# Barriers, Facilitators, and Potential Solutions to Advancing Interoperable Clinical Decision Support: Multi-Stakeholder Consensus Recommendations for the Opioid Use Case

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## Abstract

*With the advent of interoperability standards such as FHIR, SMART, CDS Hooks, and CQL, interoperable clinical decision support (CDS) holds great promise for improving healthcare. In 2018, the Agency for Healthcare Research and Quality (AHRQ)-sponsored Patient-Centered CDS Learning Network (PCCDS LN) chartered a Technical Framework Working Group (TechFWG) to identify barriers, facilitators, and potential solutions for interoperable CDS, with a specific focus on addressing the opioid epidemic. Through an open, multi-stakeholder process that engaged 54 representatives from healthcare, industry, and academia, the TechFWG identified barriers in 6 categories: regulatory environment, data integration, scalability, business case, effective and useful CDS, and care planning and coordination. Facilitators and key recommendations were also identified for overcoming these barriers. The key insights were also extrapolated to CDS-facilitated care improvement outside of the specific opioid use case. If applied broadly, the recommendations should help advance the availability and impact of interoperable CDS delivered at scale.*

## Introduction

In 2018, while overall opioid prescribing appears to be on a downward trend, misuse of prescription opioids continues to remain fairly stable and opioid related deaths continue to rise.[1] Opioids are the second most commonly abused substance in the United States.[2] Of the significant efforts to curb this epidemic, one is the development and dissemination of opioid prescribing recommendations for chronic pain from the Centers for Disease Control and Prevention (CDC).[3] Part of the challenge in implementing change, however, is applying recommended practices in

routine clinical care. Clinical decision support (CDS) integrated with the electronic health record (EHR) and combined with staff- and patient- oriented strategies, can change clinician behavior and increase adherence to clinical guidelines, including prescribing[4], but CDS implementation, adoption, and use remains challenging.

While the United States healthcare system has widely adopted EHR technology, and while that adoption generally includes CDS, the overall development and utilization of effective CDS remains somewhat limited. Emerging standards such as the Health Level 7 International (HL7) Fast Healthcare Interoperability Resources (FHIR), CDS Hooks, and Clinical Quality Language (CQL) specifications are becoming increasingly well adopted by EHR vendors, providing a critical link to fully integrated CDS.[5] Requiring support for application programming interfaces (APIs) for enhancing data portability and third-party application integration is also an important facilitator of CDS integration. Interoperable CDS may potentially finally unlock the benefits of converting to electronic records, particularly when patients are engaged through patient-centered CDS.

Despite the promise of widespread care improvement facilitated by interoperable CDS, the reality is that this promise remains a vision for healthcare in general. There are emerging efforts to address this challenge in multiple domains including the opioid epidemic. However, much more needs to be learned on how best to leverage interoperable CDS to improve care widely.

In 2015, the Patient-Centered CDS Learning Network (PCCDS LN) was established to improve collective learning of patient-centered CDS by the Agency for Healthcare Research and Quality (AHRQ).[6] In 2018, the PCCDS LN focused on the opioid epidemic as an important care domain for identifying how best to leverage patient-centered CDS to improve patient care. To do so, two Working Groups were chartered: an Opioid Action Plan Working Group (OAPWG) and a Technical Framework Working Group (TechFWG). The primary goal of the OAPWG was to develop a plan for patient-centered CDS applied broadly and effectively to improve pain management and opioid use. One work product of the OAPWG was the development of highly desirable, consensus patient-centered CDS-enabled future state vision scenarios for patient-centered CDS-enabled pain management/opioid use.[7]

Led by K. Kawamoto and L. Marcial, the primary goal of the TechFWG was to review this future state vision through the lens of CDS implementation and identify the current state, barriers, what resources are available, and recommendations for moving forward. This Task Force was also charged with identifying implications that can be moved forward beyond opioids. Efforts of the TechFWG focused on applying patient-centered CDS in health care delivery and the needs of the healthcare team including the prescribing clinician, with some thinking around the patient perspective. Key considerations of the opioid use case context included:

1. The need for complete and accurate understanding of past, current, and potentially most beneficial treatments in making pain treatment decisions.
2. The ability to quickly and accurately assess opioid-related risks (e.g., OUD, overdose, misuse/abuse).
3. The call to better integrate, synthesize, and interpret information in PDMP reports and other urine drug screen results.
4. To more efficiently and effectively identify trends in relevant patient outcomes over time (e.g., pain, physical function, co-morbid mental health)

Here, we describe the findings from the PCCDS LN TechFWG which encompass barriers, facilitators, implications and recommended actions for advancing patient-centered CDS to address the opioid epidemic.

## Methods

*Subject matter expert (SME) recruitment.* Participation in the TechFWG by SMEs was voluntary. Calls for participation were sent via email to the PCCDS LN mailing list and to the list serves of the HL7 CDS Work Group, HL7 Clinical Quality Improvement (CQI) Work Group, American Medical Informatics Association (AMIA) CDS Work Group, and AMIA Implementation Work Group. Interested parties were asked to complete an online form with basic demographic information, availability, and interest in serving on the TechFWG.

*TechFWG goals and charter*. The TechFWG was chartered to address four goals: 1) Facilitate shared decision-making tools delivered via CDS, 2)Discuss opportunities and barriers presented by technologies and standards such as SMART on FHIR and CDS Hooks, 3) Identify gaps in needed standards and their adoption, and 4) Produce a whitepaper and/or manuscript on barriers and facilitators.

*TechFWG deliberations.* A total of 8 web conference calls were held biweekly between June 11, 2018 and October 1, 2018. All participants were asked to contribute both during and between meetings and to volunteer to present work of their own to the broader group on CDS-related initiatives. Final report-out and vetting of the recommendations occurred during the PCCDS LN Annual Conference on October 15, 2018 in both a general session as a briefing and a breakout session to solicit additional input.

*TechFWG composition.* The TechFWG included stakeholders from various disciplines. The TechFWG members who contributed in at least 4 of the 8 calls or otherwise made substantial contributions to the final deliverables were invited to participate as co-authors of this manuscript.

*Deliverables.* The deliverables of the TechFWG, and the focus of its activities, consisted of 1) the identification of barriers, facilitators, and required actions to enable effective patient-centered CDS for pain management as envisioned by the OAPWG. Identified barriers were grouped into categories through group consensus, 2) Insights on these barriers, facilitators, and required actions for effective patient-centered CDS in general, extrapolated from these issues identified in the pain management use case, and 3) A summary of the findings and recommendations and its dissemination. This manuscript presents results of the TechFWG deliberations in terms of these deliverables.

## Results

*Membership and participation:* A total of 54 subject matter experts (SMEs) volunteered to serve on the TechFWG. Participation averaged about 20 members per biweekly call, and 20 members contributed to at least 4 of the 8 calls or otherwise made substantial contributions to the TechFWG deliverables including this manuscript. Of these 20 members, 7 were affiliated with academic institutions, 4 with consulting firms, 3 with government, 3 with research organizations, 2 with EHR vendors, and 1 with a health system (many participants had overlapping roles).

*Barriers, Facilitators, and Needed Actions for Advancing PCCDS for Pain Management:* The TechFWG members identified key barriers in six categories: (1) regulatory environment, (2) data integration, (3) scalability, (4) business case, (5) effective and useful CDS, and (6) care planning and coordination. These are detailed in Table 1 and summarized below (additional details available

from the PCCDS Learning Network[9]). Based on the findings from the specific use case of pain management, key generalizable insights were extrapolated. These generalizable insights and recommendations are summarized in Table 2.

Regulatory environment: Key identified barriers in the regulatory environment include differences in state-level regulations on the allowed use of prescription drug monitoring program (PDMP) data and allowed prescribing of controlled substances. Important identified facilitators in this area included initiatives that connect PDMPs across states as well as state regulations requiring e-prescribing of controlled substances. *Needed Actions:* In terms of recommended actions, the TechFWG recommended unifying regulations according to the evidence base on a national level, encouraging voluntary coordination at the state level, and, at the local level, defining and sharing cohesive evidence-based guidelines that incorporate federal and state regulations.

Data integration: As a key challenge, methods for capturing source data, ensuring its quality and availability, specifying the data format, facilitating patient matching, reading relevant data from and writing data into records, and visualizing relevant data can be restrictive or limited. While these data issues are large, pervasive, and perhaps daunting barriers, the TechFWG felt that a facilitator included the fact that opioids are an important national concern with a defined scope, thereby enabling a directed conversation on how specific needed data can be aggregated and analyzed effectively. *Needed Actions:* In terms of recommendations, the TechFWG recommended improving data integration by defining data needs and interoperability requirements tied directly to their clinical application. At the federal level, this might include funding the development of a set of data needs for specific decision makers, a set of consolidated requirements specifications for interoperability, and research on visualization best practices to support clinicians and patient decision making. For providers and patients, we can facilitate improved data quality by giving patients access to update their own data. Vendors need opportunities to more fully test and verify architecture and standards for semantic interoperability in an iterative fashion.

Scalability: Assuming the needed data are available, tools to scale patient-centered CDS are still somewhat nascent and often require the additional step of localization. There is substantial promise in emerging repositories to support the availability of CDS artifacts. In addition, relevant standards and support of those standards continues to mature. *Needed Actions:* To facilitate improvements in scalability, the TechFWG identified the need for a national authoritative body that agrees on and promotes human readable and computer-interpretable guidelines and funds research on best implementation strategies for desired CDS. Professional societies continue to develop and provide clinical endorsement of guidelines, while also encouraging widespread adoption of an appropriate technical framework to support interoperable CDS based on these guidelines. Vendors can also provide support in the form of approaches to better centrally manage trusted CDS.

Establishing a clear business case and providing incentives: The return on investment for CDS has still not been clearly established and the incentives of today are not yet well aligned with the needs of patients and providers. The advent of value-based care initiatives may help provide some of the needed incentives to advance CDS. *Needed Actions:* Broadly, we must establish and promote the business case for CDS using incentives across stakeholder groups to improve patient care. CMS and other payers could help by incentivizing the achievement of quality goals and best practices through the use of CDS while also funding research to identify and mitigate unintended consequences. Federal and state entities can support and further incentivize the implementation of CDS solutions. The CDS ecosystem can leverage all of its stakeholders to find ways to improve the performance and reduce the cost of CDS.

**Table 1.** Key barriers, facilitators, and needed actions for enabling effective PCCDS for pain management

| Category | Barriers | Facilitators | Needed Actions |
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| Regulatory environment | •There are state-specific regulations on controlled substances, but many states prohibit incorporating the actual PDMP source data into the EHR and CDS.<br>•State-by-state regulations for prescribing limits and/or regulations restrict the ability to prescribe opioid antagonists and there may be limits or incentives for those that can be written electronically which subsequently limits associated CDS.<br>•Federal regulations and recommendations may not align with mechanisms to facilitate CDS implementation. | •Initiatives that link resources up help, e.g., PMP InterConnect, a product from the National Association of Board of Pharmacy that connects PDMPs from 44 states.<br>•In some states there is mandated e-prescribing of controlled substances, e.g., New York.<br>•The Promoting Interoperability program includes 2 opioid e-prescribing measures: query of PDMP (optional in CY 2019 and required in CY 2020) and verification of an opioid treatment agreement (optional for CY 2019 and CY 2020). | •Federal and state lawmakers can:<br>○ support the development of unified national-level regulations and encourage voluntary coordination among state medical boards. NOTE: In general, there is a relative lack of evidence underlying regulations and policy.<br>○ enable the sharing of source data, and mandate or encourage e-prescribing for controlled substances to further enable point-of-care CDS<br>○ create policies and regulations based on evidence and support collection of evidence where lacking |
| Data integration | •It is difficult to access all relevant data across multiple health systems, and health IT systems over time (e.g., medications, supplements, lab tests, imaging, referrals, care plan/controlled substance agreements, functional status, diagnoses and side effects).<br>•Source data may have poor data quality, are temporally limited, and are difficult to both patient-level match and to de-duplicate and may not be in a structured, standard form that facilitates matching, reconciliation, and de-duplication<br>•Existing data structures were created without semantic interoperability as the goal, bi-directional information exchange may not be well supported, e.g., no clear way for controlled substance agreements to be pushed out by a prescriber to other prescribers in a state.<br>•A lack of consensus on a 'data interoperability architecture' for universal use inhibits achieving greater overall interoperability.<br>•Visualizations to support interpretation are often limited and scales are subjective, e.g., pain scale.<br>•SMART and other interoperable apps/services may be important in this ecosystem for opioid use | •Opioid use and pain management, a national focus, may serve as a catalyst for CDS.<br>•There is a need to collect well-defined data for aggregation and summarization. The OpenNotes movement could be leveraged for data cleaning and reconciliation. Some patients and health systems are already engaged in Open Notes and it could be used for patients to review and clean data. Natural Language Processing can also be used to mine free text, e.g., for after-the-fact conversion to structured data or for facilitating real-time data entry.<br>•A dashboard for relevant data, e.g., pulling up first-line treatments that have already been tried.<br>•There are some semantic interoperability standards available and adopted for relevant data that could facilitate data integration and summarization:<br>•There are some semantic interoperability approaches/efforts that could be applied to help (e.g., Argonaut project, efforts at HIT Advisory Committee (HITAC) efforts to define priority healthcare uses and needed standards).<br>•Population health management tools | •Concrete interoperability requirements need to be defined for this space. Need to identify achievable goals with associated clinical needs. This applies equally to CDS/knowledge interoperability (see also Scalability).<br>•Federal government could fund the development of a consolidated requirements specification for interoperability.<br>•Data quality and de-duplication issues are still persistent. Need to enable patients to help in this de-duplication and data reconciliation process. Patient involvement will help ensure this is a patient-centered and patient-engaged process.<br>•Probably the missing link here is the available data in structured, semantically interoperable form. Once available, SMART should be useable for data summarization. There appears to be sufficient momentum through federal funding sources such as NIH, AHRQ, CDC in this area, as well as other non-grant resources.<br>•Architecture and standards for semantically interoperable data are still not available, adopted, or verifiable to the extent needed.<br>•Terminology standards and resources are needed for relevant concepts. |

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| | management, but they have limited abilities to contribute data back in/write due to API limitations. | | |
| Establishing a clear business case and providing incentives | •The current system as it exists is generally a reflection of the current business incentives. In other words, the system we have now is optimized for the incentives we have now.<br>•Cost of implementing desired solutions can be an important barrier. There needs to be a financial ROI case for the needed CDS and other HIT solutions, but such ROI information may not be clear or even available. | •Change is happening in terms of overall incentives to incorporate CDS and improve quality:<br>o Value-based care should result in an incentive shift toward care that is better for opioid use and desired actions for opioid management.<br>o Pharma incentives to be seen as helping with this issue<br>o Providers are motivated to avoid regulation-related, penalties, lawsuits, maintain licensure, etc.<br>o Many state medical boards are starting to put in opioid related requirements | •Incentives are still limited/do not support improving pain management and opioid management. CMS is important, but private payors are also getting actively engaged in this area. We need quality measures around what is desired.<br>•One potentially promising approach would be coming up with best practice recommendations that can be adopted by state medical boards and supported by technology.<br>•Need payments for desired outcomes and potentially use of appropriate CDS tools (processes), including extra time required by clinicians for optimized patient care. |
| Effective and Useful CDS | •What makes CDS effective is still not adequately defined and CDS interventions still often fail to achieve the desired outcomes.<br>•The effectiveness of the vast majority of CDS interventions is never actually measured and it is unclear whether CDS interventions that are effective in one setting or clinical area would be useful in another setting or clinical area. Effectiveness of CDS may not be seen unless or until it exists at scale.<br>•CDS platforms, whether standards-based or EHR vendor-based, may have many limitations to effectiveness. | •There are a number of CDS best practice approaches published already.<br>•There are also guides on IT usability that address issues such as access, uptake, adherence, and effectiveness, e.g., the ONC EHR usability change package.<br>•Behavioral nudges have been shown to be important and may be fairly easy to scale for impact, e.g., the default number of opioid prescriptions dispensed.<br>•There are a number of guidelines available to serve as the basis for CDS. | •There is a need to continue to advance research to identify factors that contribute to CDS effectiveness and improve reporting of CDS intervention results.<br>•Users of CDS platforms could help define desired/needed enhancements and join together in asking for those enhancements to be made. Incentives to develop more effective CDS are needed.<br>•Sharing of CDS and good examples of effective CDS could allow for higher-quality CDS.<br>•There is a lack of agreement on documentation templates/expectations in this space, an authoritative body should step forward to develop consensus on this. |
| Scaling CDS | •Scalable clinical decision support and knowledge sharing, whether via shared knowledge artifacts, or applications, or as services, is currently in its infancy. Common interoperability architecture also needs to be defined and adopted, e.g., SMART on FHIR, CDS Hooks.<br>•There are local factors that need to be accounted for such as: business needs, practice settings, clinician types, patient populations, workflow approaches, documentation templates, and local resources. | •There are a few computer-interpretable guideline repositories.<br>•There is a white paper on how to establish trust in this ecosystem.[8]<br>•Some hybrid approaches exist where the "hard part" of guideline development is shared inter-institutionally, and each organization can adapt it to the local environment.<br>•Standard value sets, such as those from the National Library of Medicine's Value Set Authority Center. | •Trust requirements are needed, especially for centrally managed CDS.<br>•It may be useful to prioritize across domains to help ensure content quality e.g. the overall medication list, to consolidate guidelines whenever possible, and to better engage patients. |

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| Care Planning and Coordination | •There is a need for strong communication and shared mental models of care plans across organizations and providers, as well as between patients and their caregivers. Communication and information sharing among these providers can be suboptimal.<br>•Care plans are rarely synchronized while they evolve over time and are touched or updated by various stakeholders across organizational boundaries. | •Opioid use, a big enough, well recognized problem, may incentivize competing organizations to agree on common approaches to treatment and better coordination and cooperation.<br>•There is some ongoing HIE, TEFCA, etc. work on care planning and coordination, e.g., IHE models on dynamic care plans, with somewhat limited implementation. | •There is a need for demonstration projects funded by government, payors, to investigate how pay-for-value-incented providers can improve intra- and inter-institutional care planning.<br>•There is a need for more research around creating understandable and technically portable care plans for patients, and for more dynamic care planning. |

**Table 2.** Derived insights for advancing PCCDS in general

| Category | Barriers | Facilitators | Needed Actions |
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| Regulatory environment | It is challenging to harmonize across different regulatory domains and keep CDS information up to date. | Need accessible systems that link up regulatory resources and to maintain and update these centrally. | Governmental support of central management and use of source systems and data, including EBM and regulatory information, can buoy the data that underlies CDS. |
| Data integration | We rarely collect disparate source data with a fully integrated end in mind resulting in incomplete, missing, or incorrect data, limiting the effectiveness of CDS. | Various semantic interoperability standards and approaches can be used to improve the quality of source data and patients can assist with this. | Need a unifying interoperability specification to facilitate high-quality data collection informed by patient feedback. |
| Establishing a clear business case for CDS | The bulk of the challenge in establishing the ROI for CDS results from the current incentive system and the cost of implementing CDS. | Merit-based incentives and greater interoperability will help catalyze CDS integration. | Linking merit-based payments to quality measures, desired outcomes, the use of evidence-based practices, and/or the integration of CDS systems will establish a clear ROI for using CDS. |
| Effective and Useful CDS | CDS effectiveness remains poorly understood and implementations still suffer from usability (alert fatigue), adoption and information quality (trustworthiness) issues. | CDS best practices, usability best practices, quality guidelines, and behavioral nudges, are effective tools to support CDS implementations. | Engaging users in the specification, design, and implementation of CDS systems, creating publicly shareable success stories, and conducting research on factors that contribute to CDS efficacy and dissemination of CDS success stories can improve CDS implementations. |
| Scaling CDS | There is no common interoperability architecture to support the scalability of CDS. | Shareable repositories of CDS artifacts, guidelines, and standard value sets will improve CDS implementation at scale. | Emerging efforts to address trust for shared CDS will help support the expanded use of shareable CDS. |
| Care Planning and Coordination | The current environment does not support dynamic, multi-stakeholder, multi-environment care planning and coordination. | Need dynamic care plans and better engagement of the patient in the care planning process. | Need demonstration and research projects to focus on dynamic care planning (inter and intra-institutional) in the merit-based incentive context. |

Effective and useful CDS: Making effective CDS both generally and specifically for opioids requires more insights. However, there is significant knowledge regarding CDS and usability best practice approaches. In addition, there is some evidence that simple behavioral nudges may also be effective. *Needed Actions:* The key is to identify and promulgate CDS successes and the factors that ensure success. To improve our insights into effective CDS, government should continue to fund research and researchers should continue looking for the most effective approaches to improving care using CDS. Increasingly, these efforts should engage users to provide the necessary input to ensure that CDS platforms meet user-centered design goals and vendors should help identify effective CDS and best practices and share these broadly.

Care planning and coordination: The complexity of patient care requires a shared understanding of the care planning process, including any integrated data available, among all members of the care team. The scale and impact of the opioid epidemic alone could help catalyze agreement on common approaches to coordination and treatment. *Needed Actions:* To mitigate this complexity, we need to develop an approach to cross-institutional care planning to better facilitate coordination. National-level funding for cross-institution demonstration projects and opportunities to incentivize value-based care will help. Researchers need to be encouraged to develop a body of evidence to guide the dynamic care planning process. We need relevant standards to help develop, pilot, and refine approaches to care planning and coordination.

**Discussion**

*Summary of Findings.* In 2018, the AHRQ PCCDS LN convened the TechFWG with the goal of identifying technical barriers to patient-centered CDS, with a particular focus on pain management. The TechFWG recruited 54 members, of which 21 members contributed substantially. Through 8 virtual meetings and 1 face-to-face meeting, the TechFWG members started with a vision for patient-centered CDS for pain management as defined by the PCCDS LN Opioid Action Plan TechFWG, then identified the barriers to realizing this vision at this time due to technical and related barriers. The core barriers were in the areas of 1) regulatory environment, 2) data integration, 3) scalability, 4) business case, 5) effective and useful CDS, and 6) care planning and coordination. Facilitators available for these barriers were identified, and recommendations were formulated for needed actions to address these barriers. When distilled into generalizable recommendations independent of the specific use case of pain management, the main recommendations from this work were as follows:

- Advocate to address conflict and overlap between federal, state, and local regulations.
- Define data needs and interoperability requirements with achievable goals tied more directly to clinical needs.
- Reach agreement on a vision of CDS at scale and develop specifications and implementations to reach this goal.
- Establish and promote the business case for CDS by incentivizing and educating stakeholder groups.
- Identify and broadly disseminate CDS success stories and related factors.
- Develop a standards-based approach to cross-institutional care planning to facilitate care coordination.

*Strengths and Limitations*. An important strength of this work was that by looking at the opioid use case in particular, the domain was specific enough to think through the implications at a good level of detail while the impact is broad enough (national-level) to facilitate generalization beyond

this domain. A second strength is that we successfully convened a broad group of subject matter experts with insights and expertise in key domains, including standards-based interoperability, opioid and pain management CDS, and industry perspectives. Finally, a third strength is that the specific domain chosen is a critical one facing the nation, such that the insights and recommendations provided could have near-term impact on an important societal problem. With regard to limitations, one limitation is that the deliberations were based on a specific domain. Thus, it is possible that the barriers and associated recommendations are incomplete. However, many of the TechFWG members had broad experience in CDS in general, and the TechFWG explicitly sought to identify generalizable findings from their deliberations. Finally, as another related limitation, the focus on the pain management domain may have resulted in the inclusion of barriers that may not be as relevant in other patient-centered CDS use cases, such as regulatory barriers to data integration.

*Future Directions.* As the next step in this work, the PCCDS LN will be convening a Patient-facing CDS Demonstration Working Group (PFWG) which will seek to advance important components of the recommended actions developed in this work. The PFWG will tackle the patient-facing perspective of CDS and consider both design and technical factors that ease or inhibit the development of patient-centered CDS applications. The goals of the PFWG will be to actually convert an existing provider-facing SMART on FHIR CDS application based on the CDC guideline for morphine milligram equivalent dosing to a patient-facing application which can be directly accessed by patients, whether through the Web or a smartphone. In tandem with this technical development, the PFWG will also develop a set of human-centered usability design guidelines for patient-facing patient-centered CDS applications. This work will culminate in a set of recommendations for actionable steps that interested stakeholders could take to advance patient-centered CDS applications from prototype to use by patients, caregivers, and direct care clinicians.

CDS holds significant potential for improving the delivery of high-quality, patient-centered care, including for critical societal barriers such as the opioid epidemic. The findings from the PCCDS LN TechFWG could prioritize the needed actions for advancing patient-centered CDS to tackle these important barriers.

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