Safe Practice Recommendations for Safer Opioid Prescribing: Measures and Clinical Decision Support
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Decision Support

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Introduction

The United States is in the midst of a deadly opioid use epidemic. Evidence of this crisis is demonstrated by the decline in U.S. life expectancy attributed in part to deaths from drug overdoses. It is increasingly clear that we must all work together to reduce this trend. Developers of electronic health records (EHRs) and other health information technology (IT) solutions have an important role to play in responding to this crisis, including specific opportunities to increase patient safety.

The ability to use health IT to reduce patient risks has been broadly recognized and highlighted in the peer-reviewed and professional literature, by ECRI Institute’s work, and by the HIMSS Electronic Health Record Association (EHRA). Such documented safety-enhancing capabilities can also play a vital role in mitigating opioid-related safety issues. The project detailed and discussed here grew out of these compelling and reinforcing realities, and as a result, both the EHRA and ECRI Institute, working through the multistakeholder, ECRI Institute-sponsored Partnership for Health IT Patient Safety (Partnership), have become deeply engaged in this topic.

EHRA and ECRI Institute recognize the unique opportunities that can emerge from a multidisciplinary and collaborative approach to safety issues, informed by synergies from combining EHR developer expertise, information, and perspectives with the Partnership’s evidence, knowledge, data, and data analysis available from ECRI Institute in its role as a Patient Safety Organization (PSO). This project highlights what can be accomplished using such a collaborative model. EHRA’s Developer Code of Conduct reflects and recognizes the need for such synergies, as does the evolving work conducted by the Partnership.

This report contains information derived from evaluation of ECRI data sets and an evidence-based literature review, and most importantly, the deliberations of a joint EHRA/ECRI workgroup focused on applying health IT tools to our nation’s opioid overuse crisis. This wide-ranging information was used to structure recommendations and provide suggestions for strategies to execute these safe practices for prescribing for both opioid-naïve and opioid-exposed patients. The focus was on a synergistic cycle of measurement and clinical decision support (CDS). This report includes action-oriented recommendations for EHR and health IT developers, content developers, clinicians, patients, and other stakeholders.

EHRA and ECRI Institute’s Patient Safety Collaboration: A Proof-of-Concept Project

EHRA and ECRI Institute agreed to work on a proof-of-concept project to assess the viability and value of collaboration between the two organizations on health IT safety issues. For this first project, ECRI Institute and EHRA identified several potential projects and topics of focus. The groups evaluated options for which IT could be used to enhance patient safety. The key evaluation criteria were as follows:

- The topic can be defined narrowly and precisely
- The issue is a demonstrated patient safety concern and desired outcomes will positively impact patient safety
- The matter is of national concern
- EHRA members and ECRI Institute can together bring to bear relevant data, analysis, and technology-enabled approaches to impact the issue
- Significant progress can be made within the first six months of the project
- EHR developers can implement recommendations in the near-term (i.e., one to three years)

It was decided that the initial topic should be safer opioid prescribing, focusing on the synergistic and reinforcing cycle of measurement—using data in the EHR—and CDS tools. More specifically the project would address the following:

- Health IT–enabled approaches allowing clinicians and healthcare organizations to assess and measure opioid prescribing (e.g., orders, prescribing, pharmacy).
Methods to enable better and safer opioid-prescribing performance via CDS, use of e-prescribing, and availability of prescription drug monitoring program (PDMP) data in clinician workflows. Patient and clinician education would be addressed as elements of CDS.

In deciding how to approach this pilot, EHRA and ECRI Institute agreed to—

- Adapt for this project the workgroup process that has been successfully developed and employed by the Partnership
- Define deliverables and desired outcomes
- Identify roles for the collaborative participants from both EHRA and ECRI Institute’s internal Partnership team
  - ECRI Institute would carry out evidence-based research and data collection and analysis, including use of deidentified and aggregated event data from the ECRI Institute PSO
  - ECRI Institute would convene a workgroup of representatives from participating EHR developers and ECRI Institute and would co-chair the workgroup
  - EHRA would co-chair the workgroup and encourage EHRA member participation
  - EHRA would identify potential technology-enabled approaches to enhance opioid prescribing
- Together, EHRA and ECRI Institute would—
  - Work to define and complete project deliverables, meeting on a monthly basis and using innovative digital collaboration tools
  - Encourage developers to implement solutions emerging from this project as part of their regular development process

Both organizations agreed that the goal was not to create or act as a safety event reporting system but rather, to bring together relevant data from multiple sources to inform strategies to address a high-priority safety issue. The fundamental focus is a proactive learning system using an approach that is neither punitive nor regulatory.17,18

EHRA and ECRI Institute agreed that the project would be neutral on practice setting but with clear applicability to ambulatory care. They agreed to start with data currently available in EHR and allow the potential to build out to identify other data sources to add to the EHR (e.g., from Surescripts and other e-prescribing sources and PDMPs). Project deliverables highlighted the agreement on the potential benefit of vendor implementation of strategies for safer opioid prescribing informed by the data, the evidence in the literature, shared learnings, and collaboration with content developers. The identified deliverables included the following:

- A data and evidence-based literature review
- A white paper highlighting findings, including summaries of the data analysis and the evidence based-literature review
- Joint support for implementation of priority recommendations derived from data, evidence in the literature, shared learnings, and collaboration with others, including EHR and content developers and clinicians, that will facilitate safer prescribing of opioids for both opioid-naïve and opioid-exposed patients

**Workgroup Process**

EHRA and ECRI Institute identified a starter-set of opioid and health IT resources (see Appendix A), and EHRA recruited a workgroup from among its members, especially participants in its Patent Safety Workgroup and Opioid Crisis Task Force. Using online collaboration software, the workgroup, including ECRI participants, met monthly from April through September 2018. Meetings included a mix of formal presentations, group discussions and input, online collaboration, and guest speakers on specific topics, such as opioid-relevant CDS. A final meeting was held in December once draft white paper materials were updated and assembled, and participants prioritized and determined the feasibility of the proffered recommendations.

During the progression of meetings, the workgroup reviewed various resources, including the Centers for Disease Control and Prevention’s (CDC) opioid prescribing guidelines, opioid-focused quality measures, recent literature on risks associated with opioids and on CDS
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Opioid Prescribing: Measurement and Clinical Decision Support

During workgroup discussions, it became evident that much of the emphasis around the opioid crisis has been on persistent opioid use and abuse disorders. In contrast, to add additional perspectives and value, this joint project focused on integrating measures and CDS into the patient populations that have yet to experience these problems. The intent is to mitigate the risk of opioid dependence and persistent use. The populations for this attention were as follows:

- Opioid-naive patients—those never having been exposed to opioids
- Opioid-exposed patients—those not currently using opioids but who have taken opioids previously for an acute event and do not presently have an active prescription for opioids

Measures

Potential areas for measurement for safer prescribing of opioids were evaluated, weighing both measure relevance and availability of needed data in the EHR to increase clinician awareness and lead to safer prescribing.

A 2018 study indicated that measurement and dissemination of prescribing-behavior data was seen as beneficial to clinicians to influence and improve their opioid-prescribing practices. The number of days’ supply of the initial opioid prescription is one of the strongest predictors of long-term opioid use\(^\text{27}\) (see Measures to Track for Improved Opioid-Prescribing Practices).

Another measure of value is the patient satisfaction score. Today most clinicians and healthcare organizations collect and track such scores. They can be correlated with changes in organizational pain-management policies and/or implementation of stricter opioid-prescribing guidelines. Changes in patient satisfaction scores can indicate whether newly implemented policies or guidelines are meeting the patients’ needs.\(^\text{28}\) Using patient surveys, healthcare organizations can determine whether their patients believe their pain is being addressed and treated effectively. Patient satisfaction survey instruments can be used in conjunction with the EHR, even if data are not directly imported into the EHR, by leveraging the patient portals integrated with the EHR.\(^\text{29}\)

The challenge for clinicians and the health IT community is to obtain the data needed to calculate measures in an accurate and cost-effective manner. Unfortunately, not all of these data are available in a computable format. The increasing implementation of pertinent structured data using Systematized Nomenclature of Medicine — Clinical Terms (SNOMED-CT), Logical Observation Identifiers Names and Codes (LOINC\(^\text{®}\)), International Classification of Diseases (ICD), Current Procedural Terminology (CPT), RxNorm\(^\text{®}\),\(^\text{30}\) and National Drug Code (NDC), along with the data that exist in the EHR will allow for the aggregation and normalization of the data.

In addition, it is essential that clinical practices and healthcare organizations have sufficient measures available to meet their own clinical priorities, that needed data can be obtained in ways that do not increase clinician burdens or hinder EHR usability, and that credible measures can be calculated, aggregated, and reported in ways that positively affect clinical care.

Clinical Decision Support

CDS plays an ever-increasing role in daily workflow within the EHR. Alerts, order sets, guidance, documentation forms, data summaries, dashboards, predictive analytics, references, and knowledge resources are all types of CDS that can be used to influence opioid prescribing. Recognizing the power of health IT to play a vital role in enhancing patient safety, the EHRA and ECRI Institute workgroup safe practice recommendations have been

Measures to Track for Improved Opioid-Prescribing Practices

- Average daily dose in morphine milligram equivalents (MMEs)
- MMEs per prescription
- Patient satisfaction scores, pain management
crafted to support the efficient and effective use of CDS to inform opioid prescribing and to incorporate internal measurements. The goal is to prevent either opioid-naïve or opioid-exposed patients from moving towards persistent use and abuse or unintentional overdose.

The literature provides evidence that external CDS interventions, integrated into the EHR in an appropriate format and time in the prescriber’s clinical workflow, can help clinicians select the most appropriate starting dose by incorporating evidence-based clinical guidelines.

Examples of such CDS include the following:

- Age-based protocol order sets
- Opioid dosing defaults
- High opioid dose alerts
- Dispensing defaults
- Risk predictor–based alerts

One important emerging standard for integrating CDS into EHRs is the CDS Hooks API (application program interface) standard using HL7® FHIR® (Fast Healthcare Interoperability Resources). “Hooks” would invoke CDS from within the EHR workflow, based on structured data elements captured in the EHR. CDS hooks attach CDS resources at specific places in workflow. CDS resources for opioid-naïve and opioid-exposed patients, applied at appropriate places in clinical workflow, can provide prescribers with pertinent and actionable information, whether it is a lower dose or shorter duration of the opioid or an alternative treatment as a first approach to pain management. Such workflow-appropriate CDS can be used to identify appropriate treatments and therapies for opioid-naïve and opioid-exposed patients, helping to decrease the incidence of persistent use and abuse or unintentional overdose.

The workgroup realized that further work is needed to seamlessly integrate and enable EHRs to synthesize relevant opioid-prescribing data from disparate sources. More widespread adoption of standards and technology approaches will enable access to specific data elements, notably APIs using HL7® FHIR® and apps developed using the SMART on FHIR® standard—to increase the availability of external data sources to complement CDS-relevant data collected in the EHR. The integration of this information into the EHR can facilitate CDS interventions that are patient-specific and based on demographics, medication history, comorbidities, and risk.

Although using EHRs to provide CDS is not new, using a standard interaction mechanism (CDS Hooks) so that external CDS can be targeted to aggregated patient risk factors and employed to aid providers in safer prescribing is a relatively novel idea. CDS has been shown to be valuable to intervene in cases of realized persistent use. In contrast, the recommendations in this paper are targeted at using CDS to help prevent progression to persistent use by opioid-naïve and opioid-exposed patients by alerting prescribers to relevant external evidence-based guidance earlier in the prescribing process prior to the initial dose.
Methods

Data Obtained and Analyzed

Data Analysis: Focus on Inpatient Events Highlighted in the ECRI PSO Opioid Deep Dive

ECRI Institute PSO is recognized as a PSO by the U.S. Department of Health and Human Services. The PSO functions under the provisions of the Patient Safety and Quality Improvement Act of 2005. PSOs serve as patient safety contractors to healthcare organizations. The Patient Safety Act authorizes the Agency for Healthcare Research and Quality (AHRQ) to list or designate entities as PSOs that attest to having expertise in identifying the causes of and interventions to reduce the risk of and threats to the quality and safety of patient care.

Event reports are submitted to the PSO, typically by clinicians and healthcare organizations. Events submitted under the protections provided to the ECRI Institute PSO were examined to identify opioid-related issues. ECRI Institute PSO patient safety analysts reviewed 7,218 relevant event reports involving opioids from January 1, 2014, through November 30, 2016. The events were evaluated based on the reported harm; standard event report forms include the opportunity to provide a harm score developed by the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP; Figure 1).

Figure 1. Harm Scores Developed by NCC MERP

Category I: An error occurred that may have contributed to or resulted in the patient’s death

Category H: An error occurred that required intervention necessary to sustain life

Category G: An error occurred that may have contributed to or resulted in permanent harm

Category F: An error occurred that may have contributed to or resulted in temporary harm to the patient and required initial or prolonged hospitalization

Category E: An error occurred that may have contributed to or resulted in temporary harm to the patient and required intervention

Category D: An error occurred that reached the patient and required monitoring to confirm that it resulted in no harm to the patient and/or required intervention to preclude harm

Category C: An error occurred that reached the patient but did not cause patient harm

Category B: An error occurred but the error did not reach the patient (An “error of omission” does reach the patient)

Category A: Circumstances or events that have the capacity to cause error

Category: An error occurred that may have contributed to or resulted in the patient’s death

Category: An error occurred that required intervention necessary to sustain life

Category: An error occurred that may have contributed to or resulted in permanent harm

Category: An error occurred that may have contributed to or resulted in temporary harm to the patient and required intervention

Category: An error occurred that reached the patient and required monitoring to confirm that it resulted in no harm to the patient and/or required intervention to preclude harm

Category: An error occurred that reached the patient but did not cause patient harm

Category: Circumstances or events that have the capacity to cause error

Category: An error occurred that may have contributed to or resulted in the patient’s death

Definitions

Harm
Impairment of the physical, emotional, or psychological function or structure of the body and/or pain resulting therefrom

Monitoring
To observe or record relevant physiological or psychological signs

Intervention
May include change in therapy or active medical/surgical treatment

Intervention Necessary to Sustain Life
Includes cardiovascular and respiratory support (e.g., CPR, defibrillation, intubation)

To begin the analysis, a taxonomy was developed to capture the broad categories related to opioid issues. The taxonomy captured categories aligning with the steps in the medication process. These steps are prescribing, transcribing, dispensing, administering, monitoring, adverse drug reactions, and diversion. In evaluating the total event reports, 3,396 (47%) indicated the level of harm. In the category of prescribing, 30% of the time the event reached the individual and caused harm or death, 58% of the time the event reached the individual but caused no harm, and 11% of the time the event did not reach the patient (Figure 2).

Analysts next looked at PSO data sets* that would inform the questions posed to this group, namely which measures and CDS features could facilitate safer prescribing.

In ECRI Institute PSO Deep Dive: Opioid Use in Acute Care, the most common areas related to the events, the “failure modes,” were polypharmacy,† wrong dose, and duplicate orders. When analyzing issues that were most frequently related to patient harm, analysts found that these events were associated with inadequate risk assessment (e.g., review of medication history) before prescribing, failure to determine opioid tolerance, wrong rate or frequency, and wrong route of drug administration (Figure 3).

![Figure 2. Distribution of Harm in Each Taxonomy Category](image-url)

**Figure 2. Distribution of Harm in Each Taxonomy Category**

<table>
<thead>
<tr>
<th>Circumstances that could cause adverse events (A)</th>
<th>Event that did not reach the individual (B)</th>
<th>Event that reached the individual, no harm (C-D)</th>
<th>Event that reached the individual, harm or death (E-I)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prescribing</td>
<td>Transcribing</td>
<td>Dispensing</td>
<td>Administering</td>
</tr>
<tr>
<td>1%</td>
<td>0%</td>
<td>11%</td>
<td>0%</td>
</tr>
</tbody>
</table>


N = 3,396 events with a harm score indicated.

Percentages do not always add up to 100% because of rounding. See “Figure 1. Harm Scores Developed by the National Coordinating Council for Medication Error Reporting and Prevention” for definitions and groupings of harm scores.

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* The data sets analyzed are derived from event report narratives that are often sparse and do not provide all of the information analysts might want to know about events, making it challenging to identify all factors that contributed to a particular event.

† At times, polypharmacy is clinically appropriate. Some patients are on multiple medications by design and are treated safely and effectively. Concerns arise, however, when the patient has factors that increase the potential for opioid-induced respiratory depression, with polypharmacy contraindicated for this reason.
Data Analysis: Focus on Clinical Decision Support

As part of the second data analysis performed by ECRI Institute’s Partnership for Health IT Patient Safety analysts, the focus turned to CDS interventions applied to opioid prescribing. Here, 269 safety events from September of 2015 through January of 2018 were reviewed. Events were first categorized by CDS intervention type (Figure 4).

**Figure 4. CDS Intervention Type for Opioid-Prescribing Events**

![CDS Intervention Type](chart)

Note: N = 269 opioid-safety events involving CDS interventions. Total adds up to more than 100% because more than one CDS intervention could be determined from some events.

The most prevalent event category was associated with alerts and reminders. These include both alerts designed to prevent error and alerts that were informational reminders. The next largest category included data presented to the user to assist with ordering or prescribing, administration, and/or documentation (relevant data presentations). The third most common opioid-related CDS events in this focused analysis involved issues with documentation forms and templates. This broad category of documentation includes patient self-assessment forms, clinical patient assessment forms, clinician encounter documentation forms, and data flow sheets.

To better understand the role of CDS, the data were evaluated based on the function of the particular aspect of CDS that acted as a safeguard. This feature could be an alert, a reminder, or some other indication to call attention to the action being taken. Here, reports identified whether the feature was functioning as the user might expect, whether the user bypassed the available CDS, or if the associated CDS safeguard was available and operational. These events (269 identified events) were further categorized based on the CDS functional status (e.g., functioning, not available, not activated; see CDS Safeguard Functional Status). Here, the majority of identified safety events indicated that the safeguard (alert, reminder) was unacknowledged or that it was bypassed, with additional events indicating that a safeguard was not functioning as expected.

**CDS Safeguard Functional Status**

- Safeguard bypassed or NOT acknowledged........41%
- Safeguard DID NOT function as expected ........28%
- Safeguard functioned as expected..................18%
- Safeguard NOT available .........................14%
- Safeguard NOT activated..........................<1%
- Other ..........................................<1%

Literature Review

To inform the workgroup efforts, an evidence-based literature review was performed to evaluate CDS interventions to enhance the ability of clinicians to safely prescribe opioids (Figure 5). The search also assessed whether evaluating and measuring particular clinical variables could promote safer prescribing. Existing evidence was identified to examine risk factors that are associated with progression to persistent use or abuse for opioid-naïve patients. Specifically, the search examined the following key questions:

1. What resources or tools exist for creating or improving clinical decision support for appropriate opioid prescribing for both opioid-naïve and opioid-exposed patients?
2. What evidence exists that measuring particular variables (e.g., prescribing habits) improves appropriate opioid prescribing?
3. What risk factors are associated with progression to opioid abuse for opioid-naïve patients?
In addition, an environmental scan was performed to identify publically available, existing CDS artifacts aimed at improving appropriate opioid prescribing for opioid-naïve patients.

Overall, the report identified a small, substantive evidence base suggesting health IT interventions can be effective for reducing opioid prescribing. The evidence suggests that interventions including PDMPs and benchmarking prescribing rates are associated with reductions in opioid prescribing.

The review also found that patient risk factors (history of depression, alcohol or substance abuse, smoking, or pain disorder) were associated with an increased risk to persistent use or abuse. Similarly, increased opioid use (e.g., filling a prescription, number of refills, and duration for regular use) was associated with progression to persistent use and abuse. Using health IT for early identification of at-risk patients and safer prescribing can promote more efficient deployment of prevention resources and potentially reduce the risks of persistent use or abuse.

Results from the literature review can be found in the ECRI Special Report, Measures and CDS for Safer Opioid Prescribing: Literature Review (see the Executive Summary of this report in Appendix B).
Recommendations

Enable technologies to measure and monitor prescribing patterns to allow safer opioid prescribing

Ensure that EHRs can collect and access the data elements needed to support measures and drive CDS

Ensure that opioid-prescribing CDS interventions are delivered at the right time in the workflow for both opioid-naïve and opioid-exposed patients

Vendors and developers can help clinicians with health IT strategies to address the issues and aggregate clinical information to improve safety for opioid prescribing. The recommendations developed by the workgroup are setting-neutral and, therefore, applicable to prescriptions and medication orders. These recommendations focus on opioid-naïve and opioid-exposed patients so that potential issues can be identified and addressed at the earliest stage. The EHRA and ECRI Institute workgroup synthesized the findings of the data analysis, the evidence-based literature review, and its own deliberations to craft three recommendations.

The three high-level recommendations address measures for prescribing and prescribing patterns, enabling technology to capture additional elements to drive measures and seeking to ensure that the CDS is not only appropriate to the patient but also available when needed in the clinical encounter.

The full table of recommendations and implementation strategies to enable application of these recommendations can be found in Appendix C and under Priorities for Execution.

Discussion

The three high-level recommendations target two populations—opioid-naïve and opioid-exposed patients (see Identifying Those Who Are Opioid-Naïve or Opioid-Exposed is a Challenge). The workgroup set out to develop tools and product-development recommendations that can enter the EHR development, implementation, and production lifecycle in the near term—that is, one to three years. In identifying ways to evaluate potential combinations of risk factors and the role that technology can play in the tailored use of CDS, these recommendations aim to mitigate harm.

In developing these recommendations, the workgroup considered the sociotechnical model of EHR use developed by Dean Sittig and Hardeep Singh (Figure 6). In this model, EHRs are only one part of a complex socio-technical system. The sociotechnical model encompasses hardware and software, user interface, clinical content, and organizational policies, procedures, and culture.

Figure 6. Eight-Dimensional Sociotechnical Model of Safe and Effective EHR Use

Source: Menon S, Smith MW, Sittig DF, Petersen NJ, Hysong SJ, Espadas D, Modi V, Singh H. How context affects electronic health record-based test result follow-up: a mixed-methods evaluation. BMJ Open. 2014 May-Jun;4(11):e005985. Figure 1. Also available: https://dx.doi.org/10.1136/bmjopen-2014-005985. This work is licensed under a Creative Commons CC BY-NC 4.0 license.
people, regulatory constraints, workflow, policies and procedures, and system measurement. When looking to mitigate issues with opioid prescribing, it is important to evaluate each of the sociotechnical factors. Moreover, when designing CDS interventions, it is important to recognize and address all internal and external factors that affect development, dissemination, and implementation. Each workgroup recommendation was considered in this context.

The collaborative strategies emphasized by these recommendations are intended for developers of EHRs, content included in CDS, and opioid-relevant quality measures. It is also intended for those who develop and maintain systems with information about patients’ prescriptions and exposure to controlled substances (e.g., PDMP information). Making opioid-relevant measurement and CDS tools available to prescribers will promote safer prescribing for both opioid-naïve and opioid-exposed patients.

The data presented in this paper, although limited by acquisition through voluntary reporting, highlights the need to examine the risk factors that impact opioid prescribing for patients who have never taken opioids or have had only a minimal past exposure to opioids. In addition, looking at measures associated with morphine milligram equivalents* (MMEs) and duration (i.e., number of days supplied) reveals areas where technology can enhance patient safety. Also instructive is information that is available for opioid-relevant health information exchange (e.g., past medications, current opioid prescriptions from other clinicians).

**Enable Technologies to Measure and Monitor Prescribing Patterns to Allow Safer Opioid Prescribing**

**Rationale:** Using health IT to measure internal and external metrics for prescribing patterns along with transparent utilization and performance can have significant positive impact on provider prescribing practices.

Of the 269 CDS opioid safety events reviewed, 100% involved CDS delivered in the EHR as an alert or a reminder. However, 41% of the alerts or reminders were overridden (categorized as not acknowledged or bypassed), and 28% did not function as expected (see CDS Safeguard Functional Status). A 2016 study found that a large volume of inconsequential alerts occurred when opioids were prescribed in the inpatient setting. With 50% of alerts related to medication in the ambulatory care space overridden and more than 70% of alerts in the inpatient setting also overridden, there is a need for more effective ways to use this technology. Given these significant override rates, it should not be assumed that CDS intended for safer prescribing of opioids is being used as intended.

As a result, clinicians and healthcare organizations should measure and monitor override rates and identify strategies to improve safer opioid-prescribing practices. Related measures should consider:

- Alert type for opioid prescribing
  - Risk factors
  - Parameter guidance
  - Prescribing guidelines
  - Alternative therapies or treatments
  - Order sets
- The reasons cited for the override
- The clinical appropriateness of the override reason

Learnings from such evaluations can then be used to identify strategies to fine-tune CDS triggers for alerts that can improve safer prescribing without contributing to physician burden.

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* MMEs are determined by using an equivalency factor to calculate a dose of morphine that is equivalent to the ordered opioid. Daily MED is the sum of the MME of all opioids a patient is likely to take within 24 hours, and that total is used to determine whether the patient is nearing a potentially dangerous threshold.

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**Identifying Those Who Are Opioid-Naïve or Opioid-Exposed is a Challenge**

Defining and identifying the “opioid-naïve” or “opioid exposed” patient is challenging because patients may have received a prescription, but might not have filled it or might have obtained the medication but did not take it. Additionally, patients sometimes share medications or obtain medications without the appropriate prescriptions. Additional techniques may help to identify opioid-naïve and opioid-exposed patients.
The goal of this first recommendation is to ensure that clinicians and healthcare organizations can collect the data elements needed and apply them to compute and display metrics that can increase awareness about prescribing behaviors. Clinician awareness is an important first step in improving prescribing behavior; it has been shown that increased awareness has the potential to reduce the contribution of prescribers to the opioid epidemic by fostering safer opioid-prescribing behaviors.45

Specific metrics can be calculated and used to increase awareness of opioid-prescribing behaviors. Noteworthy examples are those associated with progression to persistent use or abuse, including the following:29,46-48

- Opioid prescription quantity and duration. The number of days’ supply of the initial opioid prescription is the strongest predictor of long-term opioid use.27
- MMEs. Patients taking more than 60 mg of MME preoperatively had an 80% likelihood of persistent use postoperatively.49
- Use of PDMP program information. Mandated use of PDMPs is associated with reduction in MME and duration per prescription.50
- Individual CDS override rates. Tiering of alerts based on criticality, intended to reduce the frequency of (low-value) alerts, is associated with a high rate of CDS compliance.51

Use of health IT to measure opioid-prescribing patterns associated with progression to persistent use and to provide both individual and organizational metrics for self-assessment should be maximized. Metrics for measures associated with progression to persistent use need to be delivered to clinicians and healthcare organizations as actionable data to identify outliers, trends, and patterns of unsafe practice (see Risk Factors Associated with Progression to Abuse).52-56 Harnessing health IT to measure internal and external dimensions of prescribing patterns, along with transparent utilization and performance reports, provides the opportunity for organizations to analyze the data and take action leading to safer opioid prescribing.29

Internal measure topics include—33,57
- Prescriptions and medication orders stratified by diagnosis and procedure
- Use of the PDMP
- Utilization and override rates of types of CDS interventions
- Compliance with electronic prescribing of controlled substances (EPCS), especially in states where it is not mandated

External measures include—58,59
- Centers for Medicare and Medicaid Services (CMS) quality measures
- Pharmacy Quality Alliance (PQA) Core Measure Set
- Measures based on Centers for Disease Control and Prevention (CDC) guidelines

Increasing clinician and organizational awareness of prescribing behaviors is an important first step in using health IT to tackle the opioid epidemic; knowing what data elements need to be measured and having the capability to capture and apply them in priority quality measures will allow us to focus on solutions, including targeted education for clinicians and healthcare organizations, to reduce risk with improved prescribing behavior.

Risk Factors Associated with Progression to Abuse

- Mental health disorders (e.g., anxiety, depression, mood disorders, schizophrenia, psychosis)
- Tobacco use
- Past or current substance abuse
- Concurrent drug use (e.g., benzodiazepines, antidepressants, hypnotics, muscle relaxants)
- Past or current alcohol abuse
- Socioeconomic status
Ensure That EHRS Can Collect and Access the Data Elements Needed to Support Measures and Drive CDS

Rationale: Collecting, accessing, and incorporating computable data elements to inform safer prescribing will enable the use of data elements for measure calculation and CDS use (in computable format).  

As clinicians and healthcare organizations work to address the opioid epidemic, they are turning to health IT for assistance. Of the 269 opioid safety events reviewed, 28% of the time the safeguard did not function as expected (see CDS Safeguard Functional Status). The reasons for such failures are multi-factorial. For example, the CDS intervention may not have fired because the needed data were unavailable in a computable format to trigger the CDS, the information may lack the ability to be aggregated to trigger a safeguard, or coding sets as selected and used may not have supported accurate and effective CDS use.

Much of the information needed to drive opioid-prescribing CDS is currently captured in the EHR; however, the EHR system’s ability to implement CDS is limited if the needed data are unavailable in a standardized, computable format. Additionally, if a rule or algorithm is unavailable to trigger a CDS intervention, such interventions cannot occur. Further complicating the ability to implement some types of opioid-related quality measures and CDS is that some needed data elements are stored outside of the EHR and may not be readily accessible to the user. These outside storages include—

- Calculators. MME calculators may be located outside of the EHR and require manual entry to perform the calculation. In addition, accurate MME calculation requires up-to-date data from multiple sources, including EHRs, patient records from other clinicians, PDMP data, pharmacy data, and insurance information.  

- PDMP databases. PDMPs are state-established and regulated, with specific limitations that may prohibit the EHR from retaining information returned from queries to the PDMP. More generally, integration of EHRs and PDMPs is limited and uneven. As a result, the information contained in the PDMP may not be universally available for measures or to trigger CDS interventions.

The integration of this widely distributed opioid-prescribing information will require the cooperation of federal and state governments and the clinician, payer, and health IT communities, and in some cases legislative changes (e.g., state laws).

Therefore, this workgroup proposes that EHR vendors, as an industry and working with key stakeholders, facilitate the integration, aggregation, and correlation of data elements from within the EHR and the multiple external sources. The goal of this recommendation is to ensure that EHRS can collect or access the data elements needed to drive metrics to monitor and improve quality and to inform decision support. Its successful implementation will require collaboration between EHR vendors, content developers, and policy makers; accessibility, standardization and enhancement of state PDMPs, and the development of safe practices and standards for the EHR vendor community to design solutions and for clinicians and healthcare organizations to implement the solutions.

This recommendation is foundational; the other recommendations presented here would be much harder to implement without identified computable data elements. It is also the most challenging, given issues of organizational policy, state laws, and lack of consistent implementation of standards and normalization of data.

One basic requirement for the collection of data elements to drive metrics is to more widely implement the use of standard nomenclatures, such as SNOMED-CT, LOINC®, ICD, CPT, RxNorm®, and NDC, which would allow the aggregation and normalization of data. Structured data captured or mapped for use based on agreed-upon standard nomenclatures used in a standardized fashion allows computable data elements to be captured and calculated for the identified measures and CDS.

Another strategy for using data elements to implement opioid-related CDS is to implement the CDS Hooks standard for external CDS, based on prescribing guidelines specific to both opioid-naïve and opioid-exposed patients. The use of external CDS content, accessed by the EHR via CDS Hooks, will enable rapid updates, easy accessibility, scalability, and uniformity of CDS to inform safer opioid prescribing.

It remains important that CDS is not seen as interruptive, but rather that the information is provided at the appropriate time within the workflow. As such, it is
Ensure That Opioid-Prescribing CDS Interventions Are Delivered at the Right Time in the Workflow for Both Opioid-Naïve and Opioid-Exposed Patients

**Rationale:** Providing CDS intervention at the right time in the workflow will enable safer and more effective opioid prescribing. CDS at the right time will facilitate effective use of CDS functions. Limiting repetitive CDS will reduce physicians’ burden (e.g., by eliminating unnecessary interruptions in the clinical workflow and minimizing alert fatigue).\(^{35,65}\)

For CDS to be effective, it must be delivered as needed. As seen in the 269 safety events reviewed for this project, 41% of the time the CDS interventions were not acknowledged or were bypassed. This finding parallels that of a 2017 study, which indicated that 75% of alerts were overridden, and that 40% of them were inappropriate. When health IT is inserted without careful consideration of its placement in the clinical workflow, this tool can place an increasingly significant burden on clinicians.\(^{51}\) The presentation of the right information to the right person at the right time in the clinical workflow can maximize the benefits of CDS to enable safer opioid prescribing only so long as the information provided is correct, timely, and relevant (Figure 7).

This final recommendation is intended to leverage CDS timing. CDS interventions should be triggered using information gathered from disparate sources (e.g., demographics, medication history, comorbidities) to identify opioid-naïve and opioid-exposed patients more effectively and to identify their risk factors to the clinician at the appropriate time in the workflow.\(^{33,34}\) For example, an alert triggered preoperatively—prior to prescribing a patient’s postsurgical pain management—that informs the clinician the patient has no documented history of taking an opioid or has an active order for a benzodiazepine would indicate caution when prescribing opioids for this patient.

When this information is presented to the clinician at the optimal time in the workflow, it becomes less likely that the alert will be overridden, as is too often the case with generic CDS.\(^{40}\) Presently, much knowledge-based CDS becomes available all at once rather than at the optimal place in the clinical workflow and is also not tailored to the user or to the individual patient. Information presented by CDS must be in a format that is actionable, and CDS interventions should be triggered based on criticality using risk scores supported by EHRs that facilitate the integration of medication history, problem list, PDMP data, cumulative MMEs, and evidence-based guidelines.\(^{40}\)

Providing CDS at various, appropriate points in the clinical workflow based on the patient profile—rather than solely at the point of prescribing—would allow for a more holistic approach to pain management and an opportunity for targeted education for both the clinician and the patient.

**Figure 7. Clinical Workflow**
Triggering CDS at the appropriate time in the workflow should be based on data such as patient-level predictors that predispose a patient’s progression to persistent opioid use. These various risks have been identified in the literature.\(^{52-56}\) Creating and using triggers based on such risk factors will reduce over-alerting, thereby reducing alert fatigue. Patient risk factors include the following:

- Mental health disorders (e.g., anxiety, depression, mood disorders, schizophrenia, psychosis)
- Tobacco use
- Past or current substance abuse
- Concurrent drug use (e.g., benzodiazepines, antidepressants, hypnotics, muscle relaxants)
- Past or current alcohol abuse
- Socioeconomic status

The workgroup found that data on such risk factors and other clinical factors and patient characteristics are needed to fuel predictive and prescriptive analytics and enable valid and reliable risk-factor calculation. Such analytics and risk estimates can be used to prevent unintended consequences for both opioid-naïve and opioid-exposed patients, most notably persistent use or unintentional overdose.

At the time of this report, there were no standard risk calculations. There is, however, promising research being done in this area; although results are encouraging, robust correlation of the aggregate data with patient risk will require further research and development.\(^{33,66,67}\) Although patient-level database risk assessment tools are available, clinicians may not want to rely solely on these tools because of their identified inconsistencies and lack of validation.\(^{68}\)

Overall, it is important that clinicians can use workflow-appropriate CDS, along with prescriptive analytics, accumulated risk scores, and opioid risk tools. Thus, health IT needs to be able to seamlessly integrate and incorporate the necessary data elements from outside sources with the data captured within the EHR.

### Summary Learnings and Relevant External Developments

Between 3% and 10% of opioid-naïve patients prescribed opioids progress to persistent opioid use with the potential for use or dependence.\(^{69}\) Although it is unknown exactly how clinicians’ opioid-prescribing habits are related to rates of subsequent misuse,\(^{69}\) a few studies suggest parameters for how long or at what dosage opioids can be prescribed for opioid-naïve patients without inadvertently leading to undesirable long-term use.\(^{70}\)

The scope of this current project was refined to target the opioid-naïve and opioid-exposed populations (rather than chronic pain and opioid-tolerant or opioid-dependent patients) with the goal of preventing opioid dependence in the first place. The workgroup’s intent was to craft recommendations that are site neutral, although ambulatory care is clearly at a critical locus to stem the tide of the opioid problem.

Fundamentally, improving patient safety through health IT is a shared responsibility. Although EHR and content developers can create tools and improve CDS, the realized value of these offerings also depends on decisions and actions of regulators, scientific and professional organizations (e.g., developers of practice guidelines), measure developers, content providers, health care organizations, and clinicians.

Reflecting the urgency of the opioid crisis, Congress passed legislation targeting this multifaceted problem. This bill was signed into law October 24, 2018, as the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act, P.L. 115-271. Health IT has a notable role, including opioid quality-measurement and prescribing guidelines that can drive CDS.\(^{71}\)

The SUPPORT Act also seeks to expand use of EPCS under Medicare Part D and to strengthen PDMPs, including integration into EHRs, interoperability, and standardized data and reporting formats. Wider use of EPCS and PDMPs will enhance the feasibility and usefulness of the recommendations in this report that focus on measurement and CDS, ensuring that relevant opioid-prescribing data and workflows are available for prescribers and their health IT.
This new law also has provisions to review and develop new quality measures for opioids and opioid use disorders, with a demonstration project that includes rewards for measure performance. It also calls on the U.S. Secretary of Health and Human Services to publish and periodically update opioid-prescribing guidance applicable to Medicare beneficiaries and requires the U.S. Food and Drug Administration to develop evidence-based opioid analgesic prescribing guidelines for acute pain, where they do not exist. Emphasizing such guidelines, the SUPPORT Act also requires the Secretary to annually notify outlier opioid prescribers (for their specialty and geographic area), including performance against prescribing guidelines like those from CDC.

The importance of health IT in addressing the opioid crisis is also recognized by CMS. In the agency’s 2019 Final Rules, which include updates to the inpatient Promoting Interoperability (PI) initiative and ambulatory Merit-based Incentive Payment System (MIPS) programs, CMS created new performance measures for querying a PDMP prior to prescribing any opioids and determining the presence of an opioid treatment agreement for patients receiving chronic opioid treatment.

Looking to the Future

Health IT can play a vital role in mitigating safety issues, including those associated with opioid prescribing. The safe practice recommendations from this workgroup sponsored by the EHRA and ECRI Institute are intended to provide guidance and assist with the efficient and effective use of CDS to inform opioid prescribing and to incorporate internal and external measurements to prevent either opioid-naïve or opioid-exposed patients from moving towards persistent use and abuse or unintentional overdose.

EHRA and ECRI Institute encourage developers to implement the recommendations in this report. These recommendations are derived from data, evidence in the literature, shared learnings, and collaboration with others—including content developers—that will facilitate safer prescribing of opioids for both opioid-naïve and opioid-exposed patients.

As a first priority, EHRA and ECRI Institute urge EHR developers to act on the following specifics drawn from the workgroup’s three high-level recommendations.

Priorities for Execution

For the recommendation to enable technologies to measure and monitor prescribing patterns to allow safer opioid prescribing

- Enable measurement and display of opioid prescribing for healthcare organizations and prescribers by—
  - Type of opioid
  - Dose
  - Location (e.g., practice site)
  - Diagnosis
  - Procedure

- Configured access to information at the organization level for—
  - Prescriber access to their own data
  - Prescriber access to aggregated peer data

- Seek to implement at least two available opioid-prescribing quality measures that have been endorsed by the National Quality Forum (NQF), reflecting user priorities and data already available in the EHR

- Measure and provide feedback on overrides of opioid-related CDS

For the recommendation to ensure that EHRs can collect and access the data elements needed to support measures and drive CDS

- Incorporate CDC opioid-prescribing guidelines into EHR templates and clinical decision support
- Add a structured and standardized measure of opioid risk into the EHR
- Establish data fields to track MMEs and enable population and display of this field, based on prescribing within the practice and externally obtained opioid-prescribing information, as available
For the recommendation to ensure that opioid-prescribing CDS interventions are delivered at the right time in the workflow for both opioid-naïve and opioid-exposed patients

- Implement opioid-prescribing CDS into EHR workflows, ensuring that the CDS is enabled and triggered at the appropriate places in the clinical workflow, based on industry best practices and client feedback
- As available and sufficiently mature, implement the CDS Hooks standard to enhance the ability to embed CDS in the clinical workflow

We anticipate that follow-up work will benefit from forthcoming AHRQ guidance on implementing provisions in the 21st Century Cures Act that extend PSO protections directly to health IT developers. Once implemented, this important legislative provision should expand the possibilities of additional collaborative projects such as this, to fulfill our shared goals of using health IT to enhance patient safety, opening up a broader set of data and evidence to this work.74
Safe Practice Recommendations for Safer Opioid Prescribing: Measures and Clinical Decision Support

References


Appendix A. Additional References


54. Stem the tide: addressing the opioid epidemic. Chicago (IL): American Hospital Association (AHA); 2017. 27 p. Also available: http://www.aha.org/opioidtoolkit.
Appendix B.
Measures and CDS for Safer Opioid Prescribing: A Literature Review
Executive Summary

The U.S. opioid epidemic continues to pose significant challenges for patients, families, clinicians, and public health policy. Opioids are responsible for an estimated 315,000 deaths (from 1999 to 2016) and have caused 115 deaths per day.¹ In 2017, the U.S. Department of Health and Human Services declared the opioid epidemic a public health crisis.² The total economic burden of opioid abuse in the United States has been estimated to be $78.5 billion per year.³

Although providing care for chronic opioid users is important, equally vital are efforts to prevent so-called opioid-naïve patients (patients with no history of opioid use) from developing regular opioid use, misuse, or abuse. However, much remains unclear regarding what role clinician prescribing habits play and what duration or dose of opioids may safely be prescribed without promoting long-term use.⁴,⁵

In 2013, ECRI Institute convened the Partnership for Health IT Patient Safety, and its component, single-topic-focused workgroups followed. For this subject, the Electronic Health Record Association (EHRA): Measures and Clinical Decision Support (CDS) for Safer Opioid Prescribing workgroup included members from the Healthcare Information and Management Systems Society (HIMSS) EHRA and the Partnership team. The project was oriented towards exploring methods to enable a synergistic cycle of performance measurement and identifying electronic health record (EHR)/health information technology (IT)–enabled approaches to support healthcare organizations’ ability to assess and measure opioid prescribing.

To inform workgroup efforts, a rapid literature review was performed to identify risk factors for development of persistent opioid use for opioid-naïve patients and determine the impact of measurement and registry-based interventions (e.g., benchmarking or prescription drug monitoring programs [PDMPs]). Specifically, we asked the following key questions:

1. What resources or tools exist for creating or improving CDS for appropriate opioid prescribing for both opioid-naïve and opioid-exposed patients?
2. What evidence exists that measuring particular variables (e.g., prescribing habits) improves appropriate opioid prescribing?
3. What risk factors are associated with progression to opioid abuse for opioid-naïve patients?

We searched the literature for studies published from January 2010 to June 2018 and identified 51 relevant studies.

For Key Question 1, only limited evidence (15 studies, all pre/post) evaluated the impact of resources or tools for CDS, as follows: changing EHR defaults (for pills dispensed, opioids prescribed, and alternatives to narcotics), alerts, new prescribing guidelines and electronic-tablet-based decision aids. Overall, existing evidence suggests these interventions can be effective for reducing inappropriate opioid prescribing, although for many studies, the benefit was modest. Future work should clarify which settings and parameters within which these interventions could be most effective without adversely affecting clinical workflow.

For Key Question 2, 16 articles described health IT–related measurement interventions: Two studies found that benchmarking prescription rates for emergency room (ER) physicians significantly reduced opioid prescription...
rates. In one study of eight ERs in the Ochsner clinic system, within one year of implementing this intervention, the number of sites prescribing at rates below the national benchmark increased from 25% to 100%. Future work is needed to determine whether these results are generalizable to other ERs or to other settings (e.g., ambulatory care).

Two systematic reviews and fourteen studies assessed the impact of PDMPs, which allow physicians to check whether patients have existing opioid prescriptions. Evidence was insufficient to determine whether PDMPs reduce fatal or nonfatal overdoses. However, evidence from three controlled studies suggests PDMPs are associated with reductions in opioid prescribing. In particular, a large controlled study including data from 24 states found that PDMP implementation was associated with a 33% reduction (from 5.5% to 3.7%) in prescription rates of schedule II opioids in the ambulatory setting.6

For Key Question 3, 20 studies assessed risk factors for development of long-term opioid use or abuse in opioid-naïve patients. A history of depression, alcohol or substance abuse, smoking, or pain disorder was associated with increased risk. Similarly, increased opioid use (e.g., filling a prescription, number of refills, and duration of regular use) was associated with progression to long-term use and abuse across all settings. Higher morphine milligram equivalents (MMEs) per dose increased risk, except for in surgical patients, where higher initial doses did not increase risk. Very limited evidence (from a single study) found that initiating opioid use with tramadol or a long-acting opioid instead of nalbuphine or schedule III or schedule IV opioid therapy increased risks of long-term use.

Awareness of these risk factors could serve many purposes, including the following:

- Allowing providers to address modifiable risk factors to reduce risk in opioid-naïve patients
- Facilitating alerts to physicians if patients are at higher risk when an opioid prescription is being considered
- Allowing for targeted monitoring of higher-risk opioid-naïve patients receiving opioids

Early identification of at-risk patients could promote more efficient deployment of prevention resources and potentially reduce the risks of long-term use or abuse.

Overall, this report identified a small, substantive evidence base suggesting health IT interventions can be effective for reducing opioid prescribing. Although evidence suggests that several interventions, including PDMPs and benchmarking prescribing rates, are associated with reductions in opioid prescribing, it remains unclear to what extent those reductions translate into important clinical outcomes such as reductions in opioid misuse, abuse, or overdoses. Notably, in one study, simply receiving an opioid prescription itself was associated with increased risk of long-term opioid use,7 suggesting that reduced prescribing could, in fact, have an impact. Going forward, further development of health IT interventions to reduce opioid prescribing represents one important strategy for decreasing long-term opioid abuse in opioid-naïve patients.
References


### Appendix C. Recommendation Table

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<th>Recommendation</th>
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<th>Implementation Strategies</th>
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<td>Using health information technology (IT) to measure internal and external metrics for prescribing patterns along with transparent utilization and performance can have a significant positive impact on provider prescribing practices.</td>
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<td>ii. By day</td>
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<td>c. Engagement with prescription drug monitoring program(s) (PDMPs)</td>
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<td>i. Where EHR integration is allowable, measure access</td>
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<td>d. Clinical decision support (CDS) overrides (e.g., rate of override by type of CDS)</td>
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<td>v. Order sets triggered by chief complaint (e.g., Systematized Nomenclature of Medicine - Clinical Terms [SNOMED-CT]), diagnosis codes (e.g., International Classification of Diseases [ICD] codes), or procedure codes (e.g., Current Procedural Terminology [CPT] codes)⁵-⁷</td>
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<td>2. For provider organizations (overall information for the organization)</td>
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<td>b. Prescription and medication orders stratified by procedure (CPT)⁵,⁷,¹⁰,¹²</td>
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<td>d. Use of electronic prescriptions for controlled substances (EPCS) in state and organization where it is not required</td>
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   i. Identify patients at risk  
   ii. Monitor adherence  

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| Ensure that electronic health records (EHRs) can collect and access the data elements needed to support measures and drive CDS | Collecting, accessing, and incorporating computable data elements to inform safer prescribing will enable the use of data elements for measure calculation and CDS use (in computable format).¹⁴ | 1. Dashboards  
2. Summary report format¹ |

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<td>Rationale</td>
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<td>Ensure that opioid-prescribing CDS interventions are delivered at the right time in the workflow for both opioid-naïve and opioid-exposed patients</td>
<td>Providing CDS intervention at the right time in the workflow will enable safer and more effective opioid prescribing. CDS at the right time will facilitate effective use of CDS functions. Limiting repetitive CDS will reduce physicians’ burden (e.g., by eliminating unnecessary interruptions in the clinical workflow and minimizing alert fatigue).</td>
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### Coordinate aggregate data

1. Using HL7® FHIR® (Fast Healthcare Interoperability Resources), APIs (application program interfaces), and HL7®v2 standards

   a. Trigger CDS based on:
      i. Risk factors
      ii. Calculated risk scores
      iii. Medication history
      iv. Prescription history
      v. PDMP information
      vi. Guidelines

   b. Trigger CDS for:
      i. Provider education
      ii. Prompting opioid treatment agreement
      iii. Patient education

   c. Consider using CDS hooks (cloud-based CDS enables rapid updates, easy accessibility, scalability, uniformity)

2. Standardization of the administrative features of the PDMP

3. Enable integration of—
   a. Historical prescriptions (e.g., Surescripts enabled)
   b. PDMP information
   c. Medication reconciliation
   d. Cumulative MMEs

4. Trigger CDS interventions based on criticality

   a. Associate with risk scores or other identified factors
   b. Present to the individual or individuals who are the decision makers
   c. Permit overrides of CDS based on clinical appropriateness, with documentation of the rationale for the override for higher risk scenarios

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