Commission on Collegiate Nursing Education [CCNE] and the National League for Nursing Accrediting Commission [NLNAC] should require that all nursing students demonstrate a comprehensive set of clinical performance competencies that encompass the knowledge and skills needed to provide care across settings and the lifespan” (IOM, 2011a, p. 282). Building on this recommendation, the CCNE and NLNAC could require nursing schools to offer inter-professional collaboration education and training opportunities focused specifically on the diagnostic process and the role of teams in achieving diagnostic accuracy. The Liaison Committee on Medical Education (LCME) and the ACGME include diagnostic competencies in accreditation requirements. For example, the LCME requires medical education programs to prepare students to “recognize and interpret symptoms and signs of disease” and “develop differential diagnoses and treatment plans” (LCME, 2015, p. 10). The ACGME and the American Board of Medical Specialties (ABMS) have identified six core competencies that all physicians should acquire during residency and fellowship programs and should maintain throughout practice (ACGME, 2015). The ACGME is beginning to use milestones to evaluate performance on these competencies; several of these competencies are applicable to those the committee articulated (Nasca et al., 2012). For example, the ACGME requires that participating programs provide their students with opportunities to develop the skills necessary for lifelong, self-motivated learning; communication with patients, families, and other health care professionals; and a systems understanding of health care, including the importance of coordination and inter-professional and intra-professional teamwork (ACGME, 2015).

Organizations responsible for health care professional licensure and certification can help ensure that individual health care professionals have achieved and maintain competency in the skills essential for diagnosis. For example, the United States Medical Licensing Exam for physicians and the Uniform Licensure Requirements for practicing nurses could emphasize diagnostic competencies tailored to the scope of work of these professions (NCSBN, 2015). The ABMS, which grants board certification in more than 150 medical specialties and sub-specialties, could ensure competencies in the diagnostic process in both initial board certification and in the maintenance of certification efforts. For example, some specialty boards have begun assessing clinical reasoning skills through cognitive knowledge testing that requires clinicians to evaluate clinical scenarios in addition to content knowledge (Graber et al., 2012). Initial certification of health care professionals is important, but it may be insufficient to ensure sustained diagnostic competency throughout the career trajectory. Due to advances in the biomedical sciences, the knowledge required to maintain competency is rapidly growing; at the same time health care professionals may also experience knowledge decay or the loss of previously learned knowledge (Cassel and Holmboe, 2008; IOM, 2013a; Su et al., 2000). Thus, many health care professional organizations, such as ABMS and the American Association of Physician Assistants, have developed renewal and maintenance of certification (MOC) programs (AAPA, 2015; ABMS, 2015). Though there has been controversy surrounding MOC, recent evidence suggests that it can improve performance (Iglehart and Baron, 2012; O’Neill and Puffer, 2013; Teirstein, 2015). Meaningful and effective continuing education is important for all clinicians, and MOC efforts can ensure that clinicians have the appropriate competencies in the diagnostic process throughout the career trajectory. Many health care organizations now require MOC as a precondition for renewing staff privileges. Other licensure and certification organizations, including those for other health care professions, can also emphasize competency in the diagnostic process.

The committee concluded that oversight organizations, including accreditation organizations and professional licensure and certification bodies, can play an important role in improving diagnostic performance. Thus, the committee recommends that health care professional certification and accreditation organizations should ensure that health care professionals have and maintain the competencies needed for effective performance in the diagnostic process, including:

- Clinical reasoning
- Teamwork
- Communication with patients, their families, and other health care professionals
- Appropriate use of diagnostic tests and the application of these results on subsequent...
Design of Health IT for the Diagnostic Process

The design of health IT has the potential to support the diagnostic process. In particular, by supporting the individuals involved in the diagnostic process and the tasks they perform, health IT may improve diagnostic performance and reduce the potential for diagnostic errors. The increasing complexity of health care has required health professionals to know and apply vast amounts of information, and these demands are outstripping human cognitive capacity and contributing to challenges in diagnosis. El-Kareh et al. (2013, p. ii40) asserted that “[u]naired clinicians often make diagnostic errors” because they are “[v]ulnerable to fallible human memory, variable disease presentation, clinical disease processes plagued by communication lapses, and a series of well-documented “heuristics,” biases and disease-specific pitfalls.” It is widely recognized that health IT has the potential to help health professionals address or mitigate these human limitations.

Although health IT interventions are not appropriate for every quality-of-care challenge, there are opportunities to improve diagnosis through appropriate use of health IT. For instance, a well-designed health IT system can facilitate timely access to information; communication among health care professionals, patients, and their families; clinical reasoning and decision making; and feedback and follow-up in the diagnostic process (El-Kareh et al., 2013; Schiff and Bates, 2010). Table 2 describes a number of opportunities to reduce diagnostic errors through the use of health IT. The range of these suggestions is broad; some are pragmatic opportunities for intervention and others are more visionary, given the limitations of today’s health IT tools.

A number of researchers have identified patient safety risks that may result from poorly designed health IT tools (Harrington et al., 2011; IOM, 2012a; Meeks et al., 2014; Sittig and Singh, 2012; Walker et al., 2008). In recognition of these risks, the 2012 IOM report described the key attributes of safe health IT, including (IOM, 2012a, p.78):

- Easy retrieval of accurate, timely, and reliable native and imported data
- A system the user wants to interact with
- Simple and intuitive data displays
- Easy navigation
- Evidence at the point of care to aid decision making
- Enhancements to work-flow, automating mundane tasks, and streamlining work, never increasing physical or cognitive workload
- Easy transfer of information to and from other organizations and clinicians
- No unanticipated downtime

If health IT products do not have these features, it may be difficult for users to effectively interact with the technology, contributing to workarounds (alternate pathways to achieve a particular functionality) or unsafe uses of the technology, as well as errors associated with the correct use of the technology. Although many of these risks apply to health care broadly, the committee concluded that health IT risks are particularly concerning for the diagnostic process. Poor design, poor implementation, and poor use of health IT can impede the diagnostic process at various junctures throughout the process. For instance, a confusing or cluttered user interface could contribute to errors in information integration and interpretation that result in errors in diagnosis. Poor integration of health IT tools into clinical work-flow may create cognitive burdens for clinicians that take time away from clinical reasoning activities.

To ensure that health IT supports patients and health care professionals in the diagnostic process, collaboration between the federal government and the health IT industry is warranted. The 2012 IOM report concluded that the safety of health IT is a shared responsibility and described the ways in which health IT vendors, users, governmental agencies, and others can collaborate to improve the safety of health IT. For example, by working with users, health IT vendors can work to improve safety during all phases of the design of their products, from requirements gathering to product testing. In addition, the report called on the Office of the National Coordinator for Health Information Technology (ONC) to expand funding for processes that promote safety in the development of health IT products (IOM, 2012a). In line with these recommendations, the committee recommends that health IT vendors and ONC should work together with users to ensure that health IT used in the diagnostic process demonstrates usability, incorporates human factors knowledge, integrates measurement capability, fits well within clinical work-flow, provides clinical decision support, and facilitates the timely flow of information among patients and health care professionals involved in the diagnostic process.

Collaboration among health IT vendors, ONC, and users can help to identify best practices in the design, implementation, and use of health IT products used in the diagnostic process. Further research in designing health IT for the diagnostic process is also needed. The sections below describe the importance of these various features in the design of health IT for the diagnostic process. The committee did not want to impose specific requirements for how this recommendation is implemented, because the approach would be too proscriptive. The committee’s recommendation emphasizes that collaboration is needed among the health IT vendor community, ONC, and users, and it outlines the essential characteristics of health IT.
<table>
<thead>
<tr>
<th>Role for Electronic Documentation</th>
<th>Goals and Features of Redesigned Systems</th>
</tr>
</thead>
<tbody>
<tr>
<td>Providing access to information</td>
<td>Ensure ease, speed, and selectivity of information searches; aid cognition through aggregation, trending, contextual relevance, and minimizing of superfluous data.</td>
</tr>
<tr>
<td>Recording and sharing assessments</td>
<td>Provide a space for recording thoughtful, succinct assessments, differential diagnoses, contingencies, and unanswered questions; facilitate sharing and review of assessments by both patient and other clinicians.</td>
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<tr>
<td>Maintaining dynamic patient history</td>
<td>Carry forward information for recall, avoiding repetitive patient querying and recording while minimizing copying and pasting.</td>
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<tr>
<td>Maintaining problem lists</td>
<td>Ensure that problem lists are integrated into workflow to allow for continuous updating.</td>
</tr>
<tr>
<td>Tracking medications</td>
<td>Record medications that the patient is actually taking, patient responses to medications, and adverse effects in order to avert misdiagnoses and ensure timely recognition of medication problems</td>
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<tr>
<td>Tracking tests</td>
<td>Integrate management of diagnostic test results into note workflow to facilitate review, assessment, and responsive action as well as documentation of these steps.</td>
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<tr>
<td>Ensuring coordination and continuity</td>
<td>Aggregate and integrate data from all care episodes and fragmented encounters to permit thoughtful synthesis.</td>
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<tr>
<td>Enabling follow-up</td>
<td>Facilitate patient education about potential red-flag symptoms; track follow-up.</td>
</tr>
<tr>
<td>Providing feedback</td>
<td>Provide checklists to minimize reliance on memory and directed questioning to aid in diagnostic thoroughness and problem solving.</td>
</tr>
<tr>
<td>Providing placeholder for resumption of work</td>
<td>Delineate clearly in the record where clinician should resume work after interruption, preventing lapses in data collection and thought process.</td>
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<tr>
<td>Calculating Bayesian probabilities</td>
<td>Embed calculator into notes to reduce errors and minimize biases in subjective estimation of diagnostic probabilities.</td>
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<tr>
<td>Providing access to information sources</td>
<td>Provide instant access to knowledge resources through context-specific “infobuttons” triggered by keywords in notes that link user to relevant textbooks and guidelines</td>
</tr>
<tr>
<td>Offering second opinion or consultation</td>
<td>Integrate immediate online or telephone access to consultants to answer questions related to referral triage, testing strategies, or definitive diagnostic assessments.</td>
</tr>
<tr>
<td>Increasing efficiency</td>
<td>More thoughtful design, workflow integration, and distribution of documentation burden could speed up charting, freeing time for communication and cognition.</td>
</tr>
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</table>

to improve diagnosis and reduce diagnostic errors. Users include a wide variety of clinicians (such as treating health care professionals and clinicians with diagnostic testing expertise), as well as patients and their families (HIMSS, 2014).

Usability and Human Factors

The potential benefits of health IT for improving diagnosis cannot be realized without usable, useful health IT systems. Usability has been defined as “the extent to which a product can be used by specified users to achieve specified goals with effectiveness, efficiency, and satisfaction in a specified context of use” (ISO, 1998). According to the Healthcare Information Management Systems Society (HIMSS), a system exhibits good usability when it is “easy to use and effective. It is intuitive, forgiving of mistakes and allows one to perform necessary tasks quickly, efficiently and with a minimum of mental effort. Tasks which can be performed by the software . . . are done in the background, improving accuracy and freeing up the user’s cognitive resources for other tasks” (HIMSS, 2009, p. 3).

Recent discussions of usability have focused on the importance of incorporating design principles that take human factors into account (Middleton et al., 2013). A number of terms have been used to describe the optimal design approach, including human-centered design, user-centered design, use-centered design, and participatory design. The committee opted for the more inclusive term, human-centered design, to describe how the involvement of all stakeholders, rather than just users, is affected by the health IT system. A human-centered design approach balances the requirements of both the technical system of computers and software with the larger socio-technical system (Gasson, 2003). Although some health IT vendors have adopted human-centered design principles, the practice is not universal (AHRQ, 2010). Furthermore, usability challenges may be an emergent property that only becomes evident after the system was implemented or after it was in widespread use. Accordingly, it is important to make continuous improvements to the design, implementation, and use of health IT (Carayon et al., 2008).

Although clinicians have reported a high level of use and satisfaction with certain health IT features, such as electronic prescribing (Makam et al., 2013), a number of challenges with usability remain, and the National Institute of Standards and Technology has indicated that usability is often overlooked in the adoption of EHR systems (NIST, 2015). Health IT that is not designed and implemented to support the diagnostic process can increase vulnerability to diagnostic errors. The American Medical Association (AMA) recently released a statement that health IT is misaligned with the cognitive and workflow requirements of medicine and listed eight priorities for improving the usability of EHRs (AMA, 2014). A major issue related to health IT is how it will affect the patient–clinician relationship. The hope is that health IT will enhance patient and clinician communication by, for example, improving the collaboration and engagement between them by facilitating patient access to health information and clinical visit notes. However, this needs to be facilitated by health IT tools that assist patients and their families in engaging in the diagnostic process. As discussed in Recommendation 1, patient access to clinical notes is critical, but it is hoped that health IT tools will facilitate engagement in the diagnostic process. For example, patient portals provide patients with access to their medical information, but poor usability—including navigational problems and unmet expectations about functionality—can hinder adoption of such tools among patients (Greenhalgh 2010). Additional patient-facing health IT tools include mHealth applications, such as symptom checkers, but concerns about their validity are ongoing (Jul et al. and Lupton, 2015; Semig et al., 2015). In addition, there are concerns that clinicians may be unwilling or not know how to act on information collected by patients though mHealth, wearable technologies, or other forums (Dowoskin and Walker, 2014; Ramirez, 2012).

Furthermore, there are also significant concerns that “technology is cleaving the sacred bond between doctor and patient” and that the EHR distracts clinicians from patient-centered care (Wacht et al., 2015). One article suggested that the EHR has negatively affected the clinician–patient bond by prioritizing the computer above the patient. In this view, the patient is no longer the most important thing in the examining room because the machine, rather than the patient, has become the center of the clinician’s focus (Ober, 2015). Verghese described this phenomenon as the emergence of the iPatient (or the EHR as a surrogate for a real patient), arguing that there is a real danger to reducing the attention paid to the patient: “If one eschews the skilled and repeated examination of the real patient, then simple diagnoses and new developments are overlooked, while tests, consultations, and procedures that might not be needed are ordered” (Verghese, 2008).

An important component of usability is whether it supports teamwork in the diagnostic process. Health IT has the potential to strengthen intra- and inter-professional teamwork, by providing structural support for enhanced collaboration among the health care professionals involved in the diagnostic process. There is evidence that EHRs facilitate primary care teamwork via enhanced communication, redefined team roles, and improved delegation (O’Malley et al., 2015). However, this is not the case across the board; the American Medical Association has noted that many EHR systems “are not well configured to facilitate team-based care and require physicians to enter data or perform tasks that other team members should be empowered to complete” (AMA, 2014, p. 5). Reducing the cognitive burdens on clinicians is another key feature of usable health IT systems. Health IT has the potential to support clinicians in the diagnostic process by managing information flow and filtering and presenting information in a way that facilitates decision making. A thoughtfully designed user interface has the potential to help clinicians develop a more complete view of a patient’s condition by capturing and presenting all of the patient’s health information in one place.

In particular, the problem list feature of EHRs can help clinicians to quickly see a patient’s most important health problem; it is a way of organizing a patient’s health information within the health record. The problem list derives from the problem-oriented medical record (POMR), developed by Lawrence Weed (Jacobs, 2009). “Problem-oriented” has two interrelated meanings (Weed and Weed, 2011, p. 134):

- The information in the medical record is organized by the patient problem to which the information relates (as distinguished from the traditional arrangement by source, with doctors’ notes in one place, nurses’ notes in another, lab data in another, etc.), and
- Problems are defined in terms of the patient’s complete medical needs rather than providers’ beliefs or specialty orientation (thus, for example, the record should cover not just the ‘chief complaint’ but all identified medical needs, and those needs should be defined in terms of the problems requiring solution, not in terms of providers’ diagnostic hypotheses or treatment plans).

The problem list includes all past and present diagnoses, as well as the time of occurrence and whether the problem was resolved, and links to further information on each entry in the list (Weed, 1968; AHIMA, 2011).

Although studies have shown that use of high-quality problem lists is associated with better patient care (Hartung 2005; Simborg 1976), variability in the structure and content of problem lists has limited its effectiveness in improving patient care (Holmes 2012; AHIMA 2011). There is a move to standardize the structure and content of problem lists in EHRs through the use of diagnostic and problem codes (AHIMA, 2011). To encourage this change, meaningful use criteria require that participants maintain up-to-date, coded problem list for at least 80 percent of their patients (AHIMA, 2011).

Unfortunately, poorly designed health IT systems, such as those with confusing user—interfaces and disorganized patient information, may contribute to cognitive overload rather than easing the cognitive burden on clinicians. Poorly designed systems can detract from clinician efficiency and
impede information integration and interpretation in the diagnostic process. A recent analysis of the graphical display of diagnostic test results in EHRs found that few of the current EHRs meet evidence-based criteria for how to improve comprehension of such information (Sittig et al., 2015). For example, one EHR system graphed diagnostic testing results in reverse chronological order; none of the EHRs in the analysis had graphs with y-axis labels that displayed both the name of the variable and the units of measurement. Human factors engineering approaches, such as a heuristic evaluation or an assessment of how well a particular interface design complies with established design principles for usability, could help identify usability problems and guide the design of user interfaces (CQPI, 2015). Future research on health IT usability will be important. One key feature of an effective user interface is simplicity. “Simplicity in design refers to everything from lack of visual clutter and concise information display to inclusion of only functionality that is needed to effectively accomplish tasks” (HIMSS, 2009). Clinicians have expressed dissatisfaction about EHR screens being too busy due to a high degree of display clutter (or the high density of objects). In their review, Moacdileh and Sarter (2014) found: “Displays described as cluttered have been shown to degrade the ability to monitor and detect signal changes, to delay visual search, to increase memory load, to instill confidence in wrong judgments, to lead to confusion, and to negatively affect situational awareness, reading, and linguistic processing” (p. 61).

Another principle of usability is efficiency (HIMSS, 2009). Inefficient health IT tools may impede diagnosis by adding to clinicians’ work burdens, leaving them with less time for the cognitive work involved in diagnosis and communicating with patients and the other health care professionals who are involved in the patients’ care. Clinicians need to be able to complete a task without having to undergo extra steps, such as clicking, scrolling, or switching between a keyboard and mouse; however, many health IT tools are cumbersome to navigate. One study of emergency department clinicians found that inputting information consumed more of their time than any other activity, including patient care (Hill et al., 2013). By counting computer mouse “clicks,” the researchers who performed that study found that it took six clicks to order an aspirin tablet, eight clicks to order a chest x-ray, fifteen clicks to provide a patient with one prescription, and forty clicks to document the exam of a hand and wrist injury. Hill and colleagues (2013) estimated that a clinician could make 4,000 clicks in one 10-hour shift. EHRs may also present clinicians with more alerts than they can effectively manage. For example, many comprehensive EHR systems automatically generate alerts in response to abnormal diagnostic testing results, but Singh and colleagues (2013) found that information overload may contribute to clinicians missing test results. Almost 70 percent of clinicians surveyed said that they received more alerts than they could effectively manage, and almost 30 percent of clinicians reported that they had personally missed alerts that resulted in patient care delays.

Makam and colleagues (2013) found that clinicians spend an appreciable amount of time using EHRs outside of their clinic hours. Almost half of the clinicians they surveyed reported that completing EHR documentation for each scheduled half-day clinic session required one or more extra hours of work, and 30 percent reported they spent at least one extra hour communicating electronically with patients, even though they may not get paid for this time.

Howard and colleagues (2013, p. 107) found mixed results on work burden when they studied small, independent, community-based primary care practices; “EHR use reduced some clinician work (i.e., prescribing, some lab-related tasks, and communication within the office), while increasing other work (i.e., charting, chronic disease and preventive care tasks, and some lab-related tasks).”

Measurement Capability

Health IT can also be used to measure errors in diagnosis by leveraging the vast amounts of patient data contained in health IT databases (Shenw and El-Kareh, 2014; Singh et al., 2012; Singh et al., 2007b). For instance, algorithms can be developed that periodically scan EHRs for diagnostic errors or clinical scenarios that suggest a diagnostic error has occurred. An example of the former would be cases of patients with newly diagnosed pulmonary embolism who were seen in the 2 weeks preceding diagnosis by an outpatient or emergency department clinician with symptoms that may have indicated pulmonary embolism (e.g., cough, shortness of breath, chest pain). An example of the latter may be patients who are hospitalized or seen in the emergency department within 2 weeks of an unscheduled outpatient visit, which may be suggestive of a failure to correctly diagnosis the patient at the first visit (Singh et al., 2012; Singh et al., 2007b; Sittig and Singh, 2012). In both of these instances, health IT systems need to incorporate user-friendly platforms that enable health care organizations to measure diagnostic errors or surrogate measures. For health IT systems that are used by multiple health care organizations or across multiple settings (inpatient and outpatient), common platforms for measuring diagnostic errors will permit comparisons of diagnostic error rates across organizations and settings. Improving the identification of diagnostic errors is a main recommendation of this committee, and health IT vendors should facilitate efforts to do so by developing tools that enable organizations to more easily determine the rates of diagnostic errors, especially those that are common and that have serious implications for patients (e.g., pulmonary embolism, acute myocardial infarction, and stroke).

Fit Within Clinical Work-flow

The diagnostic process is not a single task, but rather a series of tasks that involve multiple people across the health care continuum. Clinical workflow, or the sequence of physical and cognitive tasks performed by various people within and between work environments, affects the diagnostic process at many junctures (Carayon et al., 2010). A critical element of work-flow is health IT: Effective integration of health IT into the clinical work-flow is essential for preventing diagnostic errors. However, integrating health IT into the clinical work-flow is made more difficult by the wide range of work-flows used by different individuals participating in the diagnostic process, both within one setting and across care settings. According to HIMSS, there are more than 50 physician specialties, and each of these specialties has its own software needs, including the unique software needs of the other health care professionals involved in that specialty (e.g., nurses, pharmacists, physical therapists, respiratory therapists, and medical dieticians). Each specialty may have different tasks that require a range of software interface designs (HIMSS, 2009). Furthermore, the actual clinical work-flow does not always follow a formal, linear process; for example, orders may need to be executed before the proper administrative data, such as a patient’s social security number, is entered or even known (Ash et al., 2004). As a result, health IT systems need both flexibility and modularity so that they can be tailored to specific work-flow needs. Additionally, the time spent implementing and maintaining health IT systems may negatively impact work-flow and even contribute to error (IOM, 2012a). For instance, EHR systems may become temporarily inaccessible because of software updates or network failure.

Clinical Documentation

Clinical documentation is central to patient care and often occupies a significant amount of clinicians’ time (Hripcsak et al., 2011). Clinical documentation has been defined as “the process of recording historical data, observations, assessments, interventions, and care plans in an individual’s health record. The purpose of documentation is to facilitate clinical reasoning and decision making by clinicians and promote communication and coordination of care among members of the care team” (Kuperman and Rosenbloom, 2013, p. 6). Beyond supporting patient care, clinical documentation also needs to meet requirements outside of the clinical care setting, including billing, accreditation, legal, and research purposes (Hripcsak and Vawdrey, 2013).
Clinical documentation is used to justify the level of service billed to insurers, to collect information for research or quality improvement purposes, and to inform a legal record in case of litigation (Rosenbloom et al., 2011). For example, the electronic documentation of clinical decisions and activity, including both user-entered data and metadata, “may affect the course of malpractice litigation by increasing the availability of documentation with which to defend or prove a malpractice claim” (Magenmurti et al., 2010, p. 2063). Payment and liability concerns, in combination with the growth in EHRs, have resulted in extensive and growing clinical documentation—sometimes referred to as “note bloat”—that has led to a situation in which key information in a patient’s medical record can be obscured (Kuhn et al., 2015). A number of clinicians have expressed concern that clinical documentation is not promoting high-quality diagnosis and is instead primarily centered around billing and legal requirements, forcing clinicians to “focus on ticking boxes rather than on thoughtfully documenting their clinical thinking” (Schiff and Bates, 2010, p. 1066). In addition, research has shown that electronic documentation adds to clinicians’ work burden: intensive care unit residents and physicians spend substantially more time on clinical review and documentation after EHR implementation (Carayon et al., 2015). For example, extensive clinical documentation for justifying payment, facilitated by the copy/paste feature of EHRs, can contribute to cognitive overload and impede clinical reasoning. A major goal of using data collected within EHRs for legal, billing, and population-wide health management has led to a profusion of structured clinical documentation formats within health IT tools. For instance, excessive information can result from cut and paste functionalities and the need to ensure that the information contained in EHRs justifies legal and billing purposes. However, structured documentation may cause problems for clinicians because they “value different factors when writing clinical notes, such as narrative expressivity, amenability to the existing work-flow, and usability” (Rosenbloom et al., 2011, p. 181). Clinicians need to be able to record information efficiently and in ways that render it useful to other health care professionals involved in caring for a patient. Research has found “that in a shared context, concise, unconstrained, free-text communication is most effective for coordinating work around a complex task” (Ash et al., 2004, p. 106). There are also concerns that overly structured data entry has impacted clinicians’ cognitive focus and abilities to focus on and attend to relevant information in the EHR (Ash et al., 2004). Tools, such as speech recognition technology, have been developed to assist clinicians with clinical documentation, with varying degrees of success. Though several studies have found that voice recognition technology can improve the turnaround time of results reporting (Johnson et al., 2014; Prevedello et al., 2014; Singh and Pal, 2011), there are a number of issues associated with this technology that make it difficult to implement or may negatively impact the diagnostic process. This includes high implementation costs, the need for extensive user training, decreased report quality due to technology-related errors, and workflow interruptions (Bhan et al., 2008; de la Cruz, 2014; Fratzke et al., 2014; Houston and Rupp, 2000; Hoyt and Yoshihashi, 2010; Johnson et al., 2014 Quint et al., 2008).

Another technology that may help address the challenges of clinical documentation is natural language processing (Hripcsak and Vawdrey, 2013). Natural language processing extracts data from free text, converting clinicians’ notes and narratives into structured, standardized formats. When the task is sufficiently constrained and when there is sufficient time to train the system, natural language processing systems can extract information with minimal effort and very high performance (Uzuner et al., 2008). Health IT vendors have begun to incorporate natural language processing software into EHRs. Additional technologies, particularly data mining, hold promise for improving clinical documentation in the future. Data mining “relies on the collective experience of all previous notes to steer how data should be entered in a new note” (Hripcsak and Vawdrey, 2013, p. 2). These technologies also hold promise for improving clinical decision support.

**Clinical Decision Support In Diagnosis**

Health IT has the potential to support the diagnostic process through clinical decision support (CDS) tools. CDS provides clinicians and patients “with knowledge and person-specific information [that is] intelligently filtered or presented at appropriate times, to enhance health and health care” (HealthIT.gov, 2013). A number of studies have shown that clinical decision support systems can improve the rates of certain desirable clinician behaviors such as appropriate test ordering, disease management, and patient care (Carayon et al., 2010; Lobach and Hammond, 1997; Meigs et al., 2003; Roshanov et al., 2011; Sequist et al., 2005).

Diagnostic decision support tools can provide support to clinicians and patients throughout each stage of the diagnostic process, such as during information acquisition, information integration and interpretation, the formation of a working diagnosis, and the making of a diagnosis (Del Fiol et al., 2008; Zakim et al., 2008). Tools such as infobuttons can be integrated into EHRs and provide links to relevant online information resources, such as medical textbooks, clinical practice guidelines, and appropriateness criteria; there is evidence that infobuttons can help clinicians answer questions at the point of care and that they lead to a modest increase in the efficiency of information delivery (Del Fiol et al., 2008). CDS can also facilitate the ordering of the diagnostic tests that help physicians develop accurate and timely diagnoses. In its input to the committee, the American College of Radiology stated that structured decision support for image ordering and reporting is critical for reducing diagnostic errors (Allen and Thorwarth, 2014). The Protecting Access to Medicare Act, passed in 2014, includes a provision that requires clinicians to use specified criteria when ordering advanced imaging procedures and directs the U.S. Department of Health and Human Services to identify CDS tools to help clinicians order these imaging procedures. Given the growth of molecular testing and advanced imaging techniques, the importance of clinical decision support in aiding decisions involving this aspect of the diagnostic process is likely to increase.

Although decision support technologies have been around for quite some time (Weed and Zimny, 1989; Weed and Weed, 2011), there is still much room for progress. Questions about the validity and utility of diagnostic decision support tools still remain. A number of studies have assessed the performance of diagnostic decision support tools. Researchers such as Ramnarayan et al. (2003) have developed scores to measure the impact of diagnostic decision support on the quality of clinical decision making. These scores assess the performance of diagnostic decision support tools based on how often the “correct” diagnosis is produced by either the decision support system or by the clinicians after using the decision support; the scores also take into account the rank of the correct diagnosis on the list of differential diagnoses. There may be problems with these criteria, however. In particular, rare diagnoses may be less likely to be considered because of a lower ranking. More recently, a review of four differential diagnosis generators found these tools to be “subjectively assistive and functional for clinical diagnosis and education” (Bond et al., 2012). On a five-point scale (5 when the actual diagnosis was suggested on the first screen or in the first 20 suggestions, and 0 when no suggestions were close to the clinical diagnosis), the differential diagnosis generators received scores ranging from 1.70 to 3.45. Additional studies suggest that diagnostic decision support tools have the potential to improve the accuracy of diagnosis (Graber and Mathew, 2008; Kostopoulou et al., 2015; Ramnarayan et al., 2006, 2007). However, the studies assessing diagnostic decision support tools were conducted in highly controlled research settings; further research is needed to understand the performance of diagnostic decision support tools in clinical practice.

Though relatively early in its development...
the application of new computational methods, such as artificial intelligence and natural language processing, has the potential to improve clinical decision support (Arnaout, 2012). For instance, these approaches can analyze large amounts of complex patient data (such as patient notes, diagnostic testing results, genetic information, as well as clinical and molecular profiles) and compare the results to “thousands of other patient EHRs to identify similarities and associations, thus, elucidating trends in disease course and management” (Castaneda, 2015, p. 12).

In addition to these efforts involving generalized decision support tools, there are also ongoing efforts to use decision support in radiology. One such decision support tool is computer-aided detection (CAD), which is designed to help radiologists during mammography interpretation by analyzing mammogram images for patterns associated with underlying breast cancer. Despite the broad acceptance and use of CAD, there is mixed evidence demonstrating its effectiveness (Rao et al., 2010). Although CAD is not yet mature, the technology holds promise for improving detection. Challenges with the usability and acceptability of diagnostic decision support have hindered adoption of these tools in clinical practice (Bernier, 2014). For these tools to be useful, they need to be used only when appropriate, to be understandable, and to enable clinicians to quickly determine the level of urgency and relevancy. Decision support must function within the work-flow and physical environment of the diagnostic process, which may include distractions and interruptions. If decision support tools are to be optimally designed, it will be necessary to consider tailoring the support to different users based on such factors as experience and workload. For example, a highly trained or highly experienced user may be better able to navigate a computer interface that is cumbersome than a less experienced user. And the more experienced clinicians may need support to avoid pitfalls in diagnosis due to the use of system 1 processes, whereas more novice clinicians may need access to additional information to support system 2 processes. Research on how clinicians use technology may provide insight into the ways that human–automation interactions may be contributing to errors. EHR systems log users’ actions through both user-entered data (i.e., timing of events and who performed them) and metadata. EHRs can also measure the rate at which clinicians override alerts and medication-dose defaults.

In addition, there are a number of potential patient safety risks associated with decision support. A systematic review found that an overreliance on decision support has the potential to reduce independent clinician judgment and critical thinking (Goddard et al., 2012). A decision support tool could provide incorrect advice if it has incomplete information or applies outdated treatment guidelines (AHLA, 2013). This may place a clinician in a position in which he or she believes the decision support is correct, and discounts their own assessment of the issue. Although Friedman and colleagues (1999) found that the use of clinical decision support was associated with a modest increase in diagnostic accuracy, in 6 percent of cases clinicians overrode their own correct decisions due to erroneous advice from the decision support system. The presentation of information, as well as informational content, can lead to adverse events related to the use of decision support: “unintended consequences relating to content are grouped around three themes: (a) the elimination or changing roles of clinicians and staff; (b) the currency of the [clinical decision support (CDS)] content; and (c) wrong or misleading CDS content”, while those relating to presentation are associated with “(a) the rigidity of systems; (b) sources of alert fatigue; and (c) sources of potential errors” (Ash et al., 2007, pp. 27-28).

**Timely Flow of Information**

The timely and effective exchange of information among health care professionals and patients is critical to improving diagnosis, and breakdowns in that communication are a major contributor to adverse events, including diagnostic errors (Gandhi et al., 2000; Poon et al., 2004; Schiff, 2005; Singh et al., 2007a). Health IT has the potential to reduce communication breakdowns, including breakdowns in intra- and interpersonal communication, in communication among patients and health care professionals, and in information exchange (e.g., the reporting of test results) (Singh et al., 2008). Improved patient access to EHRs, including diagnostic testing results as well as clinical notes, can promote improved engagement in the diagnostic process and facilitate more timely information flow between and among patients and health care professionals. Health IT can also assist with the tracking of test results and follow up. For example, the AMA (2014) concluded that EHRs can support care coordination if they “automatically track referrals and consultations as well as ensure that the referring physician is easily able to follow the patient’s progress/activity throughout the continuum of care” (p. 5).

However, health IT tools may not be facilitating optimal communication among health care professionals, and they may even contribute to communication breakdowns. For example, Parkash and colleagues (2014) found that EHRs may not alert physicians when surgical pathology reports have been amended, which may result in an incorrect diagnosis that is based on the original pathology report, an incorrect treatment plan, and the potential for serious consequences for a patient. A lack of interoperability (discussed below) can also prevent the timely flow of information among health care professionals.

Furthermore, another effect of health IT tools may be a reduction in informal, in-person collaborations between radiologists and treating clinicians that can facilitate insights into the diagnostic process. In-person consultation between treating clinicians and the radiology department was common prior to the computerization of radiology and the introduction of the picture archival communications system (Wachter, 2015). With the transition to filmless radiology systems, there has been a decrease in in-person consultations with the radiology department (Reiner et al., 1999).

An example of the importance of the timely flow of information is illustrated by the diagnostic error of Ebola in a Dallas emergency department. As the committee was deliberating in 2014, the most widespread outbreak yet seen of the Ebola virus occurred (CDC, 2015). Although the epidemic was primarily localized to several West African countries, the United States experienced its first case of Ebola virus in September 2014. The delayed diagnosis of Ebola in a Dallas hospital was a highly publicized example of diagnostic error. The committee included this case because it demonstrates the complex etiology of diagnostic error, including the roles that health IT and interprofessional communication play in conveying information in the diagnostic process.

**Interoperability of Health IT**

Another health IT–related challenge in the diagnostic process is the lack of interoperability, or the inability of different IT systems and software applications to communicate, exchange data, and use the information that has been exchanged (HIMSS, 2014). It is not unusual for the diagnostic process to occur over a protracted period of time, with multiple clinicians across different care settings involved in the process. A free flow of information is critical to ensuring accurate and timely diagnoses since in order for health care professionals to develop a complete picture of a patient’s health problem, all relevant health information needs to be available and accessible. A lack of interoperability can impede the diagnostic process because it can limit or delay access to the data available for clinical decision making. When health care systems do not exchange data, clinical information may be inaccurate or inadequate. For instance, one version of a patient’s EHR may exist on the primary clinical information system while a variety of outdated or partial versions of the record are present in other places. Furthermore, the record on the primary clinical information system may not necessarily be complete.

Given the importance of the free flow of information to diagnosis, the Office of the National Coordinator for Health Information Technology
(ONC) can play a critical role in improving interoperability. The vision that ONC has articulated for the interoperability of health IT is of an "ecosystem that makes the right data available to the right people at the right time across products and organizations in a way that can be relied upon and meaningfully used by recipients" (ONC, 2014a, p. 2). By 2024, ONC anticipates that individuals, clinicians, communities, and researchers will have access to a variety of interoperable products. However, the progress toward achieving health information exchange and interoperability has been slow (CHCF, 2014). For example, office-based exchange of information remains low; a study conducted by Furukawa et al. (2014) found that only 14 percent of the clinicians surveyed reported sharing data with clinicians outside their organization. Recognizing that progress in interoperability is critical to improving the diagnostic process, the committee calls on ONC to more rapidly require that health IT systems meet interoperability requirements. Thus, the committee recommends that ONC should require health IT vendors to meet standards for interoperability among different health IT systems to support effective, efficient, and structured flow of patient information across care settings to facilitate the diagnostic process by 2018. This recommendation is in line with the recent legislation that repealed the sustainable growth rate, which included a provision that declared it a national objective to "achieve widespread exchange of health information through interoperable certified electronic health records (EHR) technology nationwide by December 31, 2018." The law requires the Secretary of Health and Human Services (HHS) to develop metrics to evaluate progress on meeting this objective by July 2016. Furthermore, the legislation stipulates that if interoperability has not been achieved by 2018, the secretary is required to submit a report to Congress in 2019 that identifies the barriers and makes recommendations for federal government action to achieve interoperability, including adjusting payments for not being meaningful EHR users and criteria for decertifying certified EHR technology products.

Improved interoperability across different health care organizations—as well as across laboratory and radiology information systems—is critical to improving the diagnostic process. Challenges to interoperability include the inconsistent and slow adoption of standards, particularly among organizations that are not subject to EHR certification programs, as well as a lack of incentives, including a business model that generates revenue for health IT vendors via fees associated with transmitting and receiving data (Adler–Milstein, 2015; CHCF, 2014). The IOM report Health IT and Patient Safety: Building a Safer Health System recognized interoperability as a key feature of safely functioning health IT and noted that interoperability needs to be in place across the entire health care continuum: "Currently, laboratory data have been relatively easy to exchange because good standards exist such as Logical Observation Identifiers Names and Codes (LOINC) and are widely accepted. However, important information such as problem lists and medication lists (which exist in some health IT products) are not easily transmitted and understood by the receiving health IT product because existing standards have not been uniformly adopted" (IOM, 2012a, p. 86). Although laboratory data may be relatively easy to exchange, a recent report noted that the lack of incentives (or penalties) for organizations that are not subject to the EHR certification process under the Medicare and Medicaid EHR Incentive Programs (such as clinical laboratories) also contributes to poor interoperability (CHCF, 2014).

Additionally, the interface between EHRs and laboratory and radiology information systems typically has limited clinical information, and the lack of sufficiently detailed information makes it difficult for a pathologist or radiologist to determine the proper context for interpreting findings or to decide whether diagnostic testing is appropriate (Epner, 2015). For example, one study found that important non-oncological conditions (such as Crohn's disease, human immunodeficiency virus, and diabetes) were not mentioned in 59 percent of radiology orders and the presence of cancer was not mentioned in 8 percent of orders, demonstrating that the complete patient context is not getting received (Obara, et.al, 2014). Insufficient clinical information can be problematic as radiologists and pathologists often use this information to inform their interpretations of images and suggestions for next steps (Alkasab et al., 2009; Obara et al., 2014). There have been some efforts to improve the transmission of clinical context with diagnostic testing orders; for example, a quality improvement initiative in the outpatient and emergency department settings was able to improve the consistency with which radiology orders were accompanied by a complete clinical history (Hawkins et al., 2014). In addition, the Centers for Disease Control and Prevention's Clinical Laboratory Improvement Advisory Committee (CLIA) expressed concern over the patient safety risks regarding the interoperability of laboratory data and display discrepancies in EHRs (CDC, 2014; CLIA, 2012). They recommended that laboratory health care professionals collaborate with other stakeholders to "develop effective solutions to reduce identified patient safety risks in and improve the safety of EHR systems" regarding laboratory data (CDC, 2014, p. 3).

Another emerging challenge is the interoperability between EHRs and patient-facing health IT, such as physical activity data, glucose monitoring, and other health-related mobile health applications (Marceglia et al., 2015; Otte–Trojel et al., 2014). Economic incentives are another barrier to achieving interoperability. Current market conditions create business incentives for information blocking, that is, "when persons or entities knowingly and unreasonably interfere with the exchange or use of electronic health information" (ONC, 2015, p. 8). A variety of persons or entities may engage in information blocking practices, but most complaints of information blocking are related to the actions of health IT developers. Health IT vendors may "charge fees that make it cost-prohibitive for most customers to send, receive, or export electronic health information stored in EHRs, or to establish interfaces that enable such information to be exchanged" (ONC, 2015, p. 15). For instance, clinicians generally pay $5,000 to $50,000 each to secure the right to set up connections that allow them to transmit information regularly to laboratories, health information exchanges, or governments (Allen, 2015). Additional fees may be charged each time a clinician sends, receives or even searches for (or "queries") data (ONC, 2015). Health care organizations are also capable of engaging in information blocking. For instance, larger hospital systems that already capture a large proportion of patients' clinical information internally may be less motivated to join health information exchanges. In such instances, "information is seen as a tool to retain patients within their system, not as a tool to improve care" (Tsai and Jha, 2014, p. 29).

Issues related to data security and privacy will need to be considered as interoperability and health information exchange increases. The personal information stored within health IT systems needs to be secure. However, these data also need to be easily available when patients move from one system to another. Transparency will become increasingly important as interoperability improves and as data aggregation for quality improvement and population health management becomes more common. The ONC recognizes that it will be important to "support greater transparency for individuals regarding business practices of entities that use their data, particularly those that are not covered by the HIPAA Privacy and Security Rules" (ONC, 2014a, p. 5).

**Safety of Health IT in Diagnosis**

Patient safety risks related to the use of health IT in the diagnostic process are another important concern because there is growing recognition that health IT can result in adverse events (IOM, 2012a; ONC, 2014b; Walker et al., 2008), including sentinel events that result in permanent patient harm or death (Joint Commission, 2015b). Such health IT safety risks have been described in the context of a socio-technical system, in which the system components (including technology,
people, work-flow, organizational factors, and external environment) can dynamically interact and contribute to adverse events (IOM, 2012a; Sittig and Singh, 2010). A number of health IT–related patient safety risks may affect the diagnostic process and the occurrence of diagnostic errors. For example, challenges with the usability of EHRs have led to workarounds from their intended use; although many of these workarounds are benign, there is the potential for negative effects on patient safety and diagnosis (Ash et al., 2004; Friedman et al., 2014; IOM, 2012a; Koppel et al., 2008). Clinical documentation in the EHR and the use of the copy/paste functionality of EHRs are areas of increased concern. While the use of copy/paste functionality may increase efficiency by saving time that would otherwise be spent retying or reentering information, it carries with it a number of risks, including redundancy that contributes to lengthy notes and cognitive overload as well as the spreading of inaccurate, outdated, or incomprehensible information (AHIMA, 2014; Kuhn et al., 2015; Joint Commission, 2015a).

New safety risks may also include errors related to entering and retrieving information (such as juxtaposition errors), errors in communication and coordination (mistaking information entry into an EHR system as a successful communication act), and health IT system maintainability (Ash et al., 2004). For instance, a pathologist may assume that the entry of new test results into an EHR system means that the results have been communicated to the clinician, even though this may not be the case (documentation in the EHR is not necessarily equivalent to communication).

Unfortunately, contractual provisions, intended to protect vendors’ intellectual property interests and liability from the unsafe use of health IT products, limit the free exchange of information about health IT–related patient safety risks (IOM, 2012a). Specifically, “some vendors require contract clauses that force [health IT] system purchasers to adopt vendor–defined policies that prevent the disclosure of errors, bugs, design flaws, and other HIT–software–related hazards” (Goodman et al., 2011, p. 77). These contractual barriers facing health IT vendors and users may propagate safety risks and pose significant challenges to the use of data for future patient safety and quality improvement research (IOM, 2012a). In recognition of these challenges, the American Medical Informatics Association board of directors convened a task force to help resolve issues surrounding vendor–user contracts and made a number of suggestions for improving health IT contract language. Westat prepared a report for ONC that provides an overview of the key contract terms for health care organizations to be aware of when negotiating agreements with health IT vendors (Westat, 2013).

In line with the movement toward more transparency, the IOM report on patient safety and health IT recommended that the Secretary of HHS “should ensure insofar as possible that health IT vendors support the free exchange of information about health IT experiences and issues and not prohibit sharing of such information, including details (e.g., screenshots) relating to patient safety” (IOM, 2012a, p. 7). The committee endorses this recommendation and further recommends that the Secretary of HHS should require health IT vendors to permit and support the free exchange of information about real-time user experiences with health IT design and implementation that adversely affect the diagnostic process. Health IT users can discuss patient safety concerns related to health IT products used in the diagnostic process in appropriate forums. Such forums include the forthcoming ONC national patient safety center or patient safety organizations (RTI International, 2014; Sittig et al., 2014a). In addition, the Agency for Healthcare Research and Quality has developed a common format reporting form for health IT adverse events and ONC is beginning to evaluate patient safety events related to health IT (ONC, 2014b).

Because the safety of health IT is critical for improvements to the diagnostic process, health IT vendors need to proactively monitor their products in order to identify potential adverse events, which could contribute to diagnostic errors and challenges in the diagnostic process (Carayon et al., 2011). To ensure that their products are unlikely to contribute to diagnostic errors and adverse events, vendors need to have independent, third-party evaluations performed on whichever of their health IT products are used in the diagnostic process. Thus, the committee recommends that the Secretary of HHS should require health IT vendors to routinely submit their products for independent evaluation and notify users about potential adverse effects on the diagnostic process related to the use of their products. Health IT vendors may consider using self-assessment tools, such as the SAFER guides, to prepare for the evaluations (Sittig et al., 2014b). If health IT products have the potential to contribute to diagnostic errors or have other adverse effects on the diagnostic process, health IT vendors have a responsibility to communicate this information to their customers in a timely manner.

Other Diagnostic Technologies

In addition to health IT, several emerging technologies present opportunities to improve the diagnostic process, such as telemedicine/telehealth and mHealth/wearable technologies. This section examines the use of these technologies by health care professionals and patients to improve the diagnostic process.

Telemedicine

Although the definitions vary, telemedicine and telehealth generally refer to the delivery of care, consultations, and information using communications technology (American Telemedicine Association, 2015). A 2012 IOM workshop defined both telemedicine and telehealth, saying that they “describe the use of medical information exchanged from one site to another via electronic communications to improve the patient’s health status. Although evolving, telemedicine is sometimes associated with direct patient clinical services and telehealth is sometimes associated with a broader definition of remote health care services” (IOM, 2012b, p. 3). Telemedicine encompasses an increasing array of applications and services, such as “two-way video, e-mail, smart phones, wireless tools, and other forms of telecommunication technology” (American Telemedicine Association, 2015).

Telemedicine typically is used in two settings: (1) between a clinician and a patient who is in a different location or (2) between two clinicians for consultations. The transmission of images, data, and sound can take place either synchronously (real-time), where the consulting clinician participates in the examination of the patient while diagnostic information is collected and transmitted, or asynchronously (anytime), through store-and-forward technology that transmits digital information for the consulting clinician to review at a later time. As new payment and care delivery models are being implemented and evaluated, there is a growing recognition of the potential for technological capabilities to improve patient accessibility to health care services and also to improve care coordination and affordability. Telemedicine can create additional options for how individuals receive health care, while lessening the dependence on traditional in-person methods of receiving medical treatment. Telemedicine arrangements have emerged in a number of medical specialties (e.g., radiology, pathology, dermatology, ophthalmology, cardiology, neurology, geriatrics, and psychiatry), certain hospital service lines (e.g., home health and dentistry), and certain patient populations (e.g., prison inmates).

Telemedicine poses a number of challenges in the diagnostic process that may differ from those in traditional health care visits. For example, in the absence of a prior patient–clinician relationship, a clinician may not know enough details about the patient’s history to ask pertinent questions, which may lead clinicians to over-utilize diagnostic testing (Huff, 2014). In addition, telemedicine approaches can limit a clinician’s ability to perform a comprehensive physical exam; certain medical conditions cannot be diagnosed effectively via a telemedicine encounter (Robison,
There is also the potential for technological failures and transmission errors during a telemedicine encounter that can impair the diagnostic process and medical evaluation (Carranza et al., 2010). It is important that both patients and clinicians fully understand the telemedicine process and its associated limitations and risks, including the scope of the diagnostic health care services that can be delivered safely through this medium. Additionally, health care professionals may need to document their findings differently in the absence of face-to-face interactions, given the absence of a comprehensive physical exam. Clinicians participating in telemedicine need to be attuned to care continuity and coordination issues and to effectively convey to their patients who has accountability over their care and whom they should contact for follow-up. Finally, health care professionals will need to keep abreast of professional standards of care and the relevant state laws that create heightened requirements for a particular telemedicine activity and which may affect the diagnostic process.

**Teleradiology**

Teleradiology has been a forerunner in telemedicine arrangements “with on-call emergency reporting being used in over 70 percent of radiology practices in the United States and general teleradiology by ‘nighthawk services’ around the world” (Krupinski, 2014, p. 5). In these arrangements, outsourced, off-hour radiology interpretations are provided by physicians credentialed in the United States who are either located within the United States or abroad. Continuous developments in picture archiving and communication systems and radiology information systems, have strengthened the overall teleradiology process, including image capture, storage, processing, and reporting. In response to such developments, there has been an increase in the subspecialization of radiologists along systems- and disease-related specialties. Greater sub-specialization has led to increased expansion and utilization of teleradiology in major urban as well as rural and medically underserved areas (Krupinski, 2014).

**Telepathology**

Telepathology is currently being used in select locations for a variety of clinical applications, including the diagnosis of frozen section specimens, primary histopathological diagnoses, second opinion diagnoses, and subspecialty pathology consultations, although telemedicine approaches could also be considered for clinical pathology purposes (Dunn et al., 2009; Graham et al., 2009; Kaysen et al., 2000; Massone et al., 2007). Telepathology involves a hub-site pathologist that can access a remote-site microscope and has the ability to control the movement of the slide and adjust magnification, focus, and lighting, while the images are viewed on a computer screen (Dunn et al., 2009). Because the field selection is accomplished by the consultant, the information obtained, except for digital imaging capabilities, is functionally the same as the consultant would obtain using a microscope in his or her own office. By providing immediate access to off-site pathologists as well as direct access to subspecialty pathologists, telepathology has the potential to improve both diagnostic speed (turn-around time) and accuracy for the patients at the remote site. Moreover, a telepathology consultation allows the local pathologist and consulting pathologist to examine the case at the same time, which could improve the educational potential of the interaction since the local pathologist can observe firsthand the diagnostic approach employed by the consulting pathologist (Low, 2013).

**Telenurology**

One application of telemedicine in neurology is telestroke, a widespread and growing practice model (Krupinski, 2014; Silva et al., 2012). Successful management of acute ischemic stroke is extremely time-dependent, which makes it particularly important to have technological tools that can facilitate acute stroke evaluation and management in rural areas and other areas underserved by neurologists and thus improve post-stroke outcomes (Rubin and Damera-Schalk, 2014). A recent Mayo Clinic study explored the efficiency of remote neurological assessments in diagnosing concussions in football players on the sidelines of games in rural Arizona. For the study, an off-site neurologist used a portable unit to perform neurological exams on players who had suffered possible head injuries and recommended whether the players were safe to return to the field (Vargas et al., 2012). These types of innovations may help facilitate the diagnostic process, especially for time-sensitive medical conditions.

**mHealth and Wearable Technologies**

Mobile health (mHealth) applications and wearable technologies are transforming health care delivery for both health care professionals and patients, and they have the potential to influence the diagnostic process. The recent proliferation of mHealth applications has resulted in a broad and evolving array of mHealth applications that are available to both clinicians and patients. mHealth applications are often designed to assist clinicians at the point of care and include drug reference guides, medical calculators, clinical guidelines, textbooks, literature search portals, and other decision support aids. Other mobile applications are designed specifically for patients and facilitate the gathering of diagnostic data or assist patients in coordinating care by keeping track of their medical conditions, diagnostic tests, and treatments. mHealth applications may augment traditional health care professional education by providing opportunities for interactive teaching and more personalized educational experiences for students, and have the potential to support clinical decision making at the point of care (Boulos et al., 2014).

A systematic review found an increase in the appropriateness of diagnostic and treatment decisions when mobile devices were used for clinical decision support, but the researchers who performed the study noted that the evidence was limited; thus, more research will be needed to draw reliable conclusions concerning whether and how these mobile devices help and in what circumstances and how they should be used (Divall et al., 2013).

Other mHealth applications designed for clinicians may serve as an alternative to traditional health IT tools and have the potential to improve diagnosis in emergency or low-resource settings. For example, tablets could be used to view medical images, and recent evidence suggests that they are comparable to conventional picture archiving and communications systems or liquid-crystal display monitor systems in diagnosing several conditions, although further research is needed (Johnson et al., 2012; McLaughlin et al., 2012; Park et al., 2013). Smartphones have been used in conjunction with specialized attachments to make certain laboratory-based diagnostics more accessible (Laksanasopin et al., 2015). For example, an adaptor with electrocardiogram electrodes may transmit electrical data that can be used to detect abnormal heart rhythms (Lau et al., 2013). Future generations of such technologies may be even more advanced; there is an ongoing Qualcomm Tricorder XPRIZE in which teams are competing to build a device that can accurately diagnose 16 health conditions and assess five vital signs in real time (XPRIZE, 2015).

In response to an increasing demand from patients for self-monitoring tools, a plethora of patient-centered mHealth applications have become available. They can perform a variety of functions related to such lifestyle factors as weight management, activity levels, and smoking cessation. Patients may also leverage certain mHealth applications to actively participate in the diagnostic process, such as consumer symptom checkers, which offer patients access to targeted searches based on their symptoms and enable patients to compile their own differential diagnoses, print out the results, and compare their findings with their clinicians’ findings. Other mHealth applications for patients, such as wearable technologies, are intended to facilitate data collection, and they offer an additional source of patient data which may improve clinicians’ ability to diagnose certain
conditions. For example, patients with diabetes, may synchronize a glucometer attachment to their mobile device to track blood glucose and upload the data through an Internet connection (Cafazzo et al., 2012)

Despite the potential for mHealth applications to improve diagnosis, a number of challenges remain. In particular, the quality of mobile applications can be quite variable, and there are concerns about the accuracy and safety of these applications, especially about how well they conform to evidence-based recommendations (Chomutare et al., 2011; Powell et al., 2014). For example, Semigran and colleagues (2015) evaluated available symptom trackers for patients, and concluded that “symptom checkers had deficits in both triage and diagnosis.” The evaluation found that the symptom checkers identified the correct diagnosis first in 34 percent of the cases, and listed the correct diagnosis within the top 20 list in 58 percent of the cases (Semigran et al., 2015). Jutel and Lupton (2015, p. 94) call for further research of these apps given their variable development and quality, “the sheer number and constant proliferation of mobile apps in general pose difficulties for regulatory agencies to maintain oversight of their quality and accuracy,” as well the impact of these apps on the patient-clinician relationship.

Furthermore, there is a lack of data that support or identify the best practices for their use, including integrating such technologies with EHRs, patient monitoring systems, and other health IT infrastructure (Mosa et al., 2012). Issues related to usability and health literacy will also need to be addressed in order to ensure that mHealth applications effectively meet user needs and facilitate the diagnostic process. The rapid pace of innovation and the evolving regulatory framework for mHealth are other challenges (Cortez et al., 2014).

Organizational Characteristics, the Physical Environment, & the Diagnostic Process: Improving Learning, Culture, & the Work System

This chapter focuses on the actions that health care organizations can take to design a work system that sup-ports the diagnostic process and reduces diagnostic errors. The term “health care organization” is meant to encompass all settings of care in which the diagnostic process occurs, such as integrated care delivery settings, hospitals, clinician practices, retail clinics, and long-term care settings, such as nursing and rehabilitation centers. To improve diagnostic performance, health care organizations need to engage in organizational change and participate in continuous learning. The committee recognizes that health care organizations may differ in the challenges they face related to diagnosis and in their capacity to improve diagnostic performance. They will need to tailor the committee’s recommendations to their resources and challenges with diagnosis. The first section of this chapter describes how organizational learning principles can improve the diagnostic process by providing feedback to health care professionals about their diagnostic performance and by better characterizing the occurrence of and response to diagnostic errors. The second section highlights organizational characteristics—in particular, culture and leadership—that enable organizational change to improve the work system in which the diagnostic process occurs. The third section discusses actions that health care organizations can take to improve the work system and support the diagnostic process. For example, the physical environment (i.e., the design, layout, and ambient conditions) can affect diagnosis and is often under the control of health care organizations.

Organizational Learning to Improve Diagnosis

In any health care organization, prioritizing continuous learning is key to improving clinical practice (Da vies and Nutley, 2000; IOM, 2013; WHO, 2006). The Institute of Medicine (IOM) report Best Care at Lower Cost concluded that health care organizations focused on continuous learning are able to do more “consistently deliver reliable performance, and constantly improve, systematically and seamlessly, with each care experience and transition” than systems that do not practice continuous learning (IOM, 2013, p. 1). These learning health care organizations ensure that individual health care professionals and health care teams learn from their successes and mistakes and also use this information to support improved performance and patient outcomes (Davies and Ntley, 2000).

A focus on continuous learning in the diagnostic process has the potential to improve diagnosis and reduce diagnostic errors (Dixon-Woods et al., 2011; Gandhi, 2014; Grumbach et al., 2014; IOM, 2013; Trow-bridge, 2014). To support continuous learning in the diagnostic process, health care organizations need to establish approaches to identify diagnostic errors and near misses and to implement feedback mechanisms on diagnostic performance. The challenges related to identifying and learning from diagnostic errors and near misses, as well as actions health care organizations and health care professional societies can take to achieve this goal, are discussed below.

Identifying, Learning From, and Reducing Diagnostic Errors and Near Misses

Diagnostic errors have long been an understudied and under appreciated quality challenge in health care organizations (Graber, 2005; Shewi Edna and El-Kareh, 2015; Wachter, 2010). In a presentation to the committee, Paul Epner reported that the Society to Improve Diagnosis in Medicine “know[s] of no effort initiated in any health system to routinely and effectively assess diagnostic performance” (2014; see also Graber et al., 2014). The paucity of attention on diagnostic errors in clinical practice has been attributed to a number of factors. Two major contributors are the lack of effective measurement of diagnostic error and the difficulty in detecting these errors in clinical practice (Berenson et al., 2014; Graber et al., 2012b; Singh and Sittig, 2015). Additional factors may include a health care organization’s competing priorities in patient safety and quality improvement, the perception that diagnostic errors are inevitable or that they are too difficult to address, and the need for financial resources to address this problem (Croskerry, 2003, 2012; Graber et al., 2005; Schiff et al., 2005; Singh and Sittig, 2015). These challenges make it difficult to identify, analyze, and learn from diagnostic errors in clinical practice (Graber, 2005; Graber et al., 2014; Henriksen, 2014; Singh and Sittig, 2015).

Compared to diagnostic errors, other types of medical errors—including medication errors, surgical errors, and health care–acquired infections—have historically received more attention within health care organizations (Graber et al., 2014; Kanter, 2014; Singh, 2014; Trow-bridge, 2014). This is partly attributable to the lack of focus on diagnostic errors within national patient safety and quality improvement efforts. For example, the Agency for Healthcare Research and Quality’s (AHRQ’s) Patient Safety Indicators and the Joint Commission’s list of specific sentinel events do not focus on diagnostic errors (AHRQ, 2015b; Joint Commission, 2015a; Schiff et al., 2005). The National Quality Forum’s Serious Reportable Events list includes only one event closely tied to diagnostic error, which is “patient death or serious injury resulting from a failure to follow up or communicate laboratory, pathology, or radiology test results” (NQF, 2011). The neglect of diagnostic performance measures for accountability purposes means that hospitals today could meet standards for high-quality care and be rewarded through public reporting and pay-for-performance initiatives even if they have major challenges with diagnostic accuracy (Wachter, 2010).

While current research estimates indicate that diagnostic errors are a common occurrence, health care organizations “do not have the tools and strategies to measure diagnostic safety and must have not integrated diagnostic error into their existing patient safety programs” (Singh and Sittig, 2015, p. 103). Identifying diagnostic errors within clinical practice is critical to improving diagnosis for patients, but measurement has become an “unavoidable obstacle to progress” (Singh, 2013, p. 789). The lack of comprehensive information on diagnostic errors within clinical
practice perpetuates the belief that these errors are uncommon or unavoidable and impedes progress on reducing diagnostic errors. Improving diagnosis will likely require a concerted effort among all health care organizations and across all settings of care to better identify diagnostic errors and near misses, learn from them, and, ultimately, take steps to improve the diagnostic process. Thus, the committee recommends that health care organizations monitor the diagnostic process and identify, learn from, and reduce diagnostic errors and near misses as a component of their research, quality improvement, and patient safety programs.

In addition to identifying near misses and errors, health care organizations can also benefit from evaluating factors that are contributing to improved diagnostic performance.

Given the nascent field of measurement of the diagnostic process, the committee concluded that bottom-up experimentation will be necessary to develop approaches for monitoring the diagnostic process and identifying diagnostic errors and near misses. It is unlikely that one specific method will be successful at identifying all diagnostic errors and near misses; some approaches may be more appropriate than others for specific organizational settings, types of diagnostic errors, or for identifying specific causes. It may be necessary for health care organizations to use a variety of methods in order to have a better sense of their diagnostic performance (Shojania, 2010). As further information is collected regarding the validity and feasibility of specific methods for monitoring the diagnostic process and identifying diagnostic errors and near misses, this information will need to be disseminated in order to inform efforts within other health care organizations. The dissemination of this information will be especially important for health care organizations that do not have the financial and human resources available to pilot-test some of the potential methods for the identification of diagnostic errors and near misses. In some cases, small group practices may find it useful to pool their resources as they explore alternative approaches to identify errors and near misses and monitor the diagnostic process.

There are a number of methods being employed by researchers to describe the incidence and nature of diagnostic errors, including postmortem examinations, medical record reviews, health insurance claims analysis, medical malpractice claims analysis, second reviews of diagnostic testing, and surveys of patients and clinicians. Some of these methods may be better suited than others for identifying diagnostic errors and near misses in clinical practice. Medical record reviews, medical malpractice claims analysis, health insurance claims analysis, and second reviews in diagnostic testing may be more pragmatic approaches for health care organizations because they leverage readily available data sources. Patient surveys may also be an important mechanism for health care organizations to consider. It is important to note that many of the methods described below are just beginning to be applied to diagnostic error detection in clinical practice; very few are validated or available for widespread use in clinical practice (Bhise and Singh, 2015; Graber, 2013; Singh and Sittig, 2015).

Medical record reviews can be a useful method to identify diagnostic errors and near misses because health care organizations can leverage their electronic health records (EHRs) for these analyses. The committee’s recommendation on health information technology (health IT) highlights the need for EHRs to include user-friendly platforms that enable health care organizations to measure diagnostic errors. Trigger tools, or algorithms that scan EHRs for potential diagnostic errors, can be used to identify patients who have a higher likelihood of experiencing a diagnostic error. For example, they can identify patients who return for inpatient hospitalization within two weeks of a primary care visit or patients who require follow-up after abnormal diagnostic testing results. Review of their EHRs can evaluate whether a diagnostic error occurred, using explicit or implicit criteria. For diagnostic errors, these tools have been piloted primarily in outpatient settings, but they are also being considered in the inpatient setting (Murphy et al., 2014; Shenri Edna and El-Kareh, 2015; Singh et al., 2012a). EHR surveillance, such as Kaiser Permanente’s SureNet System, is another opportunity to detect patients at risk of experiencing a diagnostic error (Graber et al., 2014; HIMSS Analytics, 2015; Kanter, 2014). The SureNet System identifies patients who may have inadvertent lapses in care (such as a patient with iron deficiency anemia who has not had a colonoscopy to rule out colon cancer) and ensures that follow-up occurs by proactively reaching out to affected patients and members of their care team. Medical malpractice claims analysis is another approach to identifying diagnostic errors and near misses in clinical practice. Health care organizations can collaborate with professional liability insurers in efforts to identify diagnostic errors and near misses in clinical practice; because of the richness of the data source, this method could also be helpful in identifying the reasons why diagnostic errors occur. However, there are limitations with malpractice claims data, because these claims may not be representative—few people who experience adverse events file claims, and the ones who do are more likely to have experienced serious harm.

Although there are few examples of using health insurance claims data to identify diagnostic errors and near misses, this may be a useful method, especially if it is combined with other approaches (e.g., if it is linked to medical records or diagnostic testing results). One of the advantages of this data source is that it makes it possible to assess the downstream clinical consequences and costs of errors. It also enables comparisons across different settings, types of clinicians, and days of the week (which can be important because there may be some days when staffing is low and the volume of patients unexpectedly high).

Second reviews of diagnostic testing results could also help health care organizations identify diagnostic errors and near misses related to the interpretive aspect of the diagnostic testing processes. A recent guideline recommended that health care organizations use second reviews in anatomic pathology to identify disagreements and potential interpretive errors (Nakhleh et al., 2015). The guideline notes that organizations will likely need to tailor the second review process that they employ and the number of reviews they conduct to their specific needs and resources (Nakhleh et al., 2015). Some organizations include anatomic pathology second reviews as part of their quality assurance and improvement efforts. The Veteran’s Health Administration requires that “[a]t least 10 percent of the cytotechnologist’s gynecologic cases that have been interpreted to be negative are routinely rescreened, and are diagnosed and documented as being negative by a qualified pathologist” (VHA, 2008, p. 32). Though the infrastructure for peer review in radiology is still evolving, there are now frameworks specific to radiology for identifying and learning from diagnostic errors (Allen and Thorwarth, 2014; Lee et al., 2013; Provenzale and Kranz, 2011). In addition to the use of peer review in identifying errors, there is an increasing emphasis on using peer review tools to promote peer learning and improve practice quality (Allen and Thorwarth, 2014; Brook et al., 2015; Fotenos and Nagy, 2012; Iyer et al., 2013; Kruskal et al., 2008). Organizations can participate in the American College of Radiology’s RADPEERTM program, which includes a second review process that can help identify diagnostic performance issues related to medical image interpretation (ACR, 2015).

Patient surveys represent another opportunity. The use of such surveys is in line with the committee’s recommendation to create environments in which patients and their families feel comfortable sharing their feedback and concerns about diagnostic error and near misses. Eliciting this information via surveys may be helpful in identifying errors and near misses, and it can also provide useful feedback to the organization and health care professionals. For example, a recent patient-initiated voluntary survey of adverse events found that harm was commonly associated with reported diagnostic errors and identified actions that patients believed could improve care (Southwick et al., 2015).

In addition to identifying diagnostic errors that have already occurred, some methods used to
monitor the diagnostic process and identify diagnostic errors can be used for error recovery. Error recovery is the process of identifying failures early in the diagnostic process so that actions can be taken to reduce or avert negative effects resulting from the failure (IOM, 2000). Methods that identify failures in the diagnostic process or catch diagnostic errors before significant harm is incurred could make it possible to avoid diagnostic errors or to intervene early enough to avert significant harm. By scanning medical records to identify lapses in care, the SureNet system supports error recovery by identifying patients at risk of experiencing a diagnostic error (HIMSS Analytics, 2015; Kanter, 2014) (see also the section on a supportive work system).

Beyond identifying diagnostic errors and near misses, organizational learning aimed at improving diagnostic performance and reducing diagnostic errors will also require a focus on understanding where in the diagnostic process the failures occur, the work system factors that contribute to their occurrence, what the outcomes were, and how these failures may be prevented or mitigated. For example, the committee’s conceptual model of the diagnostic process describes the steps within the process that are vulnerable to failure: engagement, information gathering, integration, interpretation, establishing a diagnosis, and communication of the diagnosis. If a health care organization is evaluating where in the diagnostic testing process a failure occurs, the brain-to-brain loop model may be helpful in conducting these analyses, in particular by articulating the five phases of testing: pre-pre-analytical, pre-analytical, analytical, post-analytical, and post-post-analytical (Plebani et al., 2011; Plebani and Lippi, 2011). It is also important to determine the work system factors that contribute to diagnostic errors and near misses. Some of the data sources and methods mentioned above, such as malpractice claims analyses and medical record reviews, can provide valuable insights into the causes and outcomes of diagnostic errors. Health care organizations can also employ formal error analysis and other risk assessment methods to understand the work system factors that contribute to diagnostic errors and near misses. Relevant analytical methods include root cause analysis, cognitive autopsies, and morbidity and mortality conferences (Gandhi, 2014; Graber et al., 2014; Reilly et al., 2014). Root cause analysis is a problem-solving method that attempts to identify the factors that contributed to an error; these analyses take a systems approach by trying to identify all of the underlying factors rather than focusing exclusively on the health care professionals involved (AHRQ, 2014b). Maine Medical Center recently conducted a demonstration program to inform clinicians about the root causes of diagnostic errors. They created a novel fishbone root cause analysis procedure, which visually represents the multiple cause and effect relationships responsible for an error (Trowbridge, 2014). Organizations and individuals can also take advantage of continuing education opportunities focused on using root cause analysis to study diagnostic errors in order to improve their ability to identify and understand diagnostic errors (Reilly et al., 2015). The cognitive autopsy is a variation of a root cause analysis that involves a clinician reflecting on the reasoning process that led to the error in order to identify causally relevant shortcomings in reasoning or decision making (Croskerry, 2005). Morbidity and mortality conferences bring a diverse group of health care professionals together to learn from errors (AHRQ, 2008). These can be useful, especially if they are framed from a patient safety perspective rather than focusing on attributing blame. Other analytical methods used in human factors and ergonomics research could also be applied in health care organizational settings to further elucidate the work system components that contribute to diagnostic errors (Bisantz and Roth, 2007; Carayon et al., 2014; Kirwan and Ainsworth, 1992; Rogers et al., 2012; Roth, 2008; Salas et al., 1995).

As health care organizations develop a better understanding of diagnostic errors within their organizations, they can begin to implement and evaluate interventions to prevent or mitigate these errors as part of their patient safety, research, and quality improvement efforts. To date, there have been relatively few studies that have evaluated the impact of interventions on improving diagnosis and reducing diagnostic errors and near misses; three recent systematic reviews summarized current interventions (Graber et al., 2012a; McDonald et al., 2013; Singh et al., 2012b). These reviews found that the measures used to evaluate the interventions were quite heterogeneous, and there were concerns about the generalizability of some of the findings to clinical practice. Health care organizations can take into consideration some of the methodological challenges identified in these reviews in order to ensure that their evaluations generate much-needed evidence to identify successful interventions.

The Medicare conditions of participation and accreditation organizations can be leveraged to ensure that health care organizations have appropriate programs in place to identify diagnostic errors and near misses, learn from them, and improve the diagnostic process. The Medicare conditions of participation are requirements that health care organizations must meet in order to receive Medicare and Medicaid payment (CMS, 2015a). State survey agencies and accreditation organizations (such as the Joint Commission, the Healthcare Facilities Accreditation Program, the Accreditation Commission for Health Care, the College of American Pathologists, and Det NorskeVeritas-Germanischer Lloyd) determine whether organizations are in compliance with the Medicare conditions of participation through surveys and site visits. Some of these organizations accredit the broad range of health care organizations, while others confine their scope to a single type of health care organization. Other accreditation bodies, such as the National Committee for Quality Assurance (NCQA), provide administrative and clinical accreditation and certification of health plans and provider organizations. NCQA, for example, offers accountable care organization (ACO) accreditation, which evaluates an organization’s capacity to provide the coordinated, high quality care and performance-reporting that is required of ACOs (NCQA, 2013). Accreditation processes, federal oversight, and quality improvement efforts specific to diagnostic testing can also be used to ensure quality in the diagnostic process. By leveraging the Medicare conditions of participation requirements and accreditation processes, it may be possible to use the existing oversight programs that health care organizations have in place to monitor the diagnostic process and to ensure that the organizations are identifying diagnostic errors and near misses, learning from them, and making timely efforts to improve diagnosis. Thus, the committee recommends that accreditation organizations and the Medicare conditions of participation should require that health care organizations have programs in place to monitor the diagnostic process and identify, learn from, and reduce diagnostic errors and near misses in a timely fashion. As more is learned about successful program approaches, accreditation organizations and the Medicare conditions of participation should incorporate these proven approaches into updates of these requirements.

**Postmortem Examinations**

The committee recognized that many approaches to identifying diagnostic errors are important, but the committee thought that the postmortem examination (also referred to as an autopsy) warranted additional committee focus because of its role in understanding the epidemiology of diagnostic error. Postmortem examinations are typically performed to determine cause of death and can reveal discrepancies between premortem and postmortem clinical findings. However, the number of postmortem examinations performed in the United States has declined substantially since the 1960s (Hill and Anderson, 1988; Lundberg, 1998; MedPAC, 1999). One of the contributors to the decline is that in 1971 the Joint Commission eliminated the requirement that hospitals conduct these examinations on a certain percentage of deaths in their facility—20 percent in community hospitals and 25 percent in teaching facilities—in
order to receive accreditation (Allen, 2011; CDC, 2001). Cost is another factor; according to a survey of medical institutions in eight states, researchers in 2006 estimated that the mean cost of performing a postmortem examination was $1,275 (Nemetz et al., 2006). Insurers do not directly pay for postmortem examinations, as they typically limit payment to procedures for living patients. Medicare bundles payment for postmortem examinations into its payment for quality improvement activities, which may also disincentivize their performance (Allen, 2011).

Given the steep decline in postmortem examinations, there is interest in increasing their use. For example, Hill and Anderson (1988) recommended that half of all deaths in hospitals, nursing homes, and other accredited medical facilities receive a postmortem examination. Lundberg (1998) recommended reinstating the mandate that a percentage of hospital deaths undergo postmortem examination, either to meet Medicare conditions of participation or accreditation standards. The Medicare Payment Advisory Commission proposed a number of recommendations designed to increase the postmortem examination rate and evaluate their potential for use in “quality improvement and error reduction initiatives” (MedPAC, 1999, p. xviii).

The committee concluded that a new approach to increasing the use of postmortem examinations is warranted. The committee weighed the relative merits of increasing the number of postmortem examinations conducted throughout the United States versus a more targeted approach. The requirements for postmortem examinations in the current Medicare conditions of participation state that postmortem examinations should be performed when there is an unusual death; in particular, these requirements state that “medical staff should attempt to secure an autopsy [postmortem examination] in all cases of unusual death and of medical—legal and educational interest” (CMS, 2015b, p. 210). In these circumstances, the committee concluded that health care organizations should continue to perform these postmortem examinations. In addition, the committee concluded that it is appropriate to have a limited number of highly qualified health care systems participate in conducting routine postmortem exams that produce research-quality information about the incidence and nature of diagnostic errors. Thus, the committee recommends that the U.S. Department of Health and Human Services (HHS) should provide funding for a designated subset of health care systems to conduct routine postmortem examinations on a representative sample of patient deaths. To accomplish this, a subset of health care systems (which reflect a broad array of different settings of care) could receive funding to perform routine postmortem examinations in a representative sample of patient deaths. A competitive grant process could be used to identify these systems.

In recognition that not all patients’ next of kin will consent to the performance of a postmortem examination, these systems can characterize the frequency with which the request for a postmortem examination is refused and thus better describe the risk of response bias in results. This approach will likely provide better epidemiologic data than current practice and represent an advance over current selection methods for performing postmortem examinations, because clinicians do not seem to be able to predict cases in which diagnostic errors will be found (Shojania et al., 2002; Shojania et al., 2003). The committee recognizes that the data collected from health care systems that are highly qualified to conduct routine postmortem examinations may not be representative of all systems of care. However, the committee concluded that this is a more feasible approach, given the financial and workforce demands of conducting postmortem examinations.

Findings from the health care systems that perform routine postmortem examinations can then be disseminated to the broader health care community. Participating health care systems could be required to produce annual reports on the epidemiology of diagnostic errors, the value of postmortem examinations as a tool for identifying and reducing such errors, and, if relevant, the role and value of postmortem examinations in quality improvement efforts.

These health care systems could also investigate how new, minimally invasive postmortem approaches compare with traditional full body postmortem examinations. Less invasive approaches include the use of medical imaging, laparoscopy, biopsy, histology, and cytology. Given the advances in molecular diagnostics and advanced imaging techniques, these new approaches could provide useful insights into the incidence of diagnostic error and may be more acceptable options for patients’ next of kin. For example, instead of conducting a full body postmortem exam, pathologists could biopsy tissue samples from an organ where disease is suspected and conduct molecular analysis (van der Linden et al., 2014). Some studies suggest that minimally invasive postmortem examinations (including a combination of medical imaging with other minimally invasive postmortem investigations) have been found to have accuracy similar to that of conventional postmortem examinations in fetuses, newborns, and infants (Lavanya et al., 2008; Pichereau et al., 2015; Ruegger et al., 2014; Thayil et al.; Weustink et al., 2009). Postmortem imaging in adults has shown less promise for replacing postmortem exams, but these techniques continue to be actively explored (O’Donnell and Woodford, 2008; Roberts et al., 2012). A concern with minimally invasive postmortem imaging is that it may be subject to similar limitations that affect imaging in living patients, and may not detect pre- and post-mortem discrepancies. Further understanding the benefits and limitations of minimally invasive approaches may provide critical information moving forward. If successful approaches to minimally invasive postmortem examinations are found, they could play a role in re-establishing the practice of routine postmortem investigation in medicine (Saldiva, 2014).

### Characteristics of Effective Feedback Interventions

**Feedback**
- Is non-punitive
- Is actionable
- Is timely
- Is individualized
- Comes from the appropriate individual (i.e., a trusted source)
- Targets behavior that can be affected by feedback
- Is provided to recipients who are responsible for improvement
- Includes a description of the desired performance/behavior

**SOURCE:** Hysong et al., 2006, and Ivers et al., 2014

### Improving Feedback

Feedback is a critical mechanism that health care organizations can use to support continuous learning in the diagnostic process. The Best Care at Lower Cost report called for the creation of feedback loops that support continuous learning and system improvement (IOM, 2013). As it relates to diagnosis, feedback entails informing an individual, team, or organization about its diagnostic performance, including its successes, near misses, and diagnostic errors (Black, 2011; Crockery, 2000; Gandhi, 2014; Gandhi et al., 2005; Schiff, 2008, 2014; Trowbridge, 2014). The committee received substantial input indicating that there are limited opportunities for feedback on diagnostic performance (Dhalwal, 2014; Henriksen, 2014; Redelmeier, 2014; Schiff, 2014; Singh, 2014; Trowbridge, 2014). There are often not systems in place to provide clinicians with input on whether they made an accurate, timely diagnosis or if their patients experienced a diagnostic error. The failure to follow up with patients about their diagnosis and treatment—both in the near term and long term—is a major gap in improving diagnosis.

The committee concluded that improving diagnostic performance requires feedback at all levels of health care. Feedback can help clinicians assess how well they are performing in the diagnostic process, correct over-confidence, identify when remediation efforts are needed, and reduce
the likelihood of repeated mistakes (Berner and Graber, 2008; Croskerry and Norman, 2008). Feedback on diagnostic performance can also provide opportunities for health care organizational learning and improvements to the work system (Plaza et al., 2011). To improve the opportunities for feedback, the committee recommends that health care organizations should implement procedures and practices to provide systematic feedback on diagnostic performance to individual health care professionals, care teams, and clinical and organizational leaders.

Feedback interventions in high-performing organizations have been found to share a number of characteristics, including being actionable, timely, individualized, and non-punitive; a non-punitive culture helps foster an environment in which mistakes can be viewed as opportunities for growth and improvement (Hysong et al., 2006). Other studies have found that feedback is likely to have the largest effect when baseline performance is low and feedback occurs regularly (Ivers et al., 2012; Lopez–Campos et al., 2014). Tailoring the feedback approach to the individual recipient and choosing an appropriate source of feedback (e.g., supervisor versus a peer as the provider of feedback) are important variables in determining how well recipients will respond (Ilgen et al., 1979).

Health care organizations need to be aware of the factors that can impede the provision of feedback, such as the fragmentation of the health care system, resistance to critical feedback from clinicians, and the lack of time to for follow-up (Schiff, 2008). In addition, improving feedback will likely require health care organizations to invest additional time and resources into developing systematic feedback mechanisms.

There are many opportunities to provide feedback in clinical practice. Methods to monitor the diagnostic process and identify diagnostic errors and near misses can be leveraged as mechanisms to provide feedback. Feedback opportunities include disseminating postmortem examination results to clinicians who were involved in the patient’s care; sharing the results of patient surveys, medical record reviews, or information gained through follow-up with the health care professionals; using patient actors or simulated care scenarios to assess and inform health care professionals' diagnostic performance; and others (Schwartz et al., 2012; Schwartz and Saul, 2014; Southwick et al., 2015; Weiner et al., 2010). Patients and their families have unique insights into the diagnostic process and the occurrence of diagnostic error; therefore, following up with patients and their families about their experiences and outcomes will be an important source of feedback (Schiff, 2008). Morbidity and mortality conferences, root cause analyses, departmental meetings, and leadership “WalkRounds” provide additional opportunities to provide feedback to health care professionals, care teams, and leadership about diagnostic performance.

Performance monitoring programs designed to satisfy the requirements of the Mammography Quality Standards Act have been used to improve feedback on diagnostic performance on mammography to radiologists and medical imaging facilities (Allen and Thorwarth, 2014). AHRQ recently proposed recommendations for the development of consumer and patient safety reporting systems, which organizations can use for feedback and learning purposes (AHRQ, 2011). Peer review processes, including second reviews of anatomic pathology specimens and medical images, can also be utilized for feedback, and there is an increasing emphasis on using peer-review tools to promote peer learning and improve practice quality (Allen and Thorwarth, 2014; Brook et al., 2015; Fotenos and Nagy, 2012; Iyer et al., 2013; Kruskal et al., 2008). For example, RADPEERTM allows anonymous peer review of previous image interpretations by integrating previous images into current work-flow to allow for a non-disruptive peer review process. Summary statistics of image reviews are made available to participating groups and clinicians to improve performance (AHRQ, 2015).

As of 2013, 16,450 clinicians in 1,127 groups were enrolled in the RADPEERTM program; 1,218 clinicians had used or were using the program as part of the American Board of Radiology’s Practice Quality Improvement project for maintenance of certification (AHRQ, 2013).

Leveraging Health Care Professional Societies’ Efforts to Improve Diagnosis

Health care organizations can leverage external input from health care professional societies to inform the organizations’ efforts to monitor and improve the diagnostic process. Health care professional societies can facilitate improvements in the diagnostic process by appealing to intrinsic motivation and professionalism. Prioritization efforts are an opportunity to engage health care professional societies and their members in the development of diagnosis-improvement approaches specific to their specialties. Thus, the committee recommends that health care professional societies should identify opportunities to improve accurate and timely diagnoses and reduce diagnostic errors in their specialties.

Such an effort could be modeled on the Choosing Wisely Campaign, which was initiated by the American Board of Internal Medicine Foundation to encourage patient and health care professional communication as a way to ensure high-quality, high-value care. The campaign invited health care professional societies to each develop a list of five services (i.e., tests, treatments, and procedures) that are commonly used in practice, but may be unnecessary or not supported by the evidence as improving patient care. These lists were made publicly available as a way of encouraging discussions about appropriate care between patients and health care professionals. Choosing Wisely received national media attention and engaged more than 50 health care professional societies (Choosing Wisely, 2015). A major lesson from the Choosing Wisely Campaign is the importance of beginning with a small group of founding organizations and then expanding membership. Engaging consumer groups as the program progressed was also an important component of the campaign. One factor in the campaign’s success was that it allowed flexibility within limits; participating health care professional societies and boards were given flexibility in identifying their “Top 5” services, but items on each list had to be evidence-based and within the purview of that particular society.

Early efforts on prioritization could focus on identifying the most common diagnostic errors and “don’t miss” health conditions, such as those that present the greatest likelihood for diagnostic errors and harm (Newman-Toker et al., 2013). For example, stroke, acute myocardial infarction, or pulmonary embolism may be important areas of focus in the emergency department setting while cancer is a frequently missed diagnosis in the ambulatory care setting (CRICO, 2014; Gandhi et al., 2006; Newman-Toker et al., 2013; Schiff et al., 2013). Efforts to improve diagnosis can include both improving the quality and safety of diagnosis and increasing efficiency and value, such as identifying inappropriate diagnostic testing. Another approach may be for societies to identify “low-hanging fruit,” or targets that are easily remediable, as a high priority. Doing this may increase the likelihood of having early successes that can contribute to the long-term success of the effort (Kotter, 1995). Some groups may identify particular actions, tools, or approaches to reduce errors associated with a particular diagnosis within their specialties (such as checklists, second reviews, or decision support tools). Each society could identify five high-priority areas to improve diagnosis. The groups would need to be given latitude in the identification of their targets, and, as was the case in Choosing Wisely, a primary constraint could be that there must be evidence indicating that adopting the recommendation would result in improving diagnosis or reducing diagnostic error. This could also be an opportunity for health care professional societies to collaborate, especially in cases of diagnoses that may be missed because of the inappropriate isolation of symptoms among specialties. For example, urologists, primary care clinicians, and neurologists could collaborate to make the diagnosis of normal pressure hydrocephalus (symptoms include frequent urination, a type of balance problem, and
If excellence is to be learned, it must be learned in a way that promotes the shared values, goals, and approaches that can leverage four major cultural movements in health care organizations. As discussed earlier, health care organizations can leverage four major cultural movements in health care—patient safety, professionalism, patient engagement, and collaboration—to create a local environment that supports continuous learning and improvement in diagnosis. Organizational culture refers to an organization’s norms of behavior and the shared basic assumptions and values that sustain those norms (Kotter, 2012; Schein, 2004). Though the cultures in most health care organizations exhibit common elements, they can differ considerably due to varying missions, values, and histories. Another factor that makes culture in health care organizations more complicated is the presence of subcultures (multiple distinct sets of norms and beliefs within a single organization) (Schein, 2004). Subcultures can reflect the individual attitudes of a nurse manager on a specific hospital floor or inter-professional differences that spring from the long history and social concerns of each health care profession (Hall, 2005). The existence of multiple cultures within a single health care organization may make it difficult to promote the shared values, goals, and approaches necessary for improving diagnosis.

### Important Cultural Values for Continuously Learning Health Care Systems

- **Celebration of success.** If excellence is to be pursued with vigor and commitment, its attainment needs to be valued within the organizational culture. Learning organizations value innovation and change—they are searching constantly for new ways to improve their outcomes.
- **Absence of complacency.** Learning organizations recognize that such individuals closest to processes have the best and most intimate knowledge of their potential and flaws. Therefore, the learning culture values tacit knowledge and shows a belief in empowerment (the systematic enlargement of discretion, responsibility, and competence).
- **Openness.** Because learning organizations try to foster a systems view, sharing knowledge throughout the organization is one key to developing learning capacity. “Knowledge mobility” emphasizes informal channels and personal contacts over written reporting procedures. Cross-disciplinary and multifunction teams, staff rotations, on-site inspections, and experiential learning are essential components of this informal exchange.
- **Trust.** For individuals to give their best, take risks, and develop their competencies, they must trust that such activities will be appreciated and valued by colleagues and managers. In particular, they must be confident that should they err, they will be supported, not castigated. In turn, managers must be able to trust that subordinates will use wisely the time, space, and resources given to them through empowerment programs—and not indulge in opportunistic behavior. Without trust, learning is a faltering process.
- **Outward looking.** Learning organizations are engaged with the world outside as a rich source of learning opportunities. They look to their competitors for insights into their own operations and are attuned to the experiences of other stakeholders, such as their suppliers. In particular, they are focused on obtaining a deep understanding of clients’ needs.


Some aspects of culture may promote diagnostic accuracy, such as the intrinsic motivation of health care professionals to deliver high-quality care and the dedicated focus on quality and safety found in some health care organizations. Other aspects of culture may be detrimental to efforts to improve diagnosis, including the persistence of punitive, fault-based cultures; cultural taboos on providing peer feedback; hierarchical attitudes that are misaligned with team-based practice; and the acceptance of the inevitability of errors. Punitive cultures that emphasize discipline and punishment for those who make mistakes are not conducive to improved diagnostic performance; this type of culture thrwarts the learning process because health care professionals fear the consequences of reporting errors (Hoffman and Kanzaria, 2014; Khatri et al., 2009; Larson, 2002; Schiff, 1994). Clinicians within these settings may also feel uneasy about providing feedback to colleagues about their diagnostic performance or the occurrence of diagnostic errors (Gallagher et al., 2013; Tucker and Edmondson, 2003). There have been multiple calls for health care organizations to create non-punitive cultures that encourage communication and learning (IOM, 2000, 2004, 2013). Despite these efforts, a punitive culture persists within some health care organizations (Chassin, 2013; Chassin and Loeb, 2013). For example, a recent survey found that less than half (44 percent) of health care professionals perceived that their organizations had a non-punitive response to error (AHRC, 2014a). The fault-based medical liability system and, in rare cases, clinicians who exhibit unprofessional or intimidating behavior also contribute to the persistence of punitive cultures (Chassin, 2013; Chassin and Loeb, 2013).

Cultures that continue to view diagnosis as a solitary clinician activity discount the important roles of teamwork and collaboration. A culture that values innovation and change—they are searching constantly for new ways to improve their outcomes (Kotter, 1995). Health care organizations may be hesitant to attempt culture change because of system inertia, concern that benefits due to the present culture could be lost, or because there is uncertainty regarding which approaches to improving culture work best in a given organizational setting (Chassin, 2013; Coiera, 2011; Parmelli et al., 2011).

Organizations may attempt to implement multiple change processes simultaneously, and this can lead to change fatigue, where employees experience burnout and apathy (Perlman, 2011). Other factors may include: the failure to convey the urgent need for change; poor communication of the successes that have resulted from change; the inadequate identification, preparation, or removal of barriers to change; and insufficient involvement of leadership and management in important cultural values for continuously learning health care systems.
the change initiative (Chassin, 2013; Hines et al., 2008; IOM, 2013; Kotter, 1995; Kotter, 2012).

Although the challenges to cultural change can be significant, the committee concluded that addressing organizational culture is central to improving diagnosis (Gandhi, 2014; Kanter, 2014; Thomas, 2014). Thus, the committee recommends that health care organizations should adopt policies and practices that promote a non-punitive culture that values open discussion and feedback on diagnostic performance. There are a variety of approaches that can be employed to improve culture (Davies et al., 2000; Etchegary et al., 2012; Schein, 2004; Schiff, 2014; Williams et al., 2007). The measurement of an organization’s culture is often a first step in the improvement process because it facilitates the identification of cultural challenges and the evaluation of interventions (IOM, 2013). A number of measurement tools are available, including surveys to identify health care professionals’ perception of their organization’s culture (AHRQ, 2014c; Farley et al., 2009; Modak et al., 2007; Sexton et al., 2006; Watts et al., 2010). Organizations can create a culture that supports learning and continual improvement by implementing a just culture, also referred to as a culture of safety (IOM, 2004); Kanter, 2014; Khatri et al., 2009; Larson, 2002; Marx, 2001; Milstead, 2005).

A just culture balances competing priorities—learning from error and personal accountability—by understanding that health care is a complex activity involving imperfect individuals who will make mistakes, while not tolerating reckless behavior (AHRQ, 2015a). The just culture approach distinguishes between “human error” (an inadvertent act by a clinician, such as a slip or lapse), “at-risk behavior” (taking shortcuts, violating a safety rule without perceiving it as likely to cause harm), and “reckless behavior” (conscious choices by clinicians to engage in behavior they know poses a significant risk, such as ignoring required safety steps). The just culture model recommends “consoling the clinician” involved in human error, “coaching the clinician” who engages in at-risk behavior, and reserving discipline only for clinicians whose behavior is truly reckless. Further refinements to this approach employ a “substitution test” (i.e., would three other clinicians with similar skills and knowledge do the same in similar circumstances?) to identify situations in which system flaws have developed that create predisposing conditions for the error in question to occur. Finally, whether or not the clinician has a history of repeatedly making the same or similar mistakes is considered in formulating an appropriate response to error.

Health care organizations can also look to high reliability organizations (HROs), which operate in high-stakes conditions but maintain high safety levels (such as those found in the nuclear power and aviation industries). Health care organizations can benefit from adapting the traits of HRO cultures, such as rejecting complacency and focusing on error reduction (Chassin and Loeb, 2011; Singh, 2014; Thomas, 2014; Weick and Sutcliffe, 2011). The involvement of supportive and committed leadership is another component of successful attempts to improve culture and is a key component of HRO success (Chassin, 2013; Hines et al., 2008; IOM, 2013; Kotter, 1995; Kotter, 2012).

Health care organizations can espouse cultural values that support the open discussion of diagnostic performance and improvement (Davies and Nutley, 2000). The culture needs to promote the discussion of error and offer psychological safety (Jeffe et al., 2004; Kachalia, 2013). Successes need to be celebrated, and mistakes need to be treated as opportunities to learn and improve. Complacency with regard to current diagnostic performance needs to be replaced with an enduring desire for continuing improvement. An emphasis on teamwork is critical, and it can be facilitated by a culture that values the development of trusting, mutually respectful relationships among health care professionals, patients and their family members, and organizational leadership.

Despite the difficulties one faces in implementing culture change, health care organizations have begun to make changes that can improve patient safety (Chassin and Loeb, 2013). For instance, changing culture was a critical factor in sustaining the reduction in intensive care unit–acquired central line bloodstream infections in Michigan state hospitals (Pronovost et al., 2006, 2008, 2010). Cincinnati Children’s Hospital has focused on better process design that leverages human factors expertise and on building a culture of reliability (Cincinnati Children’s Hospital, 2014). A number of health care organizations have undertaken the process of instituting a just culture by prioritizing learning and fairness and creating an atmosphere of transparency and psychological safety (Marx, 2001; Wyatt, 2013). For example, after two high-profile medical mistakes, the Dana–Farber Cancer Institute implemented a plan to develop a just culture in order to improve learning from error and care performance (Connor et al., 2007). Its plan centered on incorporating a set of principles into practice that promoted learning, the open discussion of error, individual accountability, and program evaluation; this plan was endorsed and supported by organizational leadership (Connor et al., 2007). Organizations can explore the strategies that are best suited to their needs and aims (e.g., specific strategies for small practices to improve culture) (Gandhi and Lee, 2010; Shostek, 2007).

Leadership and Management

Organizational leaders are responsible for setting the priorities and expectations that guide a health care organization and for determining the rules and policies necessary to achieve the organization’s goals. Organizational leaders can include the health care organization’s governing body, the chief executive officer and other senior managers, and clinical leaders; collaboration among these leaders is critical to achieving the organization’s quality goals. According to the Joint Commission (2009, p. 3), only “the leaders of a health care organization have the resources, influence, and control” to ensure that an organization has the right elements in place to meet quality and safety priorities, including a non-punitive culture, the availability of appropriate resources (including human, financial, physical, and informational), a sufficient number of competent staff, and an ongoing evaluation of the quality and safety of care. In particular, health care organization governing boards have an obligation to ensure the quality and safety of care within their organizations (Armwine, 2002; Callender et al., 2007; Joint Commission, 2009). As a part of their oversight function, governing boards routinely identify emerging quality of care trends and can help prioritize efforts to address these issues within an organization.

The involvement of organizational leaders and managers is crucial for successful change initiatives (Dixon-Woods et al., 2011; Firth-Cozens, 2004; Gandhi, 2014; Kotter, 1995; Larson, 2002; Moran and Brightman, 2000; Silow-Carroll et al., 2007). In many health care organizations, organizational leaders have not focused significant attention on improving diagnosis and reducing diagnostic errors (Gandhi, 2014; Graber, 2005; Graber et al., 2014; Henriksen, 2014; Wachter, 2010; Zwaan et al., 2013). However, facilitating change will require the support and involvement of these leaders. To start, health care governing boards can prioritize diagnosis and can support senior managers in implementing policies and practices that support continued learning and improved diagnostic performance. For example, potential policies and practices could focus on teamwork-based care in diagnosis, the adoption of a continuously learning culture, opportunities to provide feedback to clinicians, and approaches to monitor the diagnostic process and identify diagnostic errors and near misses. All organizational leaders can raise awareness of the quality and safety challenges related to diagnostic error as well as dispelling the myth that diagnostic errors are inevitable (Leape, 2010; Wachter, 2010). Importantly, organizational leaders can appeal to the intrinsic motivation of health care professionals to drive improvements in diagnosis.

Focusing on improving diagnosis and reducing diagnostic error is necessary to improve the quality and safety of care; in addition, it has the potential to reduce organizational costs (IOM,
organizations can take, including a focus on error recovery, such as the emergency department and the intensive care unit (Wachter, 2015). The thoughtful use of redundancies, such as second reviews of anatomic pathology specimens and medical images, consultations, and second opinions in challenging cases or complex care environments, are also a form of error recovery that health care organizations can consider (Durning, 2014; Nakhleh et al., 2015). For example, the tele-intensive care unit (tele-ICU) is a telemedicine process that helps support clinicians’ care for acutely ill patients by using off-site clinicians and software systems to provide a “second set of eyes” to remotely monitor ICU patients (Berenson et al., 2009; Khunlertkit and Carayon, 2013).

Results Reporting and Communication

The Joint Commission has identified improved communication of critical test results as a key safety issue and urges organizations to “[r]eport critical results of tests and diagnostic procedures on a timely basis” (Joint Commission, 2015b, p. 2). Input to the committee echoed this call and emphasized the importance of improving communication between treating health care professionals, pathologists, radiologists, and other diagnostic testing clinicians (Allen and Thorwarth, 2014; Epner, 2015; Gandhi, 2014; Myers, 2014). To facilitate the timely collaboration among health care professionals in the diagnostic process, the committee recommends that health care organizations should develop and implement processes to ensure effective and timely communication between diagnostic testing health care professionals and treating health care professionals across all health care delivery settings. For example, closed loop reporting systems for diagnostic testing and referral can be implemented to ensure that test results or specialist findings are reported back to the treating health care professional in a timely manner (Gandhi, 2014; Gandhi et al., 2005; Myers, 2014; SHIEP, 2012). These systems can also help to ensure that relevant information is being communicated among the appropriate health care professionals. Recent efforts to improve closed loop reporting include the American Medical Association’s Closing the Referral Loop Project and the Office of the National Coordinator for Health Information Technology’s 360X Project, which aim to develop guidelines for closed loop referral system implementation (AMA, 2015; Williams, 2012). Early lessons from the 360X Project include the importance of seamless workflow integration, tailoring the amount of information transmitted between clinicians and specialists, and the importance of national standards for system interoperability (SHIEP, 2012). A task force comprised of pathologists, radiologists, other clinicians, risk managers, patient safety specialists, and IT specialists recommended four actions to improve communication and follow-up related to clinically significant test results: (1) standardize policies and definitions across networked organizations, (2) identify the patient’s care team, (3) results management and tracking, and (4) develop shared quality and reporting metrics (Roy et al., 2013).

Health care organizations can leverage health IT resources to improve communication and collaboration among pathologists, radiologists, and treating health care professionals (Allen and Thorwarth, 2014; Gandhi, 2014; Kroft, 2014; Schiff et al., 2003). HHS Tests Results Reporting and Follow-Up SAFER Guide offers insight on how to use EHRs to safely facilitate communication and the reporting of results (HHS, 2015). Some closed loop reporting systems include an alert notification mechanism designed to inform ordering clinicians when critical diagnostic testing results are available (Lacson et al., 2014a; Lacson et al., 2014b; Singh et al., 2010). Dalal and colleagues (2014) identified an automated email notification system as a “promising strategy for managing” the results of tests that were pending when the patient was discharged. There is some evidence that the use of alert notification mechanisms improves timely communication of results reports (Lacson et al., 2014a; Lacson et al., 2014b). However, closed loop
reporting systems need to be carefully designed to support clinician cognition and work-flow in the diagnostic process; if there are a high volume of alerts, a clinician may experience cognitive overload, which can limit the effectiveness of such alerts (Singh et al., 2009; Singh et al., 2010). The use of standard formats may also improve the communication of test results. Studies have shown that structured radiology reports are more complete, have more relevant content, and greater clarity than free-form reports (Marcovici and Taylor, 2014; Schwartz et al., 2011).

Similar to a checklist, structured reports have a template with standardized headings and often use standardized language. Input to the committee suggests that similar standardized formats for anatomic and clinical pathology results reports are likely to improve communication (Gandhi, 2014; Myers, 2014). Encouraging the use of simpler and more transparent language in results reports may also improve communication between health care professionals.

Additional Work System Elements

In addition to improving error recovery and results reporting and communication, health care organizations can focus more broadly on improving the work system in which the diagnostic process occurs. To ensure that their work systems are designed to support the diagnostic process, health care organizations need to consider all the elements of the work system and recognize that these elements are interrelated and dynamically interact. For example, a new EHR system (tools and technology) will be most beneficial when an organization ensures that its health care professionals are trained on how to use the system (team members and tasks), when the system meets usability standards (external environment), and when the tool is located in the appropriate location (physical environment). The following sections highlight some of the ways in which health care organizations can improve the design of work systems for improved diagnostic performance. The actions discussed are not meant to be exhaustive; rather they are offered as examples of steps organizations can take.

In addition to improving a specific work system, health care organizations also need to recognize that patients may cross organizational boundaries when seeking a diagnosis. This fragmentation has the potential to contribute to diagnostic errors and the failures to learn from them. Though health care organizations are not solely responsible for this problem, they have a responsibility to ensure, to the best of their abilities, that the health care system as a whole supports the diagnostic process. Teamwork and health IT interoperability will help, but to meet this responsibility, organizations will need to take steps to improve communication with other organizations. One mechanism, which was discussed earlier, focuses on improving the communication of diagnostic testing results and referrals. Implementing systematic feedback mechanisms that track patient outcomes over time could also identify diagnostic errors that transcend health care organization boundaries. In addition, payment and care delivery reforms that incentivize accountability and collaboration may alleviate some of the challenges that the fragmented nature of the health care system presents for diagnosis.

Physical Environment

The design and characteristics of the physical environment can influence human performance and the quality and safety of health care (Carayon, 2012; Hogarth, 2010; Reiling et al., 2008). Elements of the physical environment include the layout and ambient conditions such as distractions, noise, temperature, and lighting. Researchers have focused primarily on the design of hospital environments and how these environments may influence patient safety, patient outcomes, and task performance. For example, a review of 600 articles on the impact of physical design found three studies that linked medication errors with factors in the hospital environment, including lighting, distractions, and interruptions (Ulrich et al., 2004). Another study found that operational failures occurring in two large hospitals were the result of insufficient workspace (29 percent), poor process design (23 percent), and a lack of integration in the internal supply chains (23 percent); only 14 percent of the failures could be attributed to training and human error (Tucker et al., 2013).

Although the impact of the physical environment on diagnostic error has not been well studied, there are indications that it may be an important contributor to diagnostic performance. For example, the emergency department has been described as a challenging environment in which to make diagnoses because of the presence of high-acuity illness, incomplete information, time constraints, and frequent interruptions and distractions (Croskerry and Sinclair, 2001). Cognitive performance is vulnerable to distractions and interruptions, which influence the likelihood of error (Chisholm et al., 2000). Other physical environment factors that could influence the diagnostic process include the location of health technologies designed to support the diagnostic process, adequate space for team members to complete their tasks related to the diagnostic process, and ambient conditions that can affect cognition, such as noise, lighting, odor, and temperature (Chellappa et al., 2011; Johnson, 2011; Mehta et al., 2012; Parsons, 2000; Ward, 2013). Poorly designed systems that require health care professionals to traverse long distances to perform their tasks may increase fatigue and reduce face-to-face time with patients (Ulrich et al., 2004). To address the challenges associated with the physical environment, health care organizations can design workplaces that align with work patterns and support work-flow, can locate health technology near the point of care, and can reduce ambient noise (Durning, 2014; Reiling et al., 2008; Ulrich et al., 2004). Other possible actions include using the appropriate lighting, providing adequate ventilation, and maintaining an appropriate temperature to ensure that the ambient conditions do not negatively affect diagnostic performance. Studies suggest that such changes may improve both patient outcomes and patient and family satisfaction with care provision (Reiling et al., 2008; Ulrich et al., 2004).

Diagnostic Team Members and Their Tasks

Health care organizations need to ensure that their clinicians have the needed competencies and support to perform their tasks in the diagnostic process. Health care professional certification and accreditation standards can be leveraged to ensure that health care professionals within an organization are well prepared to fulfill their roles in the diagnostic process. Health care organizations can also offer more opportunities for team-based training in diagnosis and can expand the use of integrated practice units, treatment planning conferences, and diagnostic management team. Ensuring adequate supervision and support of health care professionals—especially the many health care professional trainees involved in the diagnostic process—is another way for health care organizations to improve the work system (ACGME, 2011; IOM, 2009). For example, many health care organizations have adopted policies to address patient safety risks caused by fatigue (including decision fatigue), sleep deprivation, and sleep debt for medical residents (Croskerry and Musson, 2009; IOM, 2009; Zwaan et al., 2009). Health care professionals who work in high-stress environments may also experience mental health difficulties and burnout which can increase the chance of error (AHRQ, 2005; Bakker et al., 2005; Dyrby and Shanafelt, 2011). Several studies have identified certain characteristics of the workplace and high patient care demands as a cause of this stress and have suggested workforce and culture changes as potential solutions (AHRQ, 2005; Bakker et al., 2005; Dyrby and Shanafelt, 2011). For example, work scheduling practices can ensure that a health care organization has the appropriate clinicians for facilitating the diagnostic process (both amount of clinicians and appropriate areas of expertise).

Health care organizations can also make improvements to the work system to better involve patients and their families in the diagnostic process and in efforts to improve diagnosis (Kelly et al., 2013). For example, health care organizations can
improve patient access to their EHRs, incorporate patient and family advisory groups, and involve patients and their families in processes to learn about errors when appropriate. In addition, these organizations can offer patients and their families more opportunities to provide feedback on their experiences with diagnosis.

**Tools & Technologies**

Health care organizations will need to consider how the tools and technologies they provide for the delivery of health care affect the diagnostic process. For example, health IT tools need to incorporate human-centered design principles, fit within clinical work-flow, provide decision support, and facilitate the timely flow of information. Health care organizations can consider these issues when choosing health IT tools to incorporate, considering implementation issues, and ensuring that use is safe and aligned with clinical work-flow. Some organizations may need to consider work-flow redesign when adopting new health IT. Resources are available to guide health care organizations as they integrate new health IT or redesign their work-flow (HealthIT.gov, 2013).

**External Environment**

External environmental factors can influence the work system in which diagnosis occurs, and although they are typically not under the control of health care organizations, they need to be taken into account as efforts to improve the work system are implemented at the level of health care organizations.

**The External Environment Influencing Diagnosis: Reporting, Medical Liability, & Payment**

This section focuses on the external environment and how it contributes to the diagnostic process and the occurrence of diagnostic errors. The category of external environmental factors is quite broad and may include: error reporting, medical liability, payment and care delivery, and oversight processes (such as accreditation, certification, and regulatory requirements). While the committee does consider oversight processes to be external environmental factors, they are discussed in the sections on health care professional education and competency in other sections.

In this section the committee emphasizes the need for safe environments for voluntary error reporting, without the threat of legal discovery or disciplinary action, where health care organizations can analyze and learn from diagnostic errors in order to improve diagnosis. The role of medical liability reform is also described as an opportunity to increase the disclosure of diagnostic errors as well as to promote improved reporting, analysis, and learning from diagnostic errors. The committee highlights the potential for payment models—both current and new—to incentivize improved diagnostic performance. Importantly, this chapter reflects the committee’s commitment to consider recommendations from both a pragmatic and an aspirational perspective. The committee’s recommendations balance the urgent need to improve diagnosis by identifying immediate opportunities for improvement while also considering more fundamental changes that are likely to take significant effort and time to achieve. As noted elsewhere in the report, the committee’s recommendations to improve diagnosis in this chapter may also improve patient safety and health care more generally. For example, the evaluation of the Patient Safety Organization program is likely to be informative for error reporting broadly; adoption of Communication and Resolution Programs has the potential to improve disclosure and error analysis for all types of errors in health care; and reforming fee-for-service (FFS) payment and documentation guidelines could also benefit the health care system more broadly.

**Reporting & Learning From Diagnostic Errors**

The committee concluded that there need to be safe, confidential places for health care organizations and professionals to share and learn from their experiences of diagnostic errors, adverse events, and near misses. Conducting systems-based analysis of these events presents the best opportunity to learn from such experiences and to implement changes to improve the diagnostic process. The Institute of Medicine’s (IOM) *To Err Is Human: Building a Safer Health System (2000)* report recommended that reporting systems be used to collect this information. Various groups, including individual states, the Joint Commission, the Department of Veterans Affairs, and patient safety organizations (PSOs), have developed a number of reporting systems which collect different types of information for different purposes. Characteristics of successful reporting systems include: the reporting is safe for those individuals who report; reporting leads to constructive responses; adequate expertise and resources enable learning from reporting; and the results of reporting can be disseminated (Barach and Small, 200; WHO, 2005). In contrast, if health care organizations focus on punishing individuals who make mistakes, it will prevent people from reporting because they fear that a report may be used as evidence of fault, could precipitate lawsuits, or could result in disciplinary action by state professional licensing boards and employers (IOM, 2012; WHO, 2005). Thus, there is a need for safe environments in which there is not the threat of legal discovery or disciplinary action, where diagnostic errors, adverse events, and near misses can be analyzed and learned from in order to improve the quality of diagnosis and prevent future diagnostic errors. In line with the *To Err Is Human* report, the committee recommends that the Agency for Healthcare Research and Quality (AHRQ) or other appropriate agencies or independent entities should encourage and facilitate the voluntary reporting of diagnostic errors and near misses.

Unfortunately, it is often difficult to create environments where diagnostic errors, adverse events, and near misses can be shared and discussed. Health care organizations and clinicians have been challenged by the limitations of inconsistent and individual state-enacted peer review and quality improvement processes for the protection of information relating to adverse events and medical errors, the external use of such information, and what benefits the health care organizations and clinicians receive from reporting. In response to this challenge, the *To Err Is Human* report recommended that “Congress should pass legislation to extend peer review protections to data related to patient safety and quality improvement that are collected and analyzed by health care organizations for internal use or shared with others solely for purposes of improving safety and quality” (IOM, 2000, p. 10). In 2005 the Patient Safety and Quality Improvement Act (PSQIA) was passed by Congress; the act confers privilege and confidentiality protections to health care organizations that share specific types of patient safety information with federally listed PSOs (HHS, 2015). According to AHRQ, which shares responsibility for implementing PSQIA with the Office for Civil Rights, “The Act promotes increased patient safety event reporting and analysis, as adverse event information reported to a... PSO is protected from disclosure in medical malpractice cases. This legislation supports and stimulates advancement of a culture of safety in health care organizations across the country, leading to provision of safer care to patients” (AHRQ, 2015a, p. 23). The PSO program provides an important national lever to increase voluntary error reporting and analysis which is well aligned with the committee’s recommendation. However, progress in implementing the PSO program has been slow (AHRQ, 2015a; GAO, 2010). The committee is concerned that a number of challenges with the current program may limit the extent to which it can facilitate much-needed voluntary reporting, analysis, and learning of diagnostic errors and near misses (see section below on the evaluation of the PSO program).

Due to this concern, the committee’s recommendation recognizes that additional federal efforts across the U.S. Department of Health and Human Services (HHS), as well as the involvement of other independent entities, need to be considered in order to prioritize voluntary event reporting for diagnostic errors and near misses. Support of this
recommendation can be found in the IOM report *Health IT and Patient Safety: Building Safer Systems for Better Care*, which reviewed the existing reporting systems in health care and concluded that despite the various reporting systems and numerous calls for change, adverse event reports are not being collected and analyzed in a comprehensive manner (IOM, 2012). The report concluded that “learning from these systems is limited because a multitude of different data is collected by each system, hampering any attempt to aggregate data between reporting systems” (IOM, 2012, p. 152). After reviewing the opportunities to improve adverse event reporting, the committee that produced the 2012 report made a recommendation for a new entity, akin to the National Transportation Safety Board, that could investigate “patient safety deaths, serious injuries, or potentially unsafe conditions” and report results of these activities (IOM, 2012, p. 11). That committee suggested that this entity’s purview could include: (1) collecting reports of adverse events; (2) analyzing collected data to identify patterns; (3) investigating reports of patient deaths or serious injuries related to health IT; (4) investigating trends of reports of unsafe conditions; (5) recommending corrective actions; (6) providing feedback based on these investigations; and (7) disclosing the results of the investigations to the public.

Because efforts to improve voluntary reporting and analysis at the national level have been slow, the current committee also recognized the potential for more localized efforts that could be carried out while national efforts continue to be developed and improved. In the interim, smaller-scale efforts to improve voluntary reporting and learning from diagnostic errors, adverse events, and near misses may be helpful for generating and sharing the lessons learned from such efforts. For instance, at the level of health care organizations, quality and patient safety committees can incorporate the analysis of and learning from diagnostic errors, and these activities may be protected from disclosure by state statutes. In an integrated delivery system in Maine, for example, a surgical quality collaborative was established to review the quality and safety of surgical care, compare results to national and regional data, and provide feedback to participating organizations. Another option that some organizations (including PSOs) are incorporating is the use of “safe tables” forums (WSHA, 2014), which are “members-only, shared learning meeting[s] of healthcare peers to exchange patient safety experiences, discuss best practices and learn in an open, uninhibited and legally protected environment” (MHA PSO, 2015). The limitation to this approach is that the best practices and lessons learned cannot be shared beyond the participants.

### Evaluation of the PSO Program

The PSO program enables public or private organizations to be listed as a PSO, provided that they meet certain qualifications articulated in the patient safety rule (AHRQ, 2015c). PSO designation indicates that an organization is “authorized to serve providers as independent patient safety experts and to receive data regarding patient safety events that will be considered privileged and confidential” (GAO, 2010, p. 2). PSOs do not receive federal funding, but they can recruit health care organizations and clinicians to join their PSO. When health care organizations or health care professionals join a PSO, they then voluntarily send patient safety data to the PSO for analysis and feedback on how to improve care. Additionally, PSOs can send de-identified patient safety data to the Network of Patient Safety Databases (NPSD) overseen by AHRQ. The intent of the program is that AHRQ will then analyze the aggregated data and publish reports (GAO, 2010). A provision in the Affordable Care Act will likely increase the number of hospitals who join PSOs; per the HHS 2015 Payment Notice, hospitals with more than 50 beds will be required to join a PSO by January 2017 in order to contract with health plans in insurance exchanges” (AHRQ, 2015). There is very limited information about the impact that PSOs have on learning and improving the quality and safety of care. The Government Accountability Office concluded in 2010 that it was too early to evaluate the effectiveness of the PSO program (GAO, 2010). AHRQ is still in the process of implementing the NPSD, and to this point aggregated information collected from PSOs has not been analyzed or shared.

Currently there are more than 80 listed PSOs, and the PSO network is active in sharing information with their members about strategies to mitigate patient safety events, as evidenced by PSO websites (AHRQ, 2015c). AHRQ has also developed Common Formats, or generic- and event-specific forms, to encourage standardized event reporting among PSOs (AHRQ, 2015b). However, use of the Common Formats is voluntary and some organizations are implementing these variably or using legacy reporting formats (ONC, 2014). To facilitate the aggregation of patient safety data, “AHRQ established the PSO Privacy Protection Center (PSO PPC) to receive data from PSOs, facilitate the use of the common formats, de-identify data in a standardized manner, validate the quality and accuracy of PSO data, provide technical assistance to PSOs and other users of the Common Formats, and transmit non-identifiable data to the NPSD” (AHRQ, 2015a, p. 53).

The PSO PPC works with individual PSOs that wish to submit de-identified patient safety event information. In order to submit reports, PSOs are required to sign a data use agreement with the PSO PPC. By the end of fiscal year 2014, 20 of 76 listed PSOs had established data use agreements with the PSO PPC (AHRQ, 2015a). AHRQ reports that while these data use agreements “grew in number in FY 2014, and some data were transmitted to the PSO PPC, none have been of sufficient quality and volume to ensure that data transmitted to the NPSD is both accurate and non-identifiable” (AHRQ, 2015a, p. 53). For fiscal year 2015, AHRQ expects the volume of data submission to the PSO PPC and the quality of the data submitted to increase significantly. AHRQ’s goal is to gather “sufficient patient safety event reports to transmit to the NPSD,” and the fiscal year 2015 target is to transfer 25,000 patient safety event reports to the NPSD (AHRQ, 2015a, p. 53).

There are concerns that the federal privilege protections extended by PSQIA are not shielding organizations from state reporting requirements; a recent ruling by the Kentucky Supreme Court found that the information a hospital is required to generate under state law is not protected by PSQIA, even if it is shared with a PSO. This type of court decision could undermine the creation of safe environments for sharing this information and thus make voluntary submissions to PSOs much less likely.

Given that the PSO program has the potential to improve learning about diagnostic errors and to expedite the implementation of solutions and adoption of best practices, it is important to evaluate whether the program is meeting the statutory objectives of PSQIA—namely, that the PSO program is creating opportunities to examine and learn from medical errors, including diagnostic errors. Thus, the committee recommends that AHRQ should evaluate the effectiveness of PSOs as a major mechanism for voluntary reporting and learning from these events. Given the concern over the erosion of PSQIA privilege protections at the state level, the evaluation could also focus on whether these protections are consistent with Congress’s intent in enacting the legislation. While the evaluation of the PSO program is ongoing, PSOs can help support voluntary reporting efforts by educating their members about the applicable state peer review protections as well as about the PSQIA privilege protections. Health care organizations participating in PSOs can also take steps to ensure that any information and data shared with PSOs are protected by defining their patient safety evaluations systems broadly and by carefully analyzing the information they intend to submit to a PSO in order to minimize the chance that the PSQIA privilege is abrogated (or invalidated) at the state level.

The evaluation of the PSO program could also explore how the PSO program influences efforts to improve transparency within health care organizations. According to a recent report, “PSOs have the potential to foster transparency through increased reporting of complications and errors, and identification and sharing of learning and
best practices; however, it remains to be seen how successfully these groups can balance the need for a protected space to which organizations can voluntarily report errors and the need for open sharing of information outside the organization” (National Patient Safety Foundation Lucian Leape Institute, 2015, p. 16). The committee recognizes that efforts to improve diagnosis can include both a focus on improving the disclosure of medical errors to patients and their families (see discussion on communication and resolution programs) and efforts to improve voluntary reporting and learning. In addition, AHRQ’s evaluation needs to focus on how AHRQ and PSOs can improve the voluntary reporting of diagnostic errors and learning from those errors, which have not been a major focus within PSOs to date. The committee recommends that AHRQ should modify the PSO common formats for reporting of patient safety events to include diagnostic errors and near misses. To implement common formats specific to diagnostic error, AHRQ could begin with high-priority areas (such as the most frequent diagnostic errors or “don’t miss” health conditions that may result in significant patient harm, such as stroke, acute myocardial infarction, and pulmonary embolism). AHRQ could also consider whether other PSO activities, such as discussions during annual PSO meetings, could focus attention on diagnostic errors.

Medical Liability

The two core functions of the medical liability system are to compensate negligently injured patients and to promote quality by encouraging clinicians and organizations to avoid medical errors. Although the medical liability system may act as a generalized deterrent to medical errors, it is not well aligned with the promotion of high-quality, safe care (Mello et al., 2014b). Concerns about medical liability prevent clinicians from disclosing medical errors to patients and their families, despite calls from numerous groups that full disclosure is an ethical necessity (Hendrich et al., 2014; Sage et al., 2014) and despite the fact that such disclosures are a requirement for Joint Commission accreditation. Clinicians often struggle to fulfill this responsibility (Gallagher et al., 2007; Gallagher et al., 2013; Joint Commission, 2005). There is limited guidance for clinicians about how to disclose this information effectively, and a number of factors, including embarrassment, inexperience, lack of confidence, and mixed messages from risk managers and health care organizations’ senior leadership, can thwart disclosures to patients and their families (Gallagher et al., 2013; Schiff, 2014).

The current tort-based judicial system for resolving medical liability claims creates barriers to improvements in quality and patient safety and stifles continuous learning. Medical malpractice reform could be designed to permit patients and health professionals to become allies in trying to make health care safer by encouraging transparency about errors. Such an approach would allow patients to be promptly and fairly compensated for injuries that were avoidable while at the same time turning errors into lessons to improve subsequent performance (Berenson, 2005; Mello et al., 2014a; Mello and Gallagher, 2010).

The IOM report Fostering Rapid Advances in Health Care: Learning from System Demonstrations concluded that there are numerous challenges to the current medical liability system, including the many instances of negligence that do not result in litigation and, conversely, the many malpractice claims that are not the result of negligent care as well as judgments that are inconsistent with the evidence base and highly variable compensation for similar medical injuries (IOM, 2002). Patients and their families are poorly served by the current system; only a fraction of negligently injured patients receive compensation, typically after a protracted and adversarial litigation process (AHRQ, 2014; Kachalia and Mello, 2011). One analysis found that fewer than 2 percent of patients who experienced adverse events due to medical negligence actually filed malpractice claims (Localio et al., 1991); another analysis found that the rates of paid medical malpractice claims have steadily declined since the early 2000s (Mello et al., 2014b). An ongoing medical liability concern is the practice of defensive medicine. Defensive medicine “occurs when doctors order tests, procedures, or visits, or avoid high-risk patients or procedures, primarily (but not necessarily solely) to reduce their exposure to malpractice liability” (OTA, p. 13, 1994). The practice of defensive medicine is a barrier to high-quality care, because it can lead to overly aggressive and unnecessary care. For example, clinicians who practice defensive medicine may order more diagnostic tests than are necessary. (Hoffman and Kanzaria, 2014; Kessler, 2006; Mello et al., 2010). Overtesting in the diagnostic process has the potential to cause patient harm—both from the risk of the diagnostic test itself, as well as the resulting cascade of diagnostic and treatment decisions that stem from the test result (Hoffman and Kanzaria, 2014).

Diagnostic errors are a leading cause of malpractice claims, and these claims are more likely to be associated with patient deaths than other types of medical errors (Tehrani et al., 2013). Reforming the medical liability system, therefore, has the potential to improve learning from diagnostic errors and to facilitate the disclosure of diagnostic errors to patients and their families as well as to produce fairer outcomes in the medical injury resolution processes. The committee recommends that states, in collaboration with other stakeholders (health care organizations, professional liability insurance carriers, state and federal policy makers, patient advocacy groups, and medical malpractice plaintiff and defense attorneys), should promote a legal environment that facilitates the timely identification, disclosure, and learning from diagnostic errors.

There have been many calls for changes to the medical liability system. Traditional mechanisms to reform the liability system—such as imposing barriers to bringing lawsuits, limiting compensation, and changing the way that damage awards are paid—have not resulted in improvements in either compensating negligently injured patients or deterring unsafe care (Mello et al., 2014b). Thus, the committee concluded that these stakeholders need to consider alternative approaches to improving the legal environment and promoting learning from diagnostic errors. The To Err is Human report concluded that alternative approaches to the resolution of medical injuries could reduce the incentive to hide medical injuries, and in 2002 the IOM proposed state-level demonstration projects to explore alternative approaches to the current liability system that are patient-centered and focused on patient safety (IOM, 2000, 2002). In 2010, AHRQ allocated approximately $23 million in funding for demonstration and planning grants aimed at finding ways to improve medical injury compensation and patient safety (AHRQ, 2015d; Kachalia and Mello, 2011). Five of the seven demonstration grants (totaling $19.7 million in awarded funds) that were funded by AHRQ focused on communication and resolution programs (CRPs), one on safe harbors for following evidence-based clinical practice guidelines, and one on judge-directed negotiation. The 13 planning grants (totaling $3.5 million) were diverse and included CRPs, safe harbors, and other formats (AHRQ, 2015d). These demonstration and planning grants were somewhat limited, however, because they could not involve approaches that required legislative changes (such as administrative health court demonstrations) (Bovbjerg, 2010). Furthermore, while the Affordable Care Act authorized $50 million to test new approaches to the resolution of medical injury disputes, this funding was never appropriated.

Although enthusiasm for alternative approaches to the current medical liability system is growing, in general the progress toward such approaches has been slow, especially for those that involve more fundamental changes to the medical liability system. Thus, the committee took both a pragmatic and aspirational approach to considering which changes to medical liability could promote improved disclosure of diagnostic errors and opportunities to learn from these errors. A number of alternative approaches to the current medical liability system were evaluated, and the committee concluded that the most promising approaches included CRPs, the use of clinical practice guidelines as safe harbors, and administrative health courts. CRPs represent a more pragmatic approach in
that they are more likely to be implemented in the current medical liability climate, and they have a strong focus on improving patient safety as well as on reducing litigation. Thus, the committee recommends that states, in collaboration with other stakeholders (health care organizations, professional liability insurance carriers, state and federal policy makers, patient advocacy groups, and medical malpractice plaintiff and defense attorneys), should encourage the adoption of CRPs with legal protections for disclosures and apologies under state laws.

Safe harbors for adherence to clinical practice guidelines may also help facilitate improvements in diagnostic accuracy by encouraging clinicians to follow evidenced-based diagnostic approaches; however, most clinical practice guidelines address treatment, not diagnosis. Moreover, implementing safe harbors for adherence to these guidelines will be administratively complex. Administrative health courts offer a fundamental change that would promote a more open environment for identifying, studying, and learning from errors, but their implementation will be a major challenge due to operational complexity and to resistance from stakeholders who are strongly committed to preserving the current tort-based system. Thus, the committee concluded that these changes are more aspirational, and recommends that states and other stakeholders should conduct demonstration projects of alternative approaches to the resolution of medical injuries, including administrative health courts and safe harbors for adherence to evidence-based clinical practice guidelines. The following sections describe the alternative approaches, the challenges influencing their implementation, and the potential benefits for improving diagnosis.

Communication and Resolution Programs

CRPs have recently garnered significant attention as a means of improving the disclosure and resolution of medical injuries and improving patient safety. Several of the AHRQ demonstration projects focused on CRPs, and organizations such as the American College of Physicians and the American College of Surgeons have called for continued experimentation (ACP, 2014; ACS, 2015). At 14 hospitals in three health care systems across the country AHRQ is currently developing and field testing an educational toolkit on CRPs which teaches the communication and resolution of medical injuries, including administrative health courts and safe harbors for adherence to evidence-based clinical practice guidelines. The following sections describe the alternative approaches, the challenges influencing their implementation, and the potential benefits for improving diagnosis.

CRPs continued to expand in the United States. For example, the Massachusetts Alliance for Communication and Resolution following Medical Injury (MACRMI) is committed to spurring adoption of CRPs and sharing lessons learned to improve the dissemination of CRPs throughout Massachusetts (MACRMI, 2015). MACRMI supported enabling legislation that adopted the UMHS CRP model, including a six-month pre-litigation period, protections for disclosures and apologies (MACRMI, 2015).

Although establishing CRPs does not require legislative changes, CRP adoption could be facilitated by changes to state laws, such as laws protecting disclosures and apologies (Sage et al., 2014). For example, the American College of Physicians has called for “strong, broad legal protections that ensure apologies from physicians and other health care professionals are inadmissible” in a subsequent medical malpractice action (ACP, 2014). Though more than two-thirds of states have apology laws, the majority only protect the clinician’s voluntary expression of sympathy from use by a patient in malpractice litigation (Mastroianni et al., 2010). A small number of states also protect explanations of the event or expressions of fault, or both; however, Sage and colleagues concluded that no states protect “the full scope of information that patients report needing when an unexpected outcome arises: a preliminary explanation of what happened; an expression of sympathy; an admission of responsibility; and a final analysis of the causes and consequences of the event, with information about remedial actions taken to prevent such incidents in the future” (Sage et al., 2014, p. 14). Of the nine states that have disclosure laws, a majority require health care organizations to notify patients when an event has caused serious harm. “States vary on whether the disclosure receives protection from subsequent use by a plaintiff in malpractice litigation. For the most part, states provide limited, if any, procedural guidance; some states require written—versus oral—communication or timely communication” (Mastroianni et al., 2010, p. 1614).

The implementation of CRPs faces a number of challenges. One challenge is HHS’s recent interpretation of the reporting requirements to the National Practitioner Data Bank (NPDB). Federal law requires that medical liability insurers report medical malpractice payments to the NPDB, which was initially established to prevent clinicians from concealing disciplinary and malpractice histories as they moved across state lines (Sage et al., 2014). An Oregon law attempted to assert that NPDB reporting was not required if a settlement resulted from a mediation mechanism, such as a CRP (Robeznieks, 2014), but HHS concluded that any payments stemming from written demands (whether part of mediation mechanisms or not) are required to be submitted to the NPDB (HHS, 2014). There are concerns that these reporting requirements will prevent participation in CRPs: “Physicians worry that CRPs will offer compensation when the physician was not at fault, either as a compassionate gesture or because the hospital or insurer deems it prudent to settle, and that, as a result, physicians will be reported to the NPDB more often” (Sage et al., 2014, p. 16). The reporting of settlements arising from mediation mechanisms to the NPDB could have negative effects on clinicians’ reputations, credentialing, or disciplinary actions, and at least one medical specialty society, the American College of Physicians, recommends that the reporting requirement be altered to encourage CRP participation (ACP, 2014).

Other considerations will influence the implementation and effectiveness of CRPs, including the presence of organizational champions and
a culture that supports the reporting of medical errors; a focus on coaching and support services to help clinicians participate in disclosures and the CRP processes; and buy-in from and coordination with health care organizations and professional liability insurance carriers (Mello et al., 2014a).

Of particular interest is the potential for CRPs to promote widespread learning following adverse events. As growing numbers of health care organizations and professional liability insurers adopt CRPs, close collaboration among these programs and between these programs and PSOs could help ensure that the lessons learned from adverse events are shared widely within and outside the organizations where the events occurred. The establishment of a national collaborative of CRPs could be one way to accelerate the spread of CRPs and to fully realize the quality and safety benefits of these programs.

Safe Harbors For Adherence to Evidence-Based Clinical Practice Guidelines

Safe harbors for following evidence-based clinical guidelines have the potential to raise the quality of health care by creating an incentive—liability protection—for clinicians to follow evidence-based clinical practice guidelines. Safe harbors can create an affirmative defense for health care professionals who adhered to accepted and applicable clinical practice guidelines.

Input to the committee suggested that safe harbors, unlike other approaches to improving the medical liability environment, offer direct opportunities to improve diagnosis (Kachalia, 2014). While other approaches to improving medical liability focus on improving learning through improved disclosure, safe harbors focus on aligning clinical care with best practices.

Available evidence suggests that creating national standards of care against which clinicians are judged in malpractice claims can improve quality of care. Providing standardized guidelines for certain diagnostic work-ups and holding these to be the standard of care has the potential to reduce diagnostic error. Despite calls for safe harbors (ACP, 2014; Mello et al., 2014b), there is limited information about how effective safe harbors are in minimizing medical errors, partly because there have been relatively few pilot programs and those programs have had poor clinician participation (Kachalia et al., 2014; Mello et al., 2014b). A recent simulation analysis evaluated the potential impact of safe harbors and concluded that they constitute a promising approach to driving improvements in the quality of patient care, but their impact on liability costs and patient outcomes is likely to be minimal (Kachalia et al., 2014). There are a number of implementation challenges related to a safe harbor for adherence to clinical practice guidelines. For example, it requires state endorsement of specific clinical practice guidelines for use in malpractice litigation. Furthermore, safe harbor programs may be administratively complex because they require determining which clinical practice guidelines apply, when they apply, and who makes the determination. Also, given the constantly changing evidence base, ensuring the timely updating of approved guidelines and making clinicians aware of the updates could be challenging (Bovbjerg and Berenson, 2012). Clinician acceptability is another concern. Clinicians may find it burdensome to have to comply with additional clinical practice guidelines for improving diagnostic performance and avoiding liability. Clinicians already encounter multiple guidelines from specialty associations, insurers, health care organizations, hospitals, and others, and these guidelines are likely not all in alignment. Additionally, recent policy changes add to the resistance of using clinical practice guidelines for legal purposes. The legislation that repealed the sustainable growth rate included a provision that prevents the use of guidelines or standards used in federal programs as proof of negligence: The “development, recognition, or implementation of any guideline or other standard” under the Medicare and Medicaid programs and any provision in the Affordable Care Act “shall not be construed to establish the standard of care or duty of care owed by a health care provider to a patient in any medical malpractice or medical product liability action or claim.”

Administrative Health Courts

Administrative health courts have been proposed as a way to provide injured patients with expedited compensation decisions for certain types of medical errors and to promote the disclosure of medical errors (such as diagnostic errors). Administrative health courts are a non-judicial way of handling medical injuries, in which cases are filed through an administrative process. The goal in using these courts is to quickly and equitably compensate patients who have experienced avoidable injuries without requiring the patients to become plaintiffs within the medical liability system who must prove negligence in an adversarial proceeding (Berenson, 2005).

There are various versions of how such an approach might work. In one version, specially trained judges preside and are assisted by investigations and opinions provided by neutral experts on the matter under consideration. Administrative health courts also take fault—or negligence—terminology out of the determination of liability and substitute it with the concept of avoidability (IOM, 2002; Mello et al., 2006). “[A] system based on an avoidability standard would award compensation to claimants who could show that their injury would not have occurred in the hands of the best practitioner or system” (Kachalia et al., 2008, p. 388). Proving negligence requires evidence that a clinician failed to meet a standard of care, is very fact-specific, and is more challenging to demonstrate; on the other hand, avoidability represents complications that generally should not occur under competent medical care (Berenson, 2005). Although substituting the negligence standard with an avoidability standard will lower the threshold for making these determinations, claimants will still have to establish cause—that their injuries were the result of their care, rather than their underlying illnesses (Kachalia et al., 2008).

The establishment of administrative health courts could help to reduce process inefficiencies and inequities in compensation caused by shortcomings in the current system of tort liability, and adjudicated cases could be used to inform and foster the development of mechanisms to identify and mitigate medical errors (IOM, 2002; Mello et al., 2006). Administrative health courts have been described as holding theoretic appeal because “the model addresses some of the most important problems with the U.S. medical malpractice system, including the difficulty that patients have filing and prevailing in claims, the duration of litigation, the substantial overhead costs, the unpredictability of damages awards, and the punitive effect felt by physicians” (Mello et al., 2014b). Health courts have been used in other countries, including Sweden, New Zealand, and Denmark, and evidence suggests that they provide compensation to a greater number of claimants and are able to reach conclusions more quickly and at lower costs than tort-based mechanisms (ACP, 2006; Bovbjerg and Sloan, 1998; Mello et al., 2011). Health courts appear to have bipartisan support in the United States: A nationwide poll conducted in 2012 found that 68 percent of Republicans, 67 percent of Democrats, and 61 percent of independents surveyed support the creation of health courts (Howard, 2012). Legislation to experiment with, or create, health courts has been proposed in a number of states—including Georgia, Maryland, New York, Oregon, and Virginia—but none has passed (Peters, 2008). Several organizations and experts have recommended pilot-testing or using health courts in the United States, but very few systems have been implemented or even tested (ACP, 2014; Howard and Maine, 2013; IOM, 2002; Mello et al., 2014b; Peters, 2008). There are only two state systems that implement the principles of health courts, and these uses are confined to cases involving neurological birth injury (Howard and Maine, 2013; Mello et al., 2014b).

There are several challenges associated with health courts, including the need for legislative action, which has been difficult to achieve (Mello et al., 2014b; Peters, 2008). As mentioned earlier,
resistance from stakeholders strongly committed to preserving the current tort-based system will be a major challenge to overcome. Another issue that needs to be considered is how a health court should make information on paid claims of avoidable injuries available to state professional licensing boards, state hospital licensing agencies, medical specialty boards, and the NPDB. Such reporting could have a chilling effect on clinician disclosure of diagnostic errors; however, there is a competing concern about limiting the transparency of information on potentially substantial care practices.

**Risk Management**

Professional liability insurance carriers and health care organizations that participate in captive or other self-insurance arrangements have an inherent interest in improving diagnosis. Many of these organizations are actively exploring opportunities to improve diagnosis and reduce diagnostic errors. According to input the committee received, “[M]edical liability serves as a rich training area for reducing diagnostic error” (Lembitz and Boyle, 2014, p. 1). Given the expertise of professional liability insurance carriers and captive insurers in understanding the contributing factors to diagnostic errors, they can bring an important perspective to efforts to improve diagnosis, both those focused on individual health care professionals and those focused on the work system components that may contribute to diagnostic errors. Thus, the committee recommends that professional liability insurance carriers and captive insurers should collaborate with health care professionals on opportunities to improve diagnostic performance through education, training, and practice improvement approaches and they should increase participation in such programs.

One way in which these groups are helping improve diagnosis is by conducting data analyses that characterize the reasons that diagnostic errors occur. PIAA, the industry trade association representing companies in the medical liability insurance field, has a data sharing project that gathers and analyzes data on medical professional liability claims submitted by its members (Parikh, 2014). The project’s findings are used to identify opportunities to reduce risk and improve patient safety in health care organizations. Individual carriers can also provide information to help improve the understanding of diagnostic errors that lead to medical liability claims. For example, Physician Reciprocal Insurers (PRI), CRICO, and The Doctors Company have gathered data on submitted and paid malpractice claims that suggest that diagnostic errors are the cause of around 20 percent of all submitted claims and 52 percent of all paid claims (CRICO, 2014; Donohue, 2014; Troxel, 2014). CRICO synthesizes information on important issues in medical injury claims and produces reports on these issues (such as a report on diagnostic errors in ambulatory care settings) (CRICO, 2014). Professional liability insurers often have rich data because they have collected a variety of information (e.g., information from electronic health records [EHRs], statements from various participants in the diagnostic process, and information from court documents) in the course of preparing for medical malpractice lawsuits. This information can lead to important, albeit potentially non-representative, insights about the vulnerabilities in the diagnostic process and about potential areas on which to focus in order to improve care. Improved voluntary participation in malpractice claims databases among all professional liability insurance carriers and captive insurers could be helpful for aggregating information and sharing lessons learned.

Many professional liability insurers offer risk management educational services that are designed to improve diagnostic performance. The associated activities include seminars, workshops, team training, residency training programs, and newsletters (Donohue, 2014; Lembitz and Boyle, 2014). COPIC, a provider of medical liability insurance, reported that it conducts over 2,000 practice site visits each year, in which specially trained nurses use explicit criteria to identify patient safety and risk issues, including vulnerability to systems errors, communication failures, information transfer, EHR issues and standardized processes (Lembitz and Boyle, 2014). In some cases, incentives such as discounted insurance premiums are offered to individuals to induce participation (Donohue, 2014; Lembitz and Boyle, 2014). Surveys suggest that clinicians perceive these educational and training approaches as beneficial; for example, Physicians Reciprocal Insurers reported that 94 percent of the clinicians participating in their case review exercise believe that it will reduce the risk of diagnostic errors occurring in their practice (Donohue, 2014). Unfortunately, because of measurement difficulties, there is little information on the impact of these educational approaches on the occurrence of diagnostic error (Donohue, 2014; Lembitz and Boyle, 2014). However, the committee concluded that the expertise of health professional liability insurance carriers should be leveraged to improve the diagnostic process. Improved collaboration between health professional liability insurance carriers and health care professionals and organizations could help to identify resources, prioritize areas of concern, and devise interventions. Collaboration among health care professional educators and professional liability insurance carriers also could be helpful in developing interventions for trainees. An example of collaborative efforts among medical liability insurers and educators is the recent grant from The Doctors Company Foundation to the Society to Improve Diagnosis in Medicine (SIDM, 2015; TDCF, 2015). This grant will provide funding for diagnostic training, with a focus on clinical reasoning and methods to communicate with patients about diagnostic errors (SIDM, 2015).

**Payment and Care Delivery**

FFS payment, the predominant form of payment for health care services in the United States, pays health care professionals for each service they provide. FFS payment has long been recognized for its inability to incentivize well-coordinated, high-quality, and efficient health care (Council of Economic Advisors, 2009; IOM, 2001, 2013a; National Commission on Physician Payment Reform, 2013). There is relatively little information about the impact of payment on the diagnostic process. However, the committee concluded that payment is likely to have an impact on the diagnostic process, and several payment experts who provided input to the committee help elaborate on some of these consequences (Miller, 2014; Rosenthal, 2014; Wennberg, 2014).

In general, FFS payment may not incentivize a high-quality, efficient diagnostic process because the services the diagnostic process entails, the more remuneration will result. There is no disincentive for ordering unnecessary diagnostic testing that could lead to false positive results and diagnostic errors (Miller, 2014; Wennberg, 2014). There is also a financial incentive to provide treatment to patients, rather than determining that patients do not have health problems; thus inappropriate diagnoses are better compensated than determining that a patient does not have a health problem. Likewise, accuracy in the diagnostic process is not explicitly rewarded by FFS payment: Clinicians who interpret diagnostic testing or provide a diagnosis during a patient visit receive payment whether the work was done adequately to support accurate interpretation and diagnosis and whether the interpretations and diagnoses are accurate or not (Miller, 2014).

Given the importance of team-based care in the diagnostic process, the lack of financial incentives in FFS payment to coordinate care may contribute to challenges in diagnosis and diagnostic errors, particularly delays in diagnosis (Rosenthal, 2014). FFS Medicare and most commercial payers do not pay for time that a clinician spends contacting other clinicians by phone or email to facilitate the diagnostic process, for example, by helping determine the appropriate diagnostic tests for a patient. In addition, clinicians are not reimbursed for proactive outreach to patients to obtain diagnostic testing, schedule visits with specialists, or make follow-up appointments (Miller, 2014). To improve teamwork and care coordination in the diagnostic process, the committee recommends that the Centers for Medicare & Medicaid Services
in the diagnostic process, such as performing a patient’s clinical history and interview, conducting a physical exam, and decision making in the diagnostic process. Thus, the committee recommends that CMS and other payers reorient relative value fees to more appropriately value the time spent with patients in evaluation and management activities. Realigning relative value fees to better compensate clinicians for cognitive work in the diagnostic process has the potential to improve accuracy in diagnosis while also reducing incentives that drive the inappropriate utilization of diagnostic testing.

E&M payment policies and documentation guidelines also are misaligned with the goal of accurate, timely diagnosis. E&M payments penalize clinicians for spending extra time on the diagnostic process for an individual patient. There are different levels of E&M visits based on time and complexity, and practices receive better compensation if they see more patients with shorter appointment lengths. For example, in Medicare, if a clinician spends 20 minutes with a patient who is billed as a level 3 E&M visit rather than spending just 15 minutes, the clinician’s practice will receive 25 percent less revenue per hour; if a clinician spends 25 minutes for a level 4 E&M visit instead of 15 minutes for a level 3 visit, the practice will receive 11 percent less revenue per hour (Miller, 2014).

Time pressures in clinical visits can contribute to various challenges in clinical reasoning and to the occurrence of errors (Durning, 2014; Kostis et al., 2007; Sarkar et al., 2012, 2014; Schiff et al., 2009; Singh et al., 2013). Although there is evidence that the length of clinical appointments have not generally declined, there are concerns that the rising complexity of health care, the growth in patients with complicated health conditions, and increased EHR-related tasks are contributing to increased time pressures. The aging U.S. population contributes to added complexity for patient care decisions, due to the need for understanding the various factors that may be contributing to an older adult’s health, such as multiple comorbidities and polypharmacy (IOM, 2008, 2013b). While unlimited time is neither the objective nor realistic, it is important to make time for effectively addressing these complex care decisions. Making more effective use of the time available will be critical, as will making improvements to the work system in which the diagnostic process occurs (such as disseminating an organizational culture that is supportive of teamwork in the diagnostic process, the better allocation of tasks, and ensuring that health information technology (health IT) is supportive of the diagnostic process). In addition to modifying payment policies, the documentation guidelines for E&M services could also be improved to support the diagnostic process. Documentation guidelines for E&M services were created to ensure that the services performed were consistent with insurance coverage; to validate specific information, such as the site of service, the appropriateness of the care, and the accuracy of the reported information; and to prevent fraud and abuse (Berenson, 1999; CMS, 2014a). Documentation guidelines specify the extent of a patient’s clinical history and interview, the physical exam, and the complexity of medical decision making involved in the E&M visit (Berenson et al., 2011; HHS, 2010). There are a number of criticisms of the documentation guidelines; the primary argument is that the level of detail required is onerous, is often irrelevant to patient care, and shifts the purpose of the medical record toward billing rather than facilitating clinical reasoning (Berenson et al., 2011; Brett, 1998; Kassirer and Angell, 1998; Kuhn et al., 2015; Schiff and Bates, 2010).

The documentation guidelines have become an even greater concern with the broad implementation of EHRs because EHR design has focused on fulfilling documentation and legal requirements and not on facilitating the diagnostic process (Berenson et al., 2011; Schiff and Bates, 2010). EHRs tend to lack a cohesive patient narrative, which will include nuances, details, and important contextual information that all help clinicians make accurate and timely diagnoses. The orientation of EHRs to documentation, their overreliance on templates, and the cut-and-paste functionalities within EHR capabilities have resulted in “EHR-generated data dumps, including repetitive documentation of elements of patients’ histories and physical examinations, that merely result in electronic versions of clinically cumbersome, uninformative patient records” (Berenson et al., 2011, p. 1894). Generating documentation to support E&M coding (or higher levels of E&M coding than are warranted, which is called “upcoding”) can result in inaccuracies in the patient’s EHR that can contribute to diagnostic errors.

A number of payment and care delivery reforms aimed at countering the limitations of the FFS payment system are actively being considered, implemented, and evaluated. These include capitation/global payments, shared savings, bundled episodes of care, accountable care organizations, patient-centered medical homes, and pay for performance (which Medicare refers to as “value-based purchasing”). Salary is not described as a payment model, because the committee focused on third party payments rather than provider organization compensation.

CMS recently announced that it plans to have 30 percent of Medicare payments based on alternative models by the end of 2016 and 50 percent of payments by the end of 2018 (Burwell, 2015). The Medicare Access and CHIP Reauthorization Act of 2015 (which repealed the sustainable growth rate) continues down the path
toward alternative payment models, particularly for the payment of Medicare clinicians. While the impact of alternative payment and delivery systems on quality are actively being investigated (e.g., the Blue Cross Blue Shield of Massachusetts Alternative Quality Contract, as well as patient-centered medical homes), there is very limited evidence on what impact such payment and delivery models will have on the diagnostic process and on the accuracy of diagnosis, and this represents a fundamental research need. Thus, the committee recommends that CMS and other payers should assess the impact of payment and care delivery models on the diagnostic process, the occurrence of diagnostic errors, and learning from these errors. Assessing the impact of payment and care delivery reforms, including FFS, on the diagnostic process, diagnostic errors, and learning are critical areas of focus as these models are evaluated more broadly. CMS' Innovation Center is testing many of the alternative payment models, and is well suited to evaluate the impact of these models on the diagnostic process and the occurrence of diagnostic errors.

While new payment models have the potential to reduce diagnostic errors, the committee also recognized that these models may also create incentives for clinicians and health care organizations that could reduce use of appropriate testing and clinician services (e.g., specialty consultations) that may inadvertently lead to greater diagnostic errors. To address these possibilities, the committee recognized that not only is direct evaluation of the impact of payment models on diagnostic errors important, but also there is a need for better measurement tools to identify diagnostic errors in clinical practice.

Additionally, the committee asked for input from payment and delivery experts about the potential effects of new models on diagnosis and diagnostic error. Rosenthal (2014) suggested that global payment and meaningful use incentives have the potential to improve diagnosis by promoting the adoption of diagnostic test and referral tracking systems that better connect health care professionals throughout the continuum of care. Miller (2014) suggested that the development of measures for diagnostic accuracy be developed to provide feedback and reward clinicians for diagnostic accuracy. Wennberg (2014) suggested that population-based payment models, including capitation and global budgets, have the greatest potential to reduce diagnostic errors.

Even when alternate payment and care delivery approaches to FFS are employed, they are often based on or influenced by existing coding and payment rules (Berenson et al., 2011). For example, bundled payments are combinations of current codes. Thus, the current distortions in the fee schedule and other volume-based payment approaches, such as diagnosis-related group coding, will remain a dominant component of payment and care delivery models in the near future and need to be addressed. As long as fee schedules remain a predominant mechanism for determining clinician payment, the committee recommends that CMS and other payers should modify documentation guidelines for evaluation and management services to improve the accuracy of information in the EHR and to support decision making in the diagnostic process.

Conclusions & Recommendations

Illuminating the blind spot of diagnostic error and improving diagnosis in health care will require a significant re-envisioning of the diagnostic process and widespread commitment to change. Diagnostic error is a complex and multifaceted problem; no single solution will likely achieve the needed changes.

Several major conclusions emerged from the committee’s discussions. The first is that urgent change is needed to address the issue of diagnostic error, which poses a major challenge to health care quality. Diagnostic errors persist throughout all settings of care, involve common and rare diseases, and continue to harm an unacceptable number of patients. Yet, diagnosis—and, in particular, the occurrence of diagnostic errors—is not a major focus in health care practice or research. The result of this inattention is significant: it is likely that most people will experience at least one diagnostic error in their lifetime, sometimes with devastating consequences.

The committee drew this conclusion based on its collective assessment of the available evidence describing the epidemiology of diagnostic errors. In every research area that the committee evaluated, diagnostic errors were a consistent quality and safety challenge. The Harvard Medical Practice Study, which reviewed medical records, found diagnostic errors in 17 percent of the adverse events occurring in hospitalized patients (Leape et al., 1991), and a more recent study in the Netherlands found that diagnostic errors comprised 6.4 percent of hospital adverse events (Zwaan et al., 2010). Analyses of malpractice claims data indicate that diagnostic errors are the leading type of paid claims, represent the highest proportion of total payments, and are almost twice as likely to have resulted in the patient’s death compared to other claims (Tehrani et al., 2013).

However, the committee concluded that the available research estimates were not adequate to extrapolate a specific estimate or range of the incidence of diagnostic errors within clinical practice today. There is even less information available with which to assess the frequency and severity of harm related to diagnostic errors. Part of the challenge is the variety of settings in which these errors can occur, including hospitals, emergency departments, a variety of outpatient settings (such as primary and specialty care settings and retail clinics), and long-term care settings (such as nursing homes and rehabilitation centers), combined with the complexity of the diagnostic process itself. Although there are more data available to examine diagnostic errors in some of these settings, there are wide gaps in the information and great variability in the amount and quality of information available. In addition, aggregating data from various research methods—such as postmortem examinations, medical record reviews, and malpractice claims—is problematic. Each method captures information about different subgroups in the population, different dimensions of the problem, and different insights into the frequency and causes of diagnostic error. Nonetheless, the committee concluded that, taken together, the evidence suggests that diagnostic errors are a significant and common challenge in health care necessitating urgent attention.

The second conclusion is that it is very important to consider diagnosis from a patient-centered perspective, as patients bear the ultimate risk of harm from diagnostic errors. Thus, patients should be recognized as vital partners in the diagnostic process and the health care system needs to encourage and support their engagement and to facilitate respectful learning from diagnostic errors. The committee’s definition of diagnostic error—the failure to (a) establish an accurate and timely explanation of the patient’s health problem(s) or (b) communicate that explanation to the patient—reflects a patient-centered approach and highlights the key role of communication among the patient and the health care professionals involved in the diagnostic process. The term “explanation” is included in the definition to highlight the manner in which a diagnosis is conveyed to a patient, such that it facilitates patient understanding and aligns with a patient’s level of health literacy.

The committee concluded that a sole focus on reducing diagnostic errors will not achieve the extensive change that is needed. Reducing diagnostic errors will require a broader focus on improving diagnosis in health care. This conclusion reflects the input provided to the committee by Gary Klein, a senior scientist at MacroCognition, who argued that improvements in diagnosis will require balancing two interdependent efforts: reducing diagnostic errors and improving diagnostic performance (Klein, 2014). Related input from David Newman-Toker, an associate professor at Johns Hopkins University, suggested that improving diagnostic performance will require addressing diagnostic quality and efficiency in order to achieve high-value diagnostic performance (Newman-Toker, 2014; Newman-Toker et al., 2013). Thus, many of the recommendations focus on improving
diagnosis and the diagnostic process as well on the identification and mitigation of diagnostic errors.

**Recommendations**

The committee’s recommendations address eight goals to improve diagnosis and reduce diagnostic error. These recommendations apply to all diagnostic team members and settings of care. Given the early state of the field, the evidence base for some of the recommendations stems from the broader patient safety and quality improvement literature. Patients and patient advocates have much to offer on how to implement the committee’s recommendations; leveraging the expertise, power, and influence of the patient community will help spur progress.

**Goal 1: Facilitate More Effective Teamwork in the Diagnostic Process among Health Care Professionals, Patients, and their Families**

The diagnostic process requires collaboration among health care professionals, patients, and their families. Patients and their families are critical partners in the diagnostic process; they contribute valuable input that facilitates the diagnostic process and ensures shared decision making about the path of care. Health care professionals and organizations are responsible for creating environments in which patients and their families can learn about and engage in the diagnostic process and provide feedback about their experiences. One strategy is to promote the use of health information technology (health IT) tools that make a patient’s health information more accessible to patients and involving patients and their families in efforts to improve diagnosis is also critical, because they have unique insights into the diagnostic process and the occurrence of diagnostic errors.

The diagnostic process hinges on successful intra- and inter-professional collaboration among health care professionals, including primary care clinicians, physicians in various specialties, nurses, pharmacists, technologists, therapists, social workers, patient navigators, and many others. Thus, all health care professionals need to be well prepared and supported to engage in diagnostic teamwork. The roles of some health care professionals who participate in the diagnostic process have been insufficiently recognized. The fields of pathology and radiology are critical to diagnosis, but professionals in these fields are not always engaged as full members of the diagnostic team. Enhanced collaboration among pathologists, radiologists, other diagnosticians, and treating health care professionals has the potential to improve diagnostic testing. In addition, nurses are often not recognized as collaborators in the diagnostic process, despite their critical roles in ensuring communication, care coordination, and patient education; monitoring a patient’s condition; and identifying and preventing potential diagnostic errors.

**Goals for Improving Diagnosis and Reducing Diagnostic Error**

- Facilitate more effective teamwork in the diagnostic process among health care professionals, patients, and their families
- Enhance health care professional education and training in the diagnostic process
- Ensure that health information technologies support patients and health care professionals in the diagnostic process
- Develop and deploy approaches to identify, learn from, and reduce diagnostic errors and near misses in clinical practice
- Establish a work system and culture that supports the diagnostic process and improvements in diagnostic performance
- Develop a reporting environment and medical liability system that facilitates improved diagnosis through learning from diagnostic errors and near misses
- Design a payment and care delivery environment that supports the diagnostic process
- Provide dedicated funding for research on the diagnostic process and diagnostic errors

**Recommendation 1a:** In recognition that the diagnostic process is a dynamic team-based activity, health care organizations should ensure that health care professionals have the appropriate knowledge, skills, resources, and support to engage in teamwork in the diagnostic process. To accomplish this, they should facilitate and support:

- Inter-professional and intra-professional teamwork in the diagnostic process.
- Collaboration among pathologists, radiologists, other diagnosticians, and treating health care professionals to improve diagnostic testing processes.

**Recommendation 1b:** Health care professionals and organizations should partner with patients and their families as diagnostic team members and facilitate patient and family engagement in the diagnostic process, aligned with their needs, values, and preferences. To accomplish this, they should:

- Provide patients with opportunities to learn about the diagnostic process.

**Recommendation 2a:** Educators should ensure that curricula and training programs across the career trajectory:

- Create environments in which patients and their families are comfortable engaging in the diagnostic process and sharing feedback and concerns about diagnostic errors and near misses.
- Ensure patient access to electronic health records (EHRs), including clinical notes and diagnostic testing results, to facilitate patient engagement in the diagnostic process and patient review of health records for accuracy.
- Identify opportunities to include patients and their families in efforts to improve the diagnostic process by learning from diagnostic errors and near misses.

**Goal 2: Enhance Health Care Professional Education and Training that Supports Diagnosis**

Getting the right diagnosis depends on all health care professionals involved in the diagnostic process receiving appropriate education and training. The learning sciences, which study how people learn, can be used to improve education and training. For example, feedback—or information about the accuracy of a clinician’s diagnosis—is essential for improved diagnostic performance. The authenticity of the learning environment can affect the acquisition of diagnostic skills; better alignment of training environments with clinical practice promotes development of diagnostic skills.

Opportunities to improve education and training in the diagnostic process include: greater emphasis on teamwork and communication with patients, their families, and other health care professionals; appropriate use of diagnostic testing and the application of test results to subsequent decision making; and the use of health IT. In addition, the lack of focus on developing clinical reasoning and understanding the cognitive contributions to decision making represents a major gap in education within all health care professions. Proposed strategies to improve clinical reasoning include instruction and practice on generating and refining a differential diagnosis, generating illness scripts, developing an appreciation of how diagnostic errors occur and strategies to mitigate them, and engaging in metacognition and debiasing strategies.

Oversight processes play a critical role in promoting competency in the diagnostic process. Many accreditation organizations already require skills important for diagnostic performance, but diagnostic competencies need to be a larger priority within these requirements. Organizations responsible for licensure and certification can also help ensure that health care professionals have achieved and maintain competency in the skills essential for the diagnostic process.

**Recommendation 2b:** Health care professionals and organizations should ensure that curricula and training programs across the career trajectory:
• Address performance in the diagnostic process, including areas such as clinical reasoning, teamwork, communication with patients, their families, and other health care professionals, appropriate use of diagnostic tests and the application of these results on subsequent decision making, and use of health IT.
• Employ educational approaches that are aligned with evidence from the learning sciences.

Recommendation 2b: Health care professional certification and accreditation organizations should ensure that health care professionals have and maintain the competencies needed for effective performance in the diagnostic process, including the areas listed above.

Goal 3: Ensure that Health Information Technologies Support Patients and Health Care Professionals the Diagnostic Process

Health IT has the potential to improve diagnosis and reduce diagnostic errors by facilitating timely and easy access to information; communication among health care professionals, patients, and their families; clinical reasoning; and feedback and follow-up in the diagnostic process. However, many experts are concerned that health IT currently is not effectively facilitating the diagnostic process and may even be contributing to diagnostic errors. Challenges include problems with usability, poor integration into clinical workflow, difficulty sharing a patient’s health information, and a limited ability to support clinical reasoning and identification of diagnostic errors in clinical practice. Better alignment of health IT with the diagnostic process is warranted.

Because the diagnostic process occurs over time and can involve multiple health care professionals across different care settings, the free flow of information is critical. Improved interoperability across health care organizations and across laboratory and radiology information systems is needed to achieve this information flow.

Although there may be patient safety risks in the diagnostic process related to the use of health IT, it is difficult to determine the extent of the problem. Health IT vendors often limit the sharing of information about these risks. A previous IOM report recommended that the Department of Health and Human Services (HHS) ensure insofar as possible that health IT vendors support the free exchange of information about patient safety and not prohibit sharing of such information. The present committee endorses this recommendation and highlights the need for shared information about user experiences with health IT used in the diagnostic process. Independent evaluations of health IT products could also identify potential adverse consequences that contribute to diagnostic errors.

Recommendation 3a: Health IT vendors and the Office of the National Coordinator for Health Information Technology (ONC) should work together with users to ensure that health IT used in the diagnostic process demonstrates usability, incorporates human factors knowledge, integrates measurement capability, fits well within clinical workflow, provides clinical decision support, and facilitates the timely flow of information among patients and health care professionals involved in the diagnostic process.

Recommendation 3b: ONC should require health IT vendors to meet standards for interoperability among different health IT systems to support effective, efficient, and structured flow of patient information across care settings to facilitate the diagnostic process by 2018.

Recommendation 3c: The Secretary of HHS should require health IT vendors to:
• Routinely submit their products for independent evaluation and notify users about potential adverse effects on the diagnostic process related to the use of their products.
• Permit and support the free exchange of information about real-time user experiences with health IT design and implementation that adversely affect the diagnostic process.

Goal 4: Develop and Deploy Approaches to Identify, Learn From, and Reduce Diagnostic Errors and Near Misses in Clinical Practice

Due to the difficulty in identifying diagnostic errors and competing demands from existing quality and safety improvement priorities, very few health care organizations have processes in place to identify diagnostic errors and near misses. Nonetheless, identifying these experiences, learning from them, and implementing changes will improve diagnosis and reduce diagnostic errors. Health care organizations can also ensure that systematic feedback on diagnostic performance reaches individuals, care teams, and organizational leadership.

Postmortem examinations are a critical source of information on the epidemiology of diagnostic errors, but the number of postmortem examinations has declined precipitously. A greater emphasis on postmortem examination research—including more limited approaches to postmortem examinations—is warranted to better understand the incidence of diagnostic errors and the role of postmortem examinations in modern clinical practice. Health care professional societies can be engaged to identify high-priority areas to improve diagnosis, similar to the Choosing Wisely initiative on avoiding unnecessary care. Early efforts could focus on identifying the most common diagnostic errors, “don’t miss” health conditions that may result in patient harm, or diagnostic errors that are relatively easy to address.

Recommendation 4a: Accreditation organizations and the Medicare conditions of participation should require that health care organizations have programs in place to monitor the diagnostic process and identify, learn from, and reduce diagnostic errors and near misses in a timely fashion. Proven approaches should be incorporated into updates of these requirements.

Recommendation 4b: Health care organizations should:
• Monitor the diagnostic process and identify, learn from, and reduce diagnostic errors and near misses as a component of their research, quality improvement, and patient safety programs.
• Implement procedures and practices to provide systematic feedback on diagnostic performance to individual health care professionals, care teams, and clinical and organizational leaders.

Recommendation 4c: HHS should provide funding for a designated subset of health care systems to conduct routine postmortem examinations on a representative sample of patient deaths.

Recommendation 4d: Health care professional societies should identify opportunities to improve accurate and timely diagnoses and reduce diagnostic errors in their specialties.

Goal 5: Establish a Work System and Culture that Supports the Diagnostic Process and Improvements in Diagnostic Performance

Health care organizations influence the work system in which diagnosis occurs and play a role in implementing change. The work systems of many health care organizations could better support the diagnostic process, for example, by integrating mechanisms to improve error recovery and resiliency in the diagnostic process.

The culture and leadership of health care organizations are key factors in ensuring continuous learning in the diagnostic process. Organizations need to promote a non-punitive culture in which clinicians can identify and learn from diagnostic errors. Organizational leadership can facilitate this culture, provide resources, and set priorities for achieving progress in diagnostic performance and reducing diagnostic errors.
Health care organizations can also work to address diagnostic challenges related to fragmentation of the broader health care system. Although improved teamwork and interoperability will help with fragmentation in health care, organizations need to recognize that patients cross organizational boundaries and that this has the potential to contribute to diagnostic errors and failures to learn from them. Strengthening communication and reliable diagnostic test reporting is one area where this can be addressed.

Recommendation 5: Health care organizations should:

- Adopt policies and practices that promote a non-punitive culture that values open discussion and feedback on diagnostic performance.
- Design the work system in which the diagnostic process occurs to support the work and activities of patients, their families, and health care professionals and to facilitate accurate and timely diagnoses.
- Develop and implement processes to ensure effective and timely communication between diagnostic testing health care professionals and treating health care professionals across all health care delivery settings.

Goal 6: Develop a Reporting Environment and Medical Liability System that Facilitates Improved Diagnosis by Learning from Diagnostic Errors and Near Misses

Reporting

Conducting analyses of diagnostic errors, near misses, and adverse events presents the best opportunity to learn from such experiences and implement changes to improve diagnosis. There is a need for safe environments, without the threat of legal discovery or disciplinary action, to analyze and learn from these events. Previously, the IOM recommended that Congress extend peer review protections to data that are collected for improving the safety and quality of care. Subsequent legislation established the Agency for Healthcare Research and Quality- (AHRQ-) administered Patient Safety Organization (PSO) program which conferred privilege and confidentiality protections to patient safety information that is shared with PSOs. The PSO program is an important national lever to increase voluntary error reporting and analysis, but progress has been impeded by several challenges. For example, AHRQ developed common formats to encourage standardized event reporting, but the use of these formats is voluntary, and there is no common format specific to diagnostic error. Concern that the federal privilege protections do not protect organizations from state reporting requirements could also prevent voluntary submissions to PSOs and decrease the potential for improved learning.

Given the PSO program’s potential to improve learning about diagnostic errors and near misses, it is important to evaluate the program.

Medical Liability

The core functions of medical liability are to compensate negligently injured patients and to promote quality by encouraging clinicians and organizations to avoid medical errors. The current approach for resolving medical liability claims sets up barriers to improvements in quality and patient safety. In addition, patients and their families are poorly served by the current system. While medical liability is broader than diagnosis, diagnostic errors are the leading type of paid medical malpractice claims.

Traditional medical liability reforms have not been effective in compensating negligently injured patients or deterring unsafe care. Alternative approaches are needed that enable patients and clinicians to become allies in making health care safer by encouraging transparency and disclosure of medical errors. These reforms can enable prompt and fair compensation for avoidable injuries, while turning errors into opportunities for learning and improvement. Communication and resolution programs (CRPs) provide a pragmatic approach for changing medical liability, in that they are the most likely to be implemented. Safe harbors for adherence to evidence-based clinical practice guidelines could also help facilitate improvements in diagnostic accuracy by incentivizing the use of evidenced-based diagnostic approaches; however, there are few clinical practice guidelines available for diagnosis, and implementation is complex. Administrative health courts offer a fundamental change that would promote a more open environment for identifying, studying, and learning from errors, but implementation is very challenging because of their operational complexity and resistance from stakeholders who are strongly committed to preserving the current tort-based system.

Risk Management

Professional liability insurance carriers and health care organizations that participate in captive or other self-insurance arrangements have an inherent interest and expertise in improving diagnosis. Improved collaboration between health professional liability insurance carriers and health care professionals and organizations could support education, training, and practice improvement strategies focused on improving diagnosis and minimizing diagnostic errors.

Recommendation 6a: AHRQ or other appropriate agencies or independent entities should encourage and facilitate the voluntary reporting of diagnostic errors and near misses.

Recommendation 6b: AHRQ should evaluate the effectiveness of PSOs as a major mechanism for voluntary reporting and learning from these events and modify the PSO common formats for reporting of patient safety events to include diagnostic errors and near misses.

Recommendation 6c: States, in collaboration with other stakeholders (health care organizations, professional liability insurance carriers, state and federal policy makers, patient advocacy groups, and medical malpractice plaintiff and defense attorneys), should promote a legal environment that facilitates the timely identification, disclosure, and learning from diagnostic errors. Specifically, they should:

1. Encourage the adoption of CRPs with legal protections for disclosures and apologies under state laws.
2. Conduct demonstration projects of alternative approaches to the resolution of medical injuries, including administrative health courts and safe harbors for adherence to evidenced-based clinical practice guidelines.

Recommendation 6d: Professional liability insurance carriers and captive insurers should collaborate with health care professionals on opportunities to improve diagnostic performance through education, training, and practice improvement approaches and increase participation in such programs.

Goal 7: Design a Payment and Care Delivery Environment that Supports the Diagnostic Process

Fee-for-service (FFS) payment has long been recognized for its inability to incentivize well-coordinated, high-quality, and efficient health care. There is limited information about the impact of payment and care delivery models on diagnosis, but it likely influences the diagnostic process and the occurrence of diagnostic errors. For example, FFS payment lacks financial incentives to coordinate care among clinicians involved in the diagnostic process, such as the communication among treating clinicians, pathologists, and radiologists about diagnostic test ordering, interpretation, and subsequent decision making.
For all medical specialties, there are well-documented fee schedule distortions that result in more generous payments for procedures and diagnostic testing interpretations than for evaluation and management services (E&M) services. E&M services reflect the cognitive expertise and skills that all clinicians use in the diagnostic process, and these distortions may be diverting attention and time from important tasks in the diagnostic process. Realigning relative value fees to better compensate clinicians for cognitive work in the diagnostic process has the potential to improve diagnosis while reducing incentives that drive inappropriate diagnostic testing utilization. E&M documentation guidelines have been criticized as onerous, often irrelevant to patient care, and preventing clinical reasoning in the diagnostic process. Payment and liability concerns, facilitated by the growth in EHRs, have resulted in extensive clinical documentation that obscures key information in patients’ medical records, results in inaccuracies in patients’ EHRs, and can contribute to diagnostic errors.

Due to the limitations in FFS payment, a number of alternative payment and care delivery models are under evaluation; for example, half of Medicare payments are expected to be based on alternative models by 2018. There is limited evidence concerning the impact of payment and care delivery models—including FFS—on the diagnostic process and the accuracy of diagnosis, and this represents a fundamental research need. Even when alternative approaches to FFS are employed, they are often influenced by FFS. Thus, the current challenges with FFS will need to be addressed, even with the implementation of alternative payment and care delivery models.

Recommendation 7a: As long as fee schedules remain a predominant mechanism for determining clinician payment, the Centers for Medicare & Medicaid Services (CMS) and other payers should:

- Create current procedural terminology (CPT) codes and provide coverage for additional evaluation and management activities not currently coded or covered, including time spent by pathologists, radiologists, and other clinicians in advising ordering clinicians on the selection, use, and interpretation of diagnostic testing for specific patients.
- Reorient relative value fees to more appropriately value the time spent with patients in evaluation and management activities.
- Modify documentation guidelines for evaluation and management services to improve the accuracy of information in the EHR and to support decision making in the diagnostic process.
- Provide Dedicated Funding for Research on the Diagnostic Process and Diagnostic Errors

References for this activity can be found at references.cme.edu

In addition to federal-level research, there is an important role for public–private collaboration and coordination among the federal government, foundations, industry, and other stakeholders. Collaborative funding efforts extend the existing financial resources and reduce duplications in research efforts. Parties can unite around areas of mutual interest and spearhead progress.

Recommendation 7b: CMS and other payers should assess the impact of payment and care delivery models on the diagnostic process, the occurrence of diagnostic errors, and learning from these errors.

Goal 8: Provide Dedicated Funding for Research on the Diagnostic Process and Diagnostic Errors

The diagnostic process and diagnostic errors have been neglected areas within the national research agenda; federal resources devoted to diagnostic research are overshadowed by those devoted to treatment. A major barrier to research is the organization and funding of the National Institutes of Health by disease or organ systems, which facilitates the study of these specific areas but impedes research efforts that seek to provide a more comprehensive understanding of diagnosis as a distinct research area. Given the potential for federal research on diagnosis and diagnostic errors to fall between institutional missions, collaboration among agencies is needed to develop a national research agenda on these topics. Because overall federal investment in biomedical and health services research is declining, funding for diagnosis and diagnostic error will draw federal resources away from other priorities. However, given the consistent lack of resources for research on diagnosis, and the potential for diagnostic errors to contribute to patient harm and health care costs, funding for this research is necessary for broader improvements to the quality and safety of health care. In addition, improving diagnosis could potentially lead to cost savings by preventing diagnostic errors, inappropriate treatment, and related adverse events.

Recommendation 8a: Federal agencies, including HHS, the U.S. Department of Veterans Affairs, and the U.S. Department of Defense, should:

- Develop a coordinated research agenda on the diagnostic process and diagnostic errors by the end of 2016.
- Commit dedicated funding to implementing this research agenda.

Recommendation 8b: The federal government should pursue and encourage opportunities for public–private partnerships among a broad range of stakeholders, such as the Patient-Centered Outcomes Research Institute, foundations, the diagnostic testing and health IT industries, health care organizations, and professional liability insurers to support research on the diagnostic process and diagnostic errors.
21. Approximately what percentage of U.S. adults seeking outpatient care will experience a diagnostic error each year?
   A. 1%
   B. 3%
   C. 5%
   D. 9%

22. The phrase “next frontier in patient safety” has been applied to which topic of current interest in medicine?
   A. Diagnostic errors
   B. Electronic health records
   C. Inter-professional collaboration
   D. The Affordable Care Act

23. A key part of defining “diagnostic error” from a patient-centered perspective is ___________________.
   A. Determining if the error resulted in harm to a patient
   B. Including an explanation of why an error happened
   C. Communicating the diagnosis to the patient
   D. Identifying the setting in which the error occurred

24. Before initiating any treatment for a patient’s health problem, a clinician must ___________________.
   A. Rule out all other potential health problems on the differential diagnosis
   B. Verify a diagnosis by collaborating with another clinician
   C. Obtain diagnostic certainty to ensure treatment success
   D. Reduce diagnostic uncertainty enough to make an optimal decision

25. Which of the following is a potential challenge to the performance of an accurate patient medical history?
   A. Memory loss
   B. Undeveloped cognitive abilities
   C. Poor language ability
   D. All of the above

26. Which of the following phases in the “brain-to-brain loop model” of diagnostic testing is least susceptible to error?
   A. Pre-analytic
   B. Analytic
   C. Post-analytic
   D. Post-post analytic

27. What type of diagnostic testing is growing rapidly and, thus, posing a challenge for clinicians?
   A. PET scanning
   B. fMRI imaging
   C. Molecular/genetic testing
   D. Allergan testing

28. Which of the following is not a potential source of error when using medical imaging technology?
   A. Inadequate reimbursement for use of a particular modality of medical imaging
   B. Inadequate patient education and preparation
   C. Inadequate device sensitivity
   D. Inadequate device specificity

29. Which of the following is a model for more closely involving pathologists and radiologists in the diagnostic process?
   A. Integrated practice units
   B. Patient-centered medical homes
   C. Mandatory consultation procedures
   D. Diagnostic management teams

30. A potential limitation of using an empiric treatment strategy is that ___________________.
   A. Using a treatment in situations of high diagnostic uncertainty is inherently unethical.
   B. Response rates to treatment can be highly variable, hence reducing the diagnostic value of the approach.
   C. The treatment may do more harm than good to the patient.
   D. Empiric treatment strategies are seldom reimbursed by payors.

31. The current understanding of clinical reasoning is based on which theory of decision making?
   A. The bounded rationality theory
   B. The brain-to-brain loop theory
   C. The cognitive feedback theory
   D. The dual-process theory

32. Which of the following is an example of a situation involving slow system 2 cognitive processing?
   A. Diagnosis of myocardial infarction based on atypical presentation
   B. Face recognition
   C. Diagnosis of Lyme disease from a bulls-eye rash
   D. Intuitive diagnosis of a disease from a patient’s presentation
33. What is the formal name for the universal tendency to believe that we know more than we actually do?
   A. Base-rate neglect
   B. Overconfidence bias
   C. Hubris bias
   D. Representativeness heuristic

34. Which type of cognitive processing typically performs best in highly reliable and predictable environments?
   A. Analytical processing
   B. System 2
   C. Parallel processing
   D. System 1

35. What can be the result of a diagnostic process in which the outcomes of the decision-making process are unknown?
   A. The outcomes will be treated as favorable, which can lead to poor calibration.
   B. The outcomes will be treated as unfavorable, which can distort the calibration process.
   C. The unknown outcomes will be ignored, with only known favorable or unfavorable outcomes influencing the calibration process.
   D. The unknown outcomes will be ignored, which can distort the calibration process.

36. Because of fatigue, a radiologist misses identifying a suspicious spot on a lung x-ray. When the attending physician reviews the x-ray, she notices the irregularity and consults with the radiologist, who recognizes his mistake. No harm occurred to the patient. What is the proper label for this kind of situation?
   A. Unavoidable misdiagnosis
   B. Diagnostic error
   C. Near-miss process problem
   D. Preventable diagnostic error

37. Over-diagnosis is considered a form of diagnostic error.
   A. TRUE
   B. FALSE

38. Which of the following is not a recommended motivation for instituting a system for measuring diagnostic error?
   A. Determining the causes of diagnostic errors
   B. Evaluation of interventions to reduce diagnostic errors
   C. Reducing liability exposure
   D. Building the accountability of a health care system

39. Which of the following is not a method for estimating the incidence of diagnostic errors?
   A. Postmortem examinations
   B. Malpractice claims
   C. Medicaid diagnostic error reports
   D. Surveys of clinicians

40. __________ was reported to reduce hospitalization time and costs, improve service provision, and enhance patient satisfaction, staff motivation, and team innovation in the United Kingdom’s National Health Service.
   A. Teamwork
   B. Implementation of electronic medical records
   C. Incentivizing the reduction of medical errors
   D. Eliminating incentives to control costs

41. Which group is considered to be at the center of the diagnostic process?
   A. Doctors
   B. Patients and their family members
   C. Nurses
   D. Diagnosticians

42. __________ can ensure communication and care coordination among diagnostic team members, monitor a patient over time to see if the patient’s course is consistent with a working diagnosis, and identify potential diagnostic errors.
   A. Primary care physicians
   B. Diagnosticians
   C. Nurses
   D. Clinical care coordinators

43. Accountable Care Organizations (ACOs) were created to address delivery system fragmentation and to align incentives to improve communication and collaboration among health care professionals.
   A. TRUE
   B. FALSE
44. Morbidity and mortality conferences bring health care professionals from different disciplines together to consider the diagnosis and treatment of specific patients.
   A. TRUE   B. FALSE

45. A survey of low-income patients faced with major medical decisions found that _____ wanted to be very involved in the decision-making process.
   A. 35%.
   B. 45%.
   C. 65%.
   D. 75%

46. An identified problem with electronic health records is that ________.
   A. Health care professionals prefer to take patient histories and to record information by hand, rather than with a computer.
   B. Use of EHRs increases the overall cost of diagnosing and treating patients.
   C. Health care professionals may be distracted from communicating with patients as they enter information.
   D. Use of EHRs may increase the rate of diagnostic errors.

47. Evidence shows that disclosing medical or diagnostic errors to patients and their families ________.
   A. Increases malpractice claims, but improves levels of patient satisfaction
   B. Improves patient outcomes and may reduce malpractice claims
   C. Improves the moral of medical personnel
   D. Improves the public perception of the accountability of a health care organization

48. The phrase “heuristic failure” means ________.
   A. Errors resulting from the use of “mental shortcuts” during the diagnostic process
   B. Errors related to systemic shortcomings in the collaborative structures of a health care organization
   C. Poor patient outcomes arising from misdiagnoses
   D. Diagnostic errors stemming from the mis-use of electronic health record systems

49. Which statement best describes the current state of diagnostic decision support tools?
   A. Research shows that although diagnostic decision support tools can reduce the rate of medical errors, clinicians do not use these tools as often as they should.
   B. Diagnostic decision support tools have not been shown to improve the accuracy of clinical decision making.
   C. Research has shown that diagnostic decision support tools can reliably reduce the rate of diagnostic errors in clinical practice.
   D. Further research is needed to understand the performance of diagnostic decision support tools in clinical practice.

50. What fundamental change is recommended to increase the utility of health IT systems as they relate to improving diagnosis?
   A. Reducing the cost of health IT systems
   B. Improving interoperability between systems
   C. Improving accessibility of health IT systems to include non-prescribing health care professionals
   D. Including check boxes for the recording of diagnostic errors

51. What does “mHealth” stand for?
   A. Mandatory health technologies
   B. Multiple health applications
   C. Medical health technologies
   D. Mobile health applications

52. What is one barrier to the use of postmortem examinations as a way of obtaining more accurate information about diagnostic errors?
   A. Hospitals are no longer required to conduct target percentages of such examinations in order to obtain accreditation
   B. Insurers do not directly pay for postmortem examinations
   C. Medicare bundles payment for postmortem examinations into its payment for quality improvement activities
   D. All of the above
53. Which of the following is not a characteristic of effective feedback interventions to reduce diagnostic errors?
A. Timely
B. Cost-effective
C. Non-punitive
D. Individualized

54. Which statement is most true about the relationship between fee-for-service (FFS) reimbursement systems and efforts to improve diagnoses?
A. FFS reimbursement systems tend to favor large-scale health care organizations with more developed inter-professional health care teams
B. FFS payment may not incentivize a high-quality, efficient diagnostic process
C. FFS payments are the best way to support high-quality diagnoses
D. FFS reimbursement systems reward evaluation and diagnosis over provision of medical treatments

55. What system has been proposed as a way to provide injured patients with expedited compensation decisions for certain types of medical errors?
A. Safe harbors
B. Communication and resolution programs (CRPs)
C. Patient safety organizations (PSOs)
D. Administrative health courts
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- **LAST NAME:** Doe
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- **PHONE NUMBER:** (480) 456-7890
- **LICENSE STATE:** AZ
- **LICENSE #:** 9876
- **LICENSE EXPIRATION DATE:** 06/30/2019
- **MAILING ADDRESS:** 1234 Cherry Street
- **CITY:** Phoenix
- **STATE:** AZ
- **ZIP CODE:** 85707
- **SPECIALTY:** Internal Medicine

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All physicians and physician assistants with an active DEA registration must complete (3) three credit hours related to opioids, substance abuse or addiction. Effective April 26, 2018, these credit hours must be earned prior to your next license renewal date. For additional information see your board’s website.

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# 2019 Arizona Medical Licensure Program

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### Mark One Answer Per Question

#### Prescriber Education for Extended-Release and Long-Acting Opioid Analgesics (PG. 42-43)

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#### Reducing Diagnostic Error in Med. (PG. 106-109)

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**Please complete the activity survey on the following page.**

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1. Assessing Patients for Treatment with ER/LA Opioid Analgesic Therapy
2. Initiating Therapy, Modifying Dosing, and Discontinuing Use of ER/LA Opioid Analgesics
3. Managing Therapy with ER/LA Opioid Analgesics
4. Counseling Patients and Caregivers about the Safe Use of ER/LA Opioid Analgesics
5. General Drug Information for ER/LA Opioid Analgesic Products
6. Specific Drug Information for ER/LA Opioid Analgesic Products
7. Have you prescribed ER/LA opioids in the past twelve months?
8. Please identify a specific change, if any, you will make in your practice related to prescribing ER/LA opioid analgesics?
9. What do you see as a barrier to making these changes?

10. Define “diagnostic error” and ways it can be measured or assessed.
11. Recognize the importance of a team approach to reducing diagnostic errors.
12. Discuss methods to improve patient engagement in the clinical diagnostic process.
13. Describe ways technology and healthcare information can reduce diagnostic error.
14. Explain external environmental variables that influence diagnostic accuracy.
15. Please identify a specific change, if any, you will make in your practice related to reducing diagnostic error in medicine.
16. What do you see as a barrier to making these changes?

17. The program was balanced, objective & scientifically valid.
18. Do you feel the program was scientifically sound & free of commercial bias or influence?
19. How can this program be improved?
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