Implementation, Adoption, and Scaling Workgroup: Exploring Challenges and Opportunities for Patient Engagement, Implementation, Adoption, and Scaling Through PC CDS Case Studies

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PURPOSE

The Clinical Decision Support (CDS) Innovation Collaborative (CDSiC) Implementation, Adoption, and Scaling Workgroup is charged with advancing the adoption and use of safe and effective patient-centered clinical decision support (PC CDS) by identifying barriers, opportunities, and resources to achieving PC CDS at scale. The Workgroup comprises 16 experts and stakeholders representing diverse perspectives related to CDS. This report is intended for use by PC CDS implementers. The report explores challenges, solutions, and areas for future research across four domains: patient engagement, implementation, adoption, and scaling. All qualitative research activities conducted by the CDSiC are reviewed by the NORC at the University of Chicago Institutional Review Board (FWA00000142).

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Executive Summary

Patient-centered clinical decision support (PC CDS) encompasses a spectrum of decision making tools that significantly incorporate patient-centered factors related to knowledge, data, delivery, and use. Throughout the PC CDS lifecycle, myriad challenges exist to realizing the benefits of PC CDS, including patient engagement, implementation, adoption, and scaling efforts. Each challenge requires careful consideration and tailored solutions to ensure successful deployment and utilization of PC CDS.

The Agency for Healthcare Research and Quality (AHRQ) has funded several projects focused on PC CDS to gain valuable insights into addressing challenges and implementing effective PC CDS solutions. These projects span various clinical areas, including chronic disease management, medication safety, and preventive care. This report aggregates the insights from nine AHRQ-funded PC CDS projects and provides practical guidance for implementers across four domains: patient engagement, implementation, adoption, and scaling.

Key Findings

- **Patient Engagement.** Projects highlighted the importance of engaging diverse patient populations in the design and development of PC CDS, emphasizing inclusivity and relevance, to solicit patient feedback effectively. Challenges in this domain included difficulties in engaging underrepresented communities and individuals with varying levels of health and digital literacy. Strategies include providing incentives for engagement, involving information technology (IT) and usability experts in codesign, preparing patients for engagement activities, and developing PC CDS that tailor to varying levels of digital health literacy.
- **Implementation.** Data interoperability emerged as a key challenge that projects experienced in PC CDS implementation. Solutions include enhancing data interoperability standards, expanding IT resource capacity and knowledge, and evaluating data quality to ensure accurate and reliable decision support. These strategies highlight the need for expertise in informatics and interoperability standards, underscoring the necessity for robust data infrastructure and skilled IT resources.
- **Adoption.** Adoption hurdles center around enhancing the utility of PC CDS, clinician acceptance, and ensuring adequate clinician resources for successful integration into clinical workflows. Challenges in guideline translation and integration into clinical workflows are addressed through strategies to enhance PC CDS utility and improve clinician readiness to use PC CDS. Usability and design enhancements aim to make PC CDS more user-friendly and better integrated into clinician workflows and patient lifeflows.
- **Scaling.** Scaling PC CDS across different settings requires addressing implementation barriers and cost considerations. Enhancing generalizability, addressing electronic health record (EHR) limitations, and exploring cost-effective deployment options are recommended to facilitate wider adoption and scalability.

Recommendations for Future Work

The AHRQ-funded projects also identified recommendations for addressing long-standing challenges of PC CDS implementation to guide future research. These recommendations include:

- Diversifying recruitment methods and refining feedback mechanisms to ensure representation across diverse patient populations in PC CDS research and implementation.
- Enhancing data interoperability standards, expanding and optimizing IT resource capacity, and investing in data quality review of PC CDS logic inputs.
- Improving PC CDS utility and functionality for both patients and clinicians.
- Addressing EHR limitations and exploring cost-effective deployment options.

Conclusion. This report offers practical insights and recommendations for implementing and scaling PC CDS. By addressing challenges in patient engagement, data interoperability, and user acceptance, PC CDS stakeholders can accelerate the integration of PC CDS into clinical practice, ultimately improving patient outcomes and enhancing the delivery of patient-centered care. By implementing the suggested solutions and recommendations outlined in this report, stakeholders can harness the full potential of PC CDS to improve patient outcomes and enhance the quality of healthcare delivery.

1. Introduction

Patient-centered clinical decision support (PC CDS) encompasses a spectrum of decision making tools that significantly incorporate patient-centered factors related to knowledge, data, delivery, and use. [2] Knowledge refers to the use of comparative effectiveness research or patient-centered outcomes research (PCOR) findings. Data focuses on the incorporation of patient-generated health data, patient preferences, social determinants of health, and other patient-specific information. Delivery refers to directly engaging patients and/or caregivers across different settings. Finally, use focuses on facilitating bi-directional information exchange in support of patient-centered care, including shared decision making.

Who Can Receive PC CDS Recommendations?

PC CDS can be patient-facing, clinician-facing, or both. Patient-facing PC CDS can be delivered in a range of ways including via mobile phone apps, text messages, and patient portals.[1] Clinician-facing PC CDS is traditionally provided through the EHR interface. Some PC CDS tools may deliver guidance directly to both patients and clinicians.

Patient-centered outcomes researchers, PC CDS and electronic health record (EHR) developers, and healthcare implementers of PC CDS encounter challenges in real-world settings throughout the PC CDS lifecycle.[3] These challenges span various phases, including development, implementation, and integration with clinical workflows and patient lifeflows. Issues related to data interoperability, clinician and patient user acceptance, integration with existing health information technology (IT) systems, and ensuring privacy and security of patient data are common hurdles previously reported by PC CDS implementers.[4] Furthermore, effectively engaging patients and caregivers throughout the process poses its own set of challenges, including designing user-friendly interfaces, addressing health literacy, and meeting diverse patient needs and preferences.[2]

Previous implementation experiences offer valuable lessons for the PC CDS community regarding challenges they may encounter in the PC CDS lifecycle, solutions to address these challenges, and future work. By aggregating and analyzing common challenges, along with corresponding solutions and opportunities for future work, this report aims to provide insights for future PC CDS implementations. These insights not only anticipate potential hurdles but also offer tested strategies to address implementation barriers, foster adoption, and scale PC CDS effectively. Through continuous refinement and innovation, PC CDS can reach its full potential in improving patient outcomes and experiences.

1.1 What Does this Case Study Report Cover?

This case study report aggregates the insights from nine AHRQ-funded PC CDS projects about their challenges and solutions for implementing, adopting, and scaling PC CDS. By doing so, this report provides practical guidance to aid PC CDS implementers in overcoming common challenges.

In the following sections, this report describes the methods to collect information about and from the projects (Section 2), presents challenges encountered by the case study projects, and suggests approaches for addressing the challenges (Section 3). Finally, the report outlines recommendations for future work to support patient engagement, implementation, adoption, and scaling of PC CDS (Section 4).

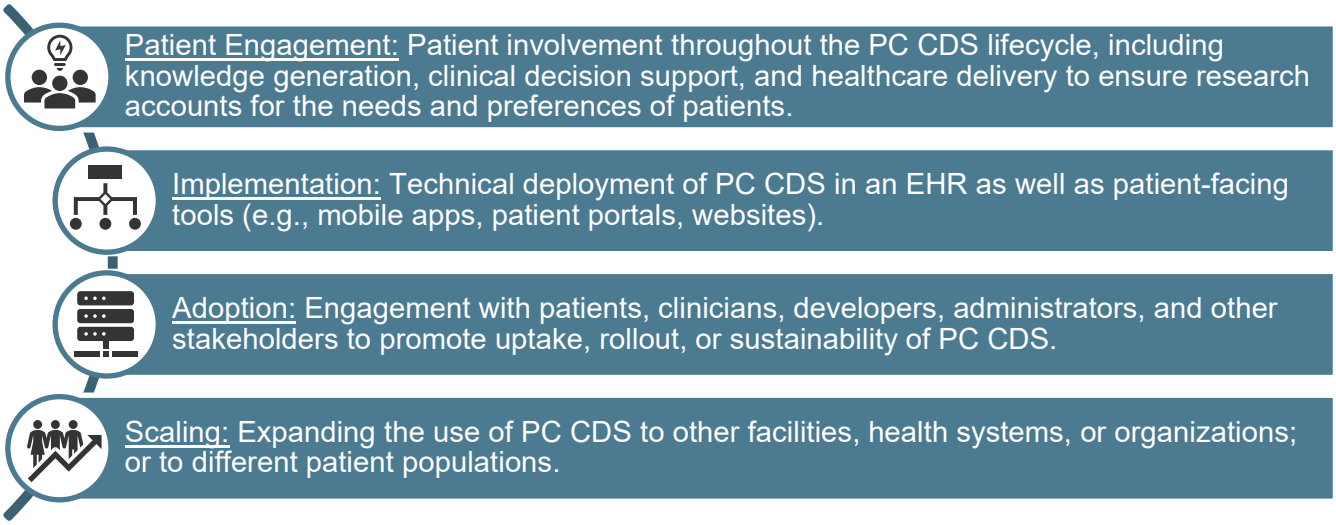
2. Methods

This case study report draws from the experiences of nine PC CDS implementation case studies developed from a purposive sample of completed or current AHRQ-funded research projects. Below, we describe the domains we used as our organizing framework for the case studies and our processes for document review and key informant interviews.

2.1 Domains of the Organizing Framework

In consultation with the Clinical Decision Support Innovation Collaborative (CDSiC) Implementation, Adoption, and Scaling Workgroup, we categorized key findings from each case study and defined four domains to serve as the organizing framework for this report: patient engagement, implementation, adoption, and scaling. The implementation, adoption, and scaling domains align with the charge of the Workgroup, with the addition of patient engagement, to capture findings related to PC CDS codesign and the delivery and use of PC CDS among patients. Exhibit 1 presents the definitions used for each domain.[3,5,6]

Exhibit 1. Domains for Organizing Framework



2.2 Case Study Identification and Project Document Review

To select the nine projects for analysis from AHRQ's Digital Healthcare Research Program,[7] we reviewed AHRQ grantee profile summary documents. We primarily focused on completed grantee projects, reviewing each project's CDS intervention to determine whether it aligned with the PC CDS factors of knowledge, patient data, delivery, and use.[8] Of the project interventions that aligned with all four PC CDS factors, we selected a convenience sample of nine projects that represented a range of care settings, technology interventions, health conditions, and patient populations.

For the selected projects, we reviewed available project documents. Document review included project profiles on the AHRQ website, project final reports, published manuscripts, and publicly available webinars. The document review involved 32 discrete documents, including eight final reports, 19 published manuscripts, and materials from five webinars. From these documents, we abstracted preliminary information about the projects, including target patient populations, patient-centered factors of PC CDS, and descriptions of each PC CDS intervention.

When available, we also abstracted information about challenges, solutions, and future recommendations, mapping this information to our domains of patient engagement, implementation, adoption, and scaling. Throughout the document review, we noted domains where more information was needed about project challenges and solutions to inform the development of discussion guides for the key informant interviews.

2.3 Key Informant Interviews

We conducted key informant interviews with the principal investigators from all nine selected projects through an initial semi-structured interview guide that probed project experiences related to patient engagement, implementation, adoption, and scaling. For each interview, the guide was customized based on preliminary data gathered during document review to focus discussions on topics that were not addressed in publicly available documents. Each interview was conducted via Zoom, audio-recorded, and lasted approximately 60 minutes. We created transcripts for each interview to comprehensively and accurately capture participant's comments for the analysis.

2.4 Analysis and Synthesis

Three independent researchers reviewed the transcripts and extracted the following information: challenges; solutions; and future recommendations for enhancing patient engagement, technical implementation, adoption and uptake of PC CDS, and for scaling to other organizations or patient populations. Following abstraction, researchers conducted a qualitative review of the notes structured around the four domains of PC CDS implementations to determine common themes and challenges, glean solutions adopted to resolve challenges, and outline future areas of research. Throughout this report, we describe the experiences of the members of the project team, which we collectively refer to as project-level findings.

3. Key Findings

Exhibit 2 briefly describes the selected projects for this case study report. Full profiles for each project are available in Appendix A.

Exhibit 2. Selected AHRQ Grantee Projects

Project	Objective
ASTHMAXcel PRO Mobile Application to Support Asthma Chronic Disease Management 08/01/2018–05/31/2022	This project aimed to adapt, test, and refine a mobile application (app), ASTHMAXcel PRO, to facilitate patient self-management of asthma and support shared decision making using patient-reported outcomes (PROs). The project conducted a randomized controlled trial (RCT) at three primary care sites in an urban area with disproportionately high rates of asthma and asthma-related mortality to compare ASTHMAXcel PRO to usual care. Field testing with patients and clinicians provided information on how to scale the app to other conditions.
A Direct-to-Patient Alert for Glycated Hemoglobin Screening Using Prediction Modeling and Mobile Health (mHealth) 04/01/2019–03/31/2022	This project developed a text-based PC CDS tool for reaching patients at high risk for undiagnosed diabetes to improve early identification of hyperglycemia. The PC CDS tool was piloted at an outpatient clinic to evaluate the feasibility of "cold" texting patients to suggest screening for diabetes from a technological and governance perspective.
Clinical Decision Support for Chronic Pain Management (CDS4CPM) 09/30/2019–12/20/2021	This project adapted and deployed an interoperable Substitutable Medical Applications and Reusable Technologies (SMART) on Fast Healthcare Interoperability Resources (FHIR) PC CDS app for both patients and clinicians for chronic pain management. The PC CDS facilitates reporting and transmitting PROs directly to the clinician.
Enabling Shared Decision Making to Reduce Harm from Drug Interactions: An End-to-End Demonstration (DDInteract) 09/30/2019–09/29/2021	This project designed, implemented, and evaluated a PC CDS dashboard that supports shared decision making around drug-drug interactions (DDI). The dashboard enables interaction with CDS artifacts in CDS Connect. The PC CDS is both clinician- and patient-facing, with tools to support a shared decision making conversation about treatment to reduce risk of gastrointestinal bleeding.
Patient Outcomes Reporting for Timely Assessments of Life with Depression: PORTAL-Depression 09/30/2019–09/29/2021	This project implemented a computer-adapted test (CAT)-based PC CDS tool for screening for depression symptoms through the patient portal and evaluated whether portal-based screening improves depression screening rates and health outcomes compared with the usual standard of care. The project integrated a validated PRO for mental health into the portal to directly engage patients and streamline dataflow to their clinicians.
Scalable Decision Support and Shared Decision Making for Lung Cancer Screening (Decision Precision+) 07/01/2019–07/31/2022	This project adapted a standalone PC CDS tool for lung cancer screening that can be integrated seamlessly into clinical workflows among different EHRs using SMART on FHIR. The project implemented the PC CDS tool into two different EHR developer systems and conducted a two-phase clinical trial. The tool incorporates patient-specific lung cancer risk factor information in the EHR and provides information to promote shared decision making by describing benefits and risks of lung cancer screening personalized to the patient.
Scaling Interoperable Clinical Decision Support for Patient-Centered Chronic Pain Care (MyPAIN & PainManager) 09/13/2021–08/31/2024	This project tailored and scaled implementation of AHRQ's interoperable PC CDS resources, MyPAIN and PainManager, to expand upon the shared decision making processes used in chronic pain management. MyPAIN is a patient-facing CDS app, and PainManager is an EHR-integrated dashboard application. The project evaluated barriers and facilitators to further scaling to other systems with different EHRs.
Shareable, Interoperable Clinical Decision Support for Older Adults: Advancing Fall Assessment and Prevention Patient-Centered Outcomes Research Findings Into Diverse Primary Care Practices (ASPIRE) 08/01/2020–12/31/2022	This project developed, refined, and tested a shareable, interoperable fall preventing PC CDS using AHRQ's CDS Connect Authoring Tool and the Health Level 7 (HL7) Clinical Quality Language (CQL) standards. This clinician-facing PC CDS supports fall risk assessment and prevention and includes patient-centered educational materials that clinicians can share with their patients during shared decision making clinical encounters.
Translating Hypertension Guidelines Into Practice: Development of Interoperable Clinical Decision Support (COACH) 09/30/2019–12/31/2021	This project translated hypertension treatment guidelines into a PC CDS tool available in both the EHR and patient portal. The tool incorporated CQL query modules, CDS artifacts using the CDS Connect Authoring Tool, and an FHIR standard-based application that fosters shared decision making and provides guidance to patients and clinicians. The project conducted usability testing with both patients and clinicians and produced an implementation guide for PC CDS to effectively engage patients in blood pressure management.

In the sections that follow, we describe the challenges the projects experienced in the development, implementation, and use of PC CDS. Each section includes a summary of solutions based on the facilitators and opportunities that the projects employed to address the challenges they faced. These findings are organized by the domains of patient engagement, implementation, adoption, and scaling. The list of challenges and solutions presented are not exhaustive and represent only those described by the nine included projects. We also note that several of the challenges—particularly those related to technical implementation—are relevant to traditional CDS as well as CDS that is patient-centered. Within this report, we present both the challenges and solutions within the context of PC CDS. Each domain is accompanied by a summary table of the key findings.

We also note that not every challenge discussed in this report has an explicit solution, as projects may have encountered challenges that they were not immediately able to address. In addition, the solutions presented include activities the project implemented to address a specific challenge as well as activities the projects believe could have resolved a challenge in retrospect. Readers of this report should remain cognizant of these distinctions when considering the challenges and solutions presented in the following sections.

3.1 Patient Engagement

Direct patient engagement activities for projects (e.g., focus groups, key informant interviews) were primarily focused on soliciting patient feedback in the design and development of PC CDS. Other activities included engaging patients in the implementation and adoption of patient-facing PC CDS. Exhibit 3 summarizes the challenges encountered and solutions to enhance patient engagement in the design and development of PC CDS. Challenges and solutions related to patients' uptake of PC CDS are discussed in Section 3.3 on Adoption.

Exhibit 3. Patient Engagement Challenges and Solutions

Challenges	Solutions
Patient Recruitment • Engaging a broad range of patients in PC CDS design and development **Soliciting Patient Feedback** • Making patients comfortable to participate in engagement activities • Receiving feedback focused on the PC CDS **Analyzing and Implementing Patient Feedback** • Planning for expertise needed to synthesize qualitative findings • Incorporating feedback within project timelines	**Engagement** • Provide incentives for engagement • Engage patients individually • Prepare patients for engagement activities • Involve IT and usability experts in codesign **Project Planning** • Ensure sufficient resources to leverage user-centered design

3.1.1 Challenges to Patient Engagement

Eight of the projects engaged patients in PC CDS design and development activities. Challenges highlighted by projects included difficulties in engaging diverse populations in PC CDS design and development activities, soliciting feedback from patients about PC CDS during engagement activities, and incorporating patient feedback post-engagement. We elaborate on these challenges below.

Patient Recruitment

Lack of patient representativeness in design and development activities can lead to incomplete feedback that limits the potential use of PC CDS. Failure to include underrepresented communities or individuals across a range of digital and health literacy levels can result in missed opportunities to gather input that can improve the functionality, usability, or user interface of PC CDS.

Engaging a Broad Range of Patients in PC CDS Design and Development. Several projects spoke to the need to better engage a broad range of patients in PC CDS design and development, and two projects specifically noted that the patients they engaged were not representative of the population impacted by the disease/condition of interest.[9] One project highlighted that recruiting patients who have lower levels of literacy and digital health literacy—defined as "the ability to seek, find, understand, and appraise health information from electronic sources and apply the knowledge gained to address or solve a health problem"[10]—can be challenging when using virtual engagement platforms. Individuals who volunteer for virtual engagement (i.e., interviews and focus groups via Zoom) are often more comfortable working with computers and other digital technologies. Engaging individuals with a range of digital health literacy levels is critical to developing PC CDS that are accessible to patients and align with their level of agency. One project emphasized the importance of meeting patients where they are in terms of baseline health literacy, noting that some patients may need additional coaching or support.

Soliciting Patient Feedback

PC CDS codesign ensures that decision support tools meet the needs of end users. Engaging patients in these activities can create CDS that delivers evidence-based information in a way that will resonate with patients.[11] Projects used a range of methods to engage patients in PC CDS design and development, including group discussions (e.g., patient forums, focus groups), surveys, discussions using simulated vignettes, and participatory design sessions (a collaborative approach that involves patients in the design process). Multiple project teams noted that these engagement activities resulted in actionable feedback that was incorporated to improve their PC CDS. However, three projects encountered challenges in making patients comfortable during engagement activities or in receiving feedback that was focused on the PC CDS.

Making Patients Comfortable to Participate. One project shared that their selected modality of focus groups for patient engagement may have limited the feedback they received. The project team noted that some focus group participants seemed overwhelmed by the more vocal members of the group and may have found it difficult to share opinions in a group setting. Another project observed that patients may feel uncomfortable providing feedback in a research setting because they feel like there should be a "right" response to the questions about the PC CDS.

> “Sometimes when you put patients in these research situations, they feel a little inadequate because they don’t know what the right response is, even though there is no right response, but they feel like there should be a right response. So, sometimes there is a little bit of apprehension from patients.”

Receiving Feedback Focused on PC CDS. Two projects noted that they received feedback about broader aspects of clinical care during engagement activities that were not always actionable within the context of the project. For example, patients provided thoughts on the use of preventive screenings, clinical guidance about changing health behaviors, the role of the clinician in the decision making process, and the use of patient-facing tools. A project shared that it was a challenge to get patient partners to focus on the design of its PC CDS during focus groups, partially because patients may need additional support in understanding how the CDS will be used by patients and/or clinicians as part of clinical care delivery.

> “[Patients] talk about things other than the CDS tool, for example, like how they feel about being screened and being reminded [that] they should quit smoking. It’s a little bit harder to get feedback on the tool design itself, and you need to do a lot of work in conceptualizing the whole idea.”

Analyzing and Incorporating Patient Feedback

An inability to incorporate patient feedback can create PC CDS that does not meet the needs of end-users, which can impact adoption and use. Two projects noted potential challenges in either analyzing data or incorporating findings from patient engagement activities.

Planning for Expertise Needed to Synthesize Qualitative Data. One project highlighted that the analysis of data from focus groups and other engagement activities required experienced qualitative researchers who also understood the complexity of developing CDS in various settings. Furthermore, the project needed sufficient resources to compile findings, abstract key takeaways, and synthesize lessons learned from gathered patient feedback in a way that was useful for the CDS developers to make modifications to the CDS. One project also noted the importance of factoring in time to share how CDS tools were changed based on qualitative research activities with patient partners so that patient partners can see how their feedback was addressed.

Incorporating Feedback within Project Timelines. One project shared that they were unable to fully incorporate patient feedback due to the timing of the engagement activities. Specifically, the project engaged patients in a group forum, but the discussion about the tool’s wireframes happened too late in the design process to fully redesign the PC CDS to align with patient feedback.

> “...just from a pure user-centered design usability standpoint, we wished that we'd started [before] the wireframes...What really would solve your problem? What apps or services do you use today? How are you doing shared decision making already with your clinician? We could ask some of those questions, but at the stage at which we started that engagement, we couldn't really use answers to those questions to do a lot of redesign or redevelopment.”

3.1.2 Approaches to Overcoming Patient Engagement Challenges

To address the challenges faced when engaging patients, projects identified several approaches for mitigating the challenges they encountered. Below, we summarize the main solutions that projects identified and/or adopted to resolve challenges faced when engaging patients in PC CDS design and development.

Engagement

Provide Incentives for Engagement. Recruiting diverse and representative patients was a challenge for several projects. One project noted that they engaged patient participants who were compensated for their time by the health system. The project noted that these types of models help recruit more diverse and representative perspectives than relying on uncompensated volunteers.

Engage Patients Individually. Focus groups present challenges for patients who are not comfortable sharing their opinions in group settings. To ensure that patients feel comfortable in providing feedback, and to mitigate the risk of one or two patient participants taking over group discussions, one project recommended using individual interviews instead of focus groups or other group activities.

Prepare Patients for Engagement Activities. Projects shared that the patients may not focus their feedback on the PC CDS itself or may have trouble understanding the process and context in which the PC CDS will be delivered. One project used simulated clinical scenarios where the patients received two short clinical vignettes to read before interviews to help ground discussions.[12]

Involve IT and Usability Experts in Codesign. To ensure that the project received actionable feedback on their PC CDS, one project had IT experts participate in codesign sessions with patients to provide information on the feasibility of patient recommendations and to offer alternatives. This approach may also ensure that the feedback is actionable within the context of project timelines and resources. Another project had a usability and human factors expert lead feedback sessions with clinicians—a model that could be replicated for patient engagement activities.

Project Planning

Ensure Sufficient Resources to Leverage User-Centered Design. Projects noted that researchers should plan for sufficient time, staffing, and resources to conduct patient-centered design feedback sessions, and utilize feedback to develop and implement improvements to the features and functionality of the PC CDS. For example, one project noted that in retrospect it would have allocated time and resources to test interview guides to help mitigate challenges related to focusing patient feedback on the PC CDS.

3.2 Implementation

PC CDS integration into the EHR or patient-facing technologies is a key component of technical deployment and implementation success. However, known barriers to integration include inadequate standards for data exchange and consequently, lack of syntactic and semantic interoperability.[13] Exhibit 4 summarizes implementation challenges projects encountered and the solutions they used to achieve

technical deployment. While several of these challenges and solutions are relevant to CDS, many are amplified in the context of PC CDS given the use of FHIR-based apps and the need to write patient-provided data back to the EHR. Technical challenges specific to PC CDS include the limitations of available terminology and interoperability standards to support the standardized collection and integration of patient-provided data such as patient-reported outcomes into the EHR.

Exhibit 4. Technical Challenges and Solutions to Improving PC CDS Implementation

Challenges	Solutions
Informatics Expertise • Scarcity of informatics resources with FHIR and PC CDS integration expertise • Local customization of PC CDS artifacts is resource intensive **Interoperability Standards Adoption and Use** • Inadequate adoption of FHIR by EHR developers • Variation in FHIR standards supported by EHR developers • Limitations of existing FHIR standards • Insufficient implementation of standard terminologies **Data Infrastructure** • Navigating application hosting and licensing fees • Insufficient functionality within EHR testing environments	**Identify Informatics Expertise** • Identify IT resource capacity and knowledge early in the implementation process **Interoperability Standards Adoption and Use** • Implement application programming interface (API) middleware to facilitate data interoperability • Evaluate data quality

3.2.1 Challenges to Technical Implementation of PC CDS

The most common technical implementation challenges resulted from a workforce with limited informatics expertise.

Informatics Expertise

Skilled informatics resources at both the healthcare organization and EHR developer are necessary to accomplish PC CDS integration.

Scarcity of Informatics Resources with Fast Healthcare Interoperability Resources (FHIR®) and PC CDS Integration Expertise. A health IT workforce with limited knowledge of FHIR represents a barrier to the use of FHIR to facilitate PC CDS integration.[14] Two-thirds of projects called attention to varying degrees of implementation site IT resource "readiness" and experience using FHIR standards. Even among health systems with technical infrastructure resources, implementation delays resulted from the lack of IT resources with expertise implementing FHIR, FHIR applications, and EHR integration. Specifically, multiple projects reported subject matter expertise was underdeveloped in two areas: designing and developing open-source CDS applications and implementing FHIR APIs.

In addition to reported project delays and expenditures, two projects that supplemented local IT resources with EHR developer support to facilitate PC CDS integration reported that inconsistent and

incomplete developer support resulted in difficulties in resolving implementation challenges promptly. However, outsourcing informatics expertise can create challenges related to the sustainability of PC CDS.

> "Our internal IT resources are thin, and it costs a lot of money to hire external consultants, and they charge double. Once they do the project, they don't stick around, so they can't help fix problems. If the internal resources can't absorb research projects, they hire external consultants from [EHR developer], who then leave. If your tool isn't perfect and you need help solving problems, then the consultants are no longer available. "

Local Customization of PC CDS Artifacts is Resource Intensive. PC CDS implementers can use standards-based PC CDS artifacts, such as those publicly available from the CDS Connect Repository, to implement decision support relevant to their organization.[15] The use of standards-based PC CDS artifacts can improve scaling to other healthcare organizations, including those with different EHRs. However, implementation of standards-based PC CDS still requires adaptation to local environments as these CDS artifacts are not "plug-and-play." While the level of adaptation that is required to deploy a PC CDS artifact in a new environment differs, the resources associated with these adaptations can be substantial.

One project reported high software development costs associated with adapting patient- and clinician-facing SMART on FHIR PC CDS artifacts to another clinical setting. While the project used the open-source implementation guide and benefited from implementation site FHIR expertise, a substantial amount of time and budget was used to make user interface improvements and modify the patient-facing components of the PC CDS.

Interoperability Standards Adoption and Use

FHIR has emerged as a national standard to promote interoperability and can support PC CDS integration in EHRs and apps using standards-based APIs.[16] However, the use of FHIR to facilitate PC CDS integration is still in its early phases, creating significant barriers to interoperability.[14,17] Barriers to the use of FHIR to facilitate PC CDS integration include inadequate EHR developer adoption of available FHIR standards,[13,14] variation in the FHIR versions supported by EHR developers, limitations to the current FHIR standards, and insufficient implementation of standard terminologies.

Inadequate Adoption of FHIR by EHR Developers. A few projects reported that the inadequate adoption of FHIR by their EHR developer directly impacted their approach to technical implementation. As a result, these projects needed to translate data stored using proprietary EHR developer codes to FHIR to integrate their otherwise standards-based PC CDS.[18]

These projects also noted the lack of EHR developer support for the FHIR Patient Questionnaire Resource their apps used to collect patient-reported pain and physical function data that necessitated the use of a workaround to integrate patient-provided information into the EHR. One project stated this lack of EHR developer support was the most difficult implementation challenge encountered. Another project reported that the need to use EHR developer specific workarounds to integrate patient-provided data into the EHR resulted in hurdles to clinician use of the PC CDS because the data were integrated

outside of the clinicians' workflows. As a result, clinicians did not consistently review patient-reported data, which negatively impacted patients' perception of the utility of the PC CDS.

Variation in FHIR Standards Supported by EHR Developers. Another project reported variations in EHR developer support for the most recent version of FHIR at the time (R4), noting that the FHIR APIs offered by the EHR developer supported a range of FHIR resources across versions. Additionally, variability in the FHIR Resources and versions supported across EHR developers makes development of sharable PC CDS that can be implemented in different EHRs difficult. While projects anecdotally reported improvement in EHR developer support for FHIR since project completion, variation across EHR developer implementations remains a challenge to sharing PC CDS artifacts.

> "I think the issue is that if you were building it all within a single vendor system environment, you could really highly customize [it] all and really [fine-tune] it carefully … But if you know anything about electronic health record implementation, you know that you've implemented [in] one [EHR developer], that's pretty much it."

Limitations of Existing FHIR Standards. In addition to variations in EHR developer support for FHIR, one project also encountered challenges using the FHIR APIs available (i.e., "native") in the EHR to access data from both EHR and external sources for integration into their app. The FHIR Clinical Guidelines Implementation Guide did not support the population-level queries necessary to identify eligible patients. The immaturity of the bulk-FHIR standard was also noted by another project, although this lack of standard maturity did not contribute to implementation challenges.[9]

Insufficient Implementation of Standard Terminologies. Utilizing standard terminologies establishes a foundation for interoperability. However, the implementation of these standards for EHR data is highly variable and can impact the quality of data used to develop computable clinical knowledge.

One project reported that low rates of standard terminology use and data mappings resulted in data quality issues that impacted PC CDS performance. The project evaluated standards conformance and the completeness of the data and logic required for their FHIR-based PC CDS. Approximately 60 percent of the concepts used to measure adherence to the clinical guideline recommendations were either unused or inaccurate, and patient-specific data (e.g., history of previous treatment, tobacco use, and adverse events) were missing for slightly more than 65 percent of patients; both issues contributing to data for half of the patient use case scenarios of insufficient quality for accurate alerting.[19] Furthermore, this project noted that the directions for how to administer medications were commonly stored as free text, thus limiting available structured data to include in the PC CDS logic. The project also noted issues with the currency of medication data curated by national drug standards bodies.

While not tied directly to the implementation of standard terminologies, one project reported that the data needed to determine intervention eligibility was missing from the EHR for approximately one-third of patients. Specifically, the project needed detailed smoking history data to identify patients who met the United States Preventive Services Task Force (USPSTF) guidelines for lung cancer screening. As a result of this data quality issue, the PC CDS logic identified fewer patients for screening.

Data Infrastructure

In addition to the interoperability data standards, PC CDS integration can benefit from a robust data infrastructure.

Navigating Application Hosting and Licensing Fees. Often, PC CDS is a separate application and not part of the EHR. In some instances, PC CDS is hosted in the cloud or on an external platform. This hosting configuration requires implementers to address data access and data governance requirements to enable exchange between a cloud-based application and the EHR while balancing the benefits and risks.

One project encountered challenges navigating governance issues related to privacy and security regarding data storage and whether to store information in the cloud or behind the institution's firewall. Another project ultimately opted to host the PC CDS locally due to concerns regarding data exposure risk despite the benefits of reduced maintenance associated with a cloud-based application.

Projects also needed to navigate licensing applications from the PC CDS artifact developers. Three projects noted licensing, even for free applications, introduced unanticipated time and resource constraints. Finally, three projects encountered challenges because of limited staff expertise with cloud applications, which contributed to implementation delays.

Insufficient Functionality in EHR Testing Environments. Testing environments facilitate developers' capability to ensure the PC CDS functions as intended, to assess PC CDS performance and accuracy, and to support the identification and mitigation of potential patient safety issues.

However, some EHR developer sandbox and staging environments do not support the same functionality as the production environment, which can have implications for both traditional CDS and PC CDS. For example, one project stated the EHR testing environment was more constrained than the production environment, which limited their ability to fully conduct integration testing. As a result, this project experienced unexpected performance issues after migrating their PC CDS from the testing environment to the production environment.

3.2.2 Approaches to Overcoming PC CDS Implementation Challenges

Throughout each project, implementation teams identified, applied, and assessed implementation strategies to address the technical deployment challenges they encountered. These strategies offer solutions to common implementation challenges and can improve organizational readiness to implement shareable PC CDS.

Identify Informatics Expertise

Identify IT Resource Capacity and Knowledge Early in the Implementation Process. Establishing a technical implementation team before implementation helped projects prepare for resource allocation, plan implementation duration, and inform decisions regarding system architecture.[18] One project also encouraged leveraging the expertise of other healthcare organizations as well as other resources within their own EHR developer technical support teams.

"Don't go at it alone. Talking to people at other institutions who've done this kind of work is very important. You've talked to one [EHR developer] analyst, you've only talked to one. People may say something is impossible, but it's not true. It's impossible in their system, but maybe not in another system. It can be frustrating if you don't keep on pushing and see whether things are possible."

Interoperability Standards Adoption and Use

Implement API Middleware to Facilitate Data Interoperability. A FHIR API middleware, sometimes called a FHIR façade, translates data between proprietary EHR developer codes and FHIR-based APIs, thus offering an approach to addressing incomplete implementation and adoption of the FHIR standard by EHR developers. The use of middleware can also decrease the time and resources necessary to address variability in the adoption of interoperability standards across EHR developers. Implementers should assess organizational IT capacity to determine whether to develop the FHIR middleware internally, pursue a third-party solution, or implement other non-standard workarounds.

Evaluate Data Quality. Implementers should plan to evaluate data quality to assess the adequacy of the data and logic required for PC CDS, particularly for data that leverage FHIR. These assessments can occur as part of the planning process to ensure the PC CDS both performs as intended and mitigates unintended consequences (e.g., low specificity or sensitivity). One project developed an approach for assessing the adequacy of their EHR data to implement the PC CDS. This approach involved identifying relevant clinical guideline recommendations; defining key concepts (e.g., value sets); extracting EHR data for testing purposes; characterizing the quality of the value sets using established definitions; and finally, using the concepts to query the EHR test data against defined patient use cases to assess the adequacy of the logic.[19] This approach can serve as a model for other PC CDS implementers to leverage.

3.3 Adoption

Adoption activities for projects focused on engaging patients and clinicians as end-users and understanding how to promote uptake and use of the PC CDS through usability assessments. The following section provides an overview of the challenges facing projects when promoting adoption and solutions to improve adoption of PC CDS. Exhibit 5 below summarizes the adoption challenges encountered and the solutions projects used or proposed to address the challenges.

Exhibit 5. Challenges and Solutions for Promoting Adoption of PC CDS Interventions

Challenges	Solutions
Guideline Translation • Differing clinical treatment practices **PC CDS Integration** • Inappropriate integration into patient lifeflows • Inappropriate integration into clinician workflows **Clinician Resources** • Lack of local clinician champion for intervention • Clinicians with limited technical skills **Facilitating Clinical Information Exchange** • Patient uncertainty about acting upon patient-facing PC CDS recommendations without clinician endorsement	**PC CDS Integration** • Test PC CDS in patient lifeflows • Ensure sufficient resources to leverage findings from user assessments **Clinician Resources** • Leverage PC CDS clinician champions **Usability and Design** • Enhanced user interface tailored to different preferences and clinical needs

3.3.1 Challenges to Promoting PC CDS Adoption

Barriers to adoption of PC CDS affected both patient and care team users. These barriers led to low uptake, missing data, alert fatigue, and clinician burden. Below we describe the challenges projects faced promoting PC CDS adoption amongst patients and care team members.

Guideline Translation

Translating PCOR evidence into guidelines requires agreement among PC CDS stakeholders on what evidence should be translated into guidelines and PC CDS interventions.[3] Misalignment of knowledge artifacts with clinicians' beliefs and preferences may prevent uptake of the clinical recommendations.

Differing Clinical Treatment Practices. A grounded knowledge base of evidence is crucial to developing reliable PC CDS. However, challenges arise when clinicians hold divergent interpretations or differences of opinion regarding clinical guidelines, impeding the development and adoption of reliable PC CDS. One project encountered hurdles in selecting clinical guidelines to use for PC CDS due to differing views from clinicians about treatment practices. Specifically, clinicians could not reach a consensus on a single set of clinical treatment recommendations. This indecision created additional burdens for developers during selection and translation of guidelines for PC CDS.[9]

PC CDS Integration

PC CDS implementation faces challenges when tools fail to account for the intricacies of clinician workflows and patients' lifeflows (defined as the patterns and routines of daily activities). This can result in limited adoption and use.

Inappropriate Integration into Patient Lifeflows. To optimize effectiveness, PC CDS must seamlessly align with patients' routines, facilitating timely decisions and action. However, achieving successful integration presents certain barriers. For instance, one project encountered difficulties in achieving sufficient patient uptake due to inadequate integration into patient lifeflows, leading to suboptimal timing and engagement modalities. Similarly, patient representatives from another project reported instances where PC CDS alerts prompted action at inconvenient times in patient lifeflows.[20] The PC CDS was originally designed so that clinicians interacted with it to trigger notifications to patients when the clinician was available to use the PC CDS, but this timing did not align with when the patient was available to take action based on the recommendation. This underscores the importance of ensuring seamless alignment between clinician workflows that trigger PC CDS notifications and patients' availability.

Inappropriate Integration into Clinician Workflows. PC CDS that does not fit smoothly into a clinician's workflow can lead to low adoption due to alert fatigue or lack of time to use a tool during a clinical encounter. Several projects encountered limited clinician adoption because the PC CDS were not integrated appropriately into clinical workflows or had performance issues. For example, clinicians in one study missed positive depression screening results while reviewing patients' health records because of misaligned timing for when the alert of the positive result was received.[21]

In another project, clinicians also missed positive screening results when they populated in an area of the EHR that clinicians did not frequently access and were unfamiliar with how to access.[22] When positive screenings are missed, efforts made by patients to engage with the PC CDS to provide their health data did not result in action by their clinicians and resulted in worse health outcomes for the patients. Clinicians from another project expressed that they were less likely to use the PC CDS because performance issues such as long load times during the clinical encounter decreased how much time they spent engaging with patients.[18] Clinicians in a separate project who were supporting patients with multiple health issues or chronic conditions expressed similar concerns—they were unable to dedicate sufficient time to the PC CDS and shared decision making because their time with the patient was limited, and they had many health issues to discuss with the patients.[23]

Clinician Resources

The lack of a clinical champion, end-user buy-in, and readiness to use a PC CDS can hinder adoption.

Lack of Local Champion for Intervention. The presence of a local champion, either for clinicians or patients, is essential to the successful adoption of PC CDS. Lack of a CDS champion can result in adoption challenges that hinder broader engagement with PC CDS. One project noted a lack of clinical champions for their PC CDS because of clinician burnout and turnover.

Clinicians with Limited Technical Skills. Given the prevalence of EHRs, PC CDS implementers may assume that clinicians are comfortable using digital tools that are integrated into their workflow. However, one project found that early adoption was skewed to favor clinicians who were technologically literate and more comfortable with digital tools.[24] Clinicians with lower digital literacy or who were less comfortable with EHRs were less likely to be early adopters of the PC CDS. This difference led to low

uptake amongst broader groups of clinicians, disparities between patient populations whose clinicians did or did not use the PC CDS, and missing user feedback from this crucial portion of end users.

Clinical Information Exchange

Adoption of PC CDS can depend on facilitating information exchange between patients and clinicians to make meaningful and patient-centered decisions. The perspective that one's clinician is not personally involved or endorsed the recommendations provided by PC CDS may decrease adoption.

Patient Uncertainty About Acting Upon Patient-Facing PC CDS Recommendations Without Clinician Endorsement. Patients may be unwilling to adopt patient-facing CDS without agreement or consultation with their clinician. A core component of PC CDS involves demonstrating to the patient that a trusted clinician partner participated in the decision making process. One project experienced low patient uptake of the clinical treatment recommendations because patients were concerned about lack of clinician involvement in the decision making process. They found that patients were less likely to engage with the PC CDS recommendation to obtain a hemoglobin A1c test to screen for diabetes if they did not believe that their primary care clinician had reviewed or approved the recommendation. They expressed a preference that their clinician was aware of the recommendation and that this information was communicated to the patient via the PC CDS.[25]

3.3.2 Approaches to Overcoming PC CDS Adoption Challenges

Improved understanding of how to successfully integrate PC CDS into patient lifeflows and clinician workflows is needed to ensure that innovations meet user needs, are adopted, and lead to desired outcomes. Standardization of evaluation steps saves resources and provides higher quality evaluation for individual projects. The following describes strategies and approaches learned from the projects for overcoming PC CDS adoption challenges.

PC CDS Integration

Evaluation of PC CDS integration with clinical care processes and patients' lifeflows promotes adoption by identifying the areas to tailor workflows and functionality so it aligns seamlessly with end-users' preferences and needs.

Test PC CDS in Patient Lifeflows. A crucial approach to enhancing patient engagement involved assessing the most appropriate time to invite patients to engage with the PC CDS via messaging. In combination with patient-centered messaging and plain language, one project assessed patient lifeflows to understand the integration points of the PC CDS and modified the integration point by sending patient messages at a patient's preferred time of day.

Ensure Sufficient Resources to Leverage Findings from User Assessments. To address issues in which PC CDS was not integrated at the right point in the clinician workflow, PC CDS implementers may need to conduct workflow analyses and requirements gathering to better understand how to integrate PC CDS into clinician workflows. Considering where best to integrate PC CDS into clinician workflows will help use appropriate and sufficient resources, staff, and time to ensure feedback is translated into improvements to the PC CDS, ultimately promoting sustained adoption. Four projects

discussed how they leveraged various resources to conduct user-centered design reviews and workflow assessments, and these projects were able to adjust the tool as a result of having the right resources to make the changes. For one project, this review took the form of cognitive psychology experts who could elicit user feedback from patients.[26] Another project integrated IT experts into their patient-centered design reviews to provide feedback on the feasibility of suggested improvements to both the participants and the researchers.

Clinician Resources

While clinicians may be willing and interested in adopting PC CDS, limited resources may ultimately impede actual use of the tools. Clinical champions may promote adoption by developing educational materials and other resources based on early use experience among clinicians with more technological skills.

Leverage PC CDS Clinician Champions. Even when PC CDS tools are adopted by clinicians, the initial adopters may skew toward technologically savvy clinicians who are interested in trying new tools. This potential bias presents a challenge for adopting PC CDS more broadly. One project recommended engaging PC CDS champions, especially during the adoption phase, by encouraging early adopters and more technologically savvy users to share their experiences and best practices with their peers or to develop tip sheets, live demos, or videos for using the PC CDS.[27] While this project specifically made use of clinician champions to encourage peers in their use of the PC CDS, patients could also potentially serve as champions for other patient populations with similar conditions or health issues. Another project created “implementation blueprints” regarding workflow and implementation management tailored to different environments and clinician preferences.

> “To encourage adoption, the COACH team focused on building implementation blueprints that would fit into the culture and workflow of each site. While the general process across sites is similar (a team member sends a message to a patient inviting them to participate), the implementation blueprints differed in terms of the education and training plans based on sites’ needs and wants. The team conducted a lot of upfront work with the practices to determine the optimal implementation to encourage adoption.”

Usability and Design

Enhancing the user interface and user experience are important strategies to encourage adoption and reduce barriers to use.

Enhance Patient-facing PC CDS Functionality. To mitigate patient adoption challenges, two projects recommended that PC CDS developers support enhanced features or functionality for patient-facing components. For example, developers could include educational material in the PC CDS that would allow patients to better engage with the clinical treatment recommendations presented to them. Another project highlighted an effective method for improving usability and design to promote adoption, including social acceptability assessments to identify the value of deploying the tool as well as user acceptability assessments, which engage stakeholders to identify designs that optimize end-user needs.

3.4 Scaling

The process of scaling facilitates the generalizability and use of PC CDS across settings to benefit more people.[28] However, scaling PC CDS can be challenging due to the complex nature of patient-centered tools. Several clinical, technical, and economic challenges to scaling PC CDS have been cited, such as workflow integration, high costs of development and implementation, challenging regulatory environments, and poor data quality and/or data integration.[2,20] While these scaling challenges may also be relevant to traditional CDS, we present them in the context of PC CDS in the sections below. Exhibit 6 summarizes scaling challenges across projects and the solutions projects used to scale PC CDS.

Exhibit 6. Key Challenges and Solutions for Scaling PC CDS

Challenges	Solutions
Implementation across settings • Lack of generalizability • EHR limitations • Technology costs **Policy** • Misalignment of reimbursement models with PC CDS **Dissemination** • Resource intensive dissemination	**Implementation across settings** • Promote use of interoperability standards and tools • Account for variation across sites • Leverage organizational capacity and support **Dissemination** • Foster internal and external dissemination efforts

3.4.1 Challenges to Scaling PC CDS

Projects encountered scaling challenges related to implementation across settings, policy, and dissemination.

Implementation Across Settings

Implementing PC CDS across settings involves adaptation of applications to account for variations in patient populations, available resources, and technological systems. Several projects described challenges related to addressing these variations when scaling PC CDS.

Lack of Generalizability. External validation of PC CDS in real-world settings is needed to ensure generalizability across diverse patient populations in large numbers. A few projects indicated that their interventions were implemented at one implementation site or in a single healthcare system, rather than at a large group of healthcare organizations. This limited implementation can limit generalizability of the PC CDS to other settings, such as rural settings, organizations with different EHR systems, or settings with different patient case mixes.[23]

EHR Limitations. To efficiently use and scale PC CDS, it must be well integrated into EHR-based workflows.[13] This process relies heavily on standards-based APIs and FHIR standards to enable

information sharing across apps, tools, and systems.[29] Four projects cited challenges with EHR integration that limited the dissemination of shareable PC CDS. For example, the use of proprietary EHR terminology codes rather than standard terminologies to create computable value sets limits dissemination potential.[26] Additionally, limitations in API functionality within some EHRs restrict the level of functionality that can be offered across systems.[30] This includes limited write-back functionality of FHIR-based APIs, which is important for the integration of patient-provided data for PC CDS. In addition, EHR systems may support FHIR data interfaces differently, despite being standardized, or they may not support any component of the desired FHIR interfaces.[17] When scaling apps to new EHR systems, differences in the registration process to introduce apps into developer app galleries can impede the process. Finally, organizational differences exist in the governance and review processes required to implement and launch the tool within EHR systems, particularly in systems with less experience using SMART on FHIR for application integration.

Technology Costs. Costs associated with developing, deploying, and maintaining PC CDS can be a barrier to establishing return on investment (ROI) for PC CDS and subsequently scaling these tools.[31] Two projects cited challenges with costs, highlighting that high costs may be associated with implementing PC CDS across different sites, even when using standards-based PC CDS or operating within the same EHR. These costs may be due in part to limited coordination among CDS components (e.g., lack of a common information model, use of site-specific terminologies).[32] Projects noted the cost of implementing PC CDS is significant, even at a single site, and translating those costs to multiple sites may not be feasible using grant-based and time-limited funding sources.

> "For scaling, it is important to consider where an app will be hosted, where and how it will get access to EHR systems, and the associated costs with these processes."

Policy

The overarching policy environment across health systems has implications for the scaling of PC CDS. Promoting implementation of PC CDS across sites can be challenged by organizational inertia and competing priorities, particularly given differences between traditional fee-for-service reimbursement models and value-based care models.

Misalignment of Reimbursement Models and Value-based Care. Projects noted that PC CDS built for research purposes do not always receive as much resource support as PC CDS built to fulfill regulatory requirements. For example, one project shared they encountered difficulty garnering support for PC CDS that does not have any reimbursement incentive, as opposed to PC CDS that is tied to regulatory mandates that result in penalties when quality metrics are not met, or increased reimbursements when they are met. Similarly, policy requirements and financial incentives may not be supportive of shared decision making for screening, particularly in fee-for-service environments where high volume of visits is rewarded. For example, one project described being unable to sustain a population-level version of their PC CDS in the patient portal for depression screening as it was deprioritized by the health system.

> "The number one recommendation right now is just to get the clinician to tell patients to use the patient portal [for depression screening], but many clinicians don't want to do that because it creates more work for them outside of clinic work that they're not reimbursed for … I think understanding as a healthcare system how we use the patient portal, how we want to reimburse and pay for the patient portal for care outside of visits, is very important. That's a problem that's yet to be solved and until it is, scaling this will be challenging because of the barriers, the increased work it places on people, and the disincentives to do that type of work."

Dissemination

Awareness-raising efforts are needed to promote use of PC CDS outside of the setting in which it was originally developed. However, these efforts can be time and resource intensive.

Resource Intensive Dissemination. Projects acknowledged that dissemination of PC CDS can be challenging within the constraints of federal grant funding. Projects spent significant time and resources conducting broad dissemination efforts to create awareness of and promote interest in developed PC CDS among patients and clinicians, such as through conference attendance or meetings with clinicians and patients. One project also cited the need for peer-to-peer engagement and continual refreshing of users' awareness of PC CDS to promote widespread use but noted that these are two engagement strategies that may prove difficult to sustain on an ongoing basis. Published manuscripts about PC CDS can generate interest for their use in other settings, but interest generated by published manuscripts often occurs outside of the original project timeframe when financial resources are no longer available to act on the interest. Additionally, dissemination products are not always sought after by busy clinicians or patients.

> "By the time organizations start producing papers about the tool and generating press and interest, the project is already ended and there's no more funding. So, when the requests started coming in about the tool, a lot of that work we do is now pro bono … sometimes it's not feasible to support all the people who might be interested."

3.4.2 Approaches to Overcome PC CDS Scaling Challenges

To address some of the challenges associated with scaling PC CDS, projects used interoperability standards, leveraged existing organizational support for PC CDS, built flexibility into PC CDS to account for variation across sites, and spread the word about their tools internally and externally.

Implementation Across Settings

Promote Use of Interoperability Standards and Tools. Leveraging interoperability standards such as FHIR, SMART, and CDS Hooks can reduce implementation costs and enhance dissemination to other systems.[17] Four projects used interoperability and standards-based approaches to address EHR limitations and facilitate integration of their PC CDS across systems. One project used several tools, including FHIR Wrapper, Terminology Suite, and EHR Mapping Tool, to address challenges with EHR

integration. FHIR Wrapper is a tool that enables FHIR applications to interact within a consistent interface. Terminology Suite provides support for developing value sets in various domains, and the EHR Mapping Tool supports the mapping of local EHR data to standard terminology codes.[17] To facilitate integration of tools, this project also used a multistakeholder approach by identifying a clinical champion to promote acceptance among leadership, a technical champion to assist with deployment, and a legal representative to address licensing requirements. Similarly, one project used a previously developed FHIR implementation guide to port their PC CDS to other health systems, while another project partnered with an EHR developer to integrate their PC CDS directly into the EHR. One project integrated their CDS into the Logica EHR sandbox using SMART on FHIR, which allowed the team to test the tool's interoperability.

> "It's really challenging to get [PC CDS] to go beyond a single institution … we tried to rely on standards such that this becomes an interoperable tool. If you don't have that, I think you're dead in the water in terms of scaling beyond a single use case."

Account for Variation Across Sites. Due to the EHR limitations described above, the way data are handled varies at different sites and within different EHRs. To account for this variability and facilitate scaling, one project built flexibility into their PC CDS in terms of what data are received from individual sites across health systems. For example, when sending a query to the EHR for data, the project broadened or changed queries for different sites and utilized cross-referenced terminology to ensure the appropriate data was retrieved. However, this process involved mapping to proprietary systems which required significant effort.

Leverage Organizational Capacity. Institutional support and infrastructure that supports PC CDS are important to scale tools. Three projects that were aligned with wider organizational initiatives experienced smoother implementation and intra-organizational scaling than other projects without this institutional support. One project's work was part of a broader organizational initiative established to develop and implement interoperable apps to facilitate decision making and improve health outcomes.[33] As a result, the project benefited from supportive data infrastructure, governance, and best practices related to the use of interoperability standards.[45] Similarly, another project's health system already had a robust set of existing tools related to mental health as well as institutional support for improved mental healthcare, which facilitated the wider use of PC CDS for depression screening. One other project also noted its implementation path was easier because it aligned with an organization-wide approach to patient communications. In addition to leveraging existing organizational support, one project convened a stakeholder counsel to gather support for the PC CDS. Creation and promotion of institutional initiatives to support CDS implementation could facilitate scaling PC CDS within organizations.

> "We have a very large stakeholder counsel that has representatives from the major osteoporosis, orthopedic, nursing, long-term care organizations that will sign off on the CDS … We want to be able to say that we have support from the major stakeholders in this area, and that what we've implemented is both evidence-based and feasible."

Dissemination

Foster Internal and External Dissemination Efforts. The CDS Connect Repository is one mechanism that supports AHRQ's mission to scale PC CDS. As a publicly available resource, CDS Connect offers implementers access to evidence-based artifacts. Several projects leverage CDS Connect authoring tools, adapted existing artifacts, enhanced CDS Connect tools, or published their PC CDS to CDS Connect for use in future implementations. For example, one project developed a decision support dashboard to facilitate shared decision making around potential drug-drug interactions between warfarin and nonsteroidal anti-inflammatory drugs. Along with the tool, this project developed a dissemination plan to facilitate the tool's use in other settings and for additional use cases, such as by releasing tool artifacts (e.g., CQL, FHIR libraries, implementation guide) to the CDS Connect Repository and validating the tool's CQL rules for other potential drug-drug interactions.[21] The project team also planned to register the tool with the SMART® App Gallery to encourage uptake. Within their dissemination plan, this project also planned for several dissemination approaches to raise awareness and foster uptake of their PC CDS. For example, the project provided information about the tool in newsletters and listserv outreach, conducted outreach to colleagues at other healthcare organizations working on similar projects, presented the tool at webinars, and invited users to test a web-based version of the tool using an online survey.[20]

4. Recommendations for Future PC CDS Research

Lessons learned from across projects can inform a future PC CDS implementation science research agenda and apply lessons learned to resolve both emerging and long-standing challenges to patient engagement, implementation, adoption, and scaling of evidence-based PC CDS. Near-term recommendations focus on opportunities to better align the development and design of PC CDS with clinician and patient needs, which can lead to increased adoption and potential for improved health outcomes. These recommendations also seek to advance efforts to enhance the data infrastructure needed to implement and scale PC CDS and resolve persistent challenges to data interoperability and to defining a value proposition for PC CDS. Exhibit 7 summarizes the recommendations identified by the projects by domain.

Exhibit 7. Recommendations for Future PC CDS Research

Recommendations to Improve Patient Engagement	Recommendations to Improve Technical Implementation
• Engage diverse patient populations • Develop PC CDS that considers varying levels of digital health literacy	• Enhance data interoperability • Expand IT resource capacity and knowledge • Evaluate data quality
Recommendations to Improve Adoption	**Recommendations to Improve Scaling**
• Enhance utility of PC CDS • Enhance patient-facing PC CDS functionality • Study alternate approaches to using clinical champions to promote adoption	• Enhance generalizability • Address EHR limitations • Explore cost considerations

4.1 Recommendations to Improve Patient Engagement

Develop Methods to Engage Diverse Patient Populations in PC CDS Design and Development. Collectively, projects indicated that both recruiting and engaging diverse patient populations were challenging. To address these issues, the PC CDS community should develop approaches for recruiting and engaging individuals with lower health and digital health literacy as well as individuals from historically underserved and underrepresented populations in PC CDS codesign. These approaches should consider patient agency in terms of the abilities and capabilities of patients to participate in PC CDS design and development activities.[34] Project teams noted a specific need to identify methods to engage patients who have lower digital literacy in the development and use of patient portal-based PC CDS. Projects that encounter a lack of clinician consensus around clinical guidelines may also benefit from working with patients to gather their input and preferences about how the guideline recommendations do or do not fit into their healthcare decision making. Analyzing data from patient engagement activities will require qualitative researchers to interpret and translate patient feedback into the design, underscoring the importance of multidisciplinary teams in the development of PC CDS.

Develop PC CDS that Considers Varying Levels of Digital Health Literacy. Projects noted the importance of considering patient digital health literacy in the design and development of PC CDS, as this consideration will ultimately impact patient engagement and tool adoption. PC CDS should provide patients with more features within PC CDS that align with their digital and health literacy levels to make the tools more useful and accessible. As patient-facing PC CDS tools are piloted or implemented, health systems should provide training for patient populations who need more assistance with using PC CDS.

4.2 Recommendations to Improve Technical Implementation

Enhance Data Interoperability. Projects offered several recommendations to improve the adoption and use of interoperability standards. First, incorporating FHIR standards into the United States Core for Data Interoperability (USCDI) could help advance the consistent availability of FHIR across certified health IT products. Another area to enhance FHIR capabilities is continued support by standards development organizations to refine bulk-FHIR capabilities. Finally, one project recommended the creation of standardized vocabulary around directions for medication use (data currently captured as free text in clinical notes which limits its utility in PC CDS logic) in collaboration with standards development organizations.

Enhance Infrastructure for PC CDS Integration Testing. PC CDS developers would benefit from access to EHR developer testing environments that more closely resemble the production environment to allow for more comprehensive PC CDS integration testing.[35]

Expand IT Resource Capacity & Knowledge. Develop and disseminate training resources in collaboration with AHRQ, the Assistant Secretary for Technology Policy/Office of the National Coordinator for Health Information Technology (ONC), and others to support workforce development for FHIR integration expertise to scale publicly available standards-based PC CDS more efficiently.

4.3 Recommendations to Improve PC CDS Adoption

Enhancing Utility of PC CDS. To enhance the utility of PC CDS, further research is needed to determine when and how to integrate PC CDS into patient lifeflows, and to determine what clinical touch points within the clinician workflow should be associated with PC CDS events and actions to ensure patients can make informed decisions when using the tools and engage in meaningful decision making with their clinicians.

Enhance Patient-Facing PC CDS Functionality. Projects identified two features that would enhance the functionality of patient-facing PC CDS to better meet patients' needs: 1) enable search functionality to find specific educational materials, and 2) allow patients to rank PC CDS recommendations and provide this feedback to their clinician to communicate information about their preferences, which could lead to improved shared decision making.

Study Alternate Approaches to Using Clinical Champions to Promote Adoption. Implementation and adoption efforts benefit from enlisting champions, early adopters, and influencers of change and acceptance of PC CDS innovations. While clinician champions can play a considerable role in increased uptake of PC CDS, there is a need to identify and test alternate models for promoting adoption of PC CDS needs to be identified and tested, particularly in low-resource settings.

4.4 Recommendations to Scale PC CDS

Enhance Generalizability. To enhance generalizability, future research can focus on systematically evaluating PC CDS to understand its impact in improving decision making quality across settings as well as to demonstrate ROI, which is necessary for scaling.[17] Additionally, PC CDS can be designed for resource-limited settings to facilitate expansion of PC CDS into other healthcare settings, such as Federally Qualified Health Centers or rural health centers. To accomplish this expansion, developers can test PC CDS in environments outside of academic medical centers and modify the tools to ensure that they do not increase clinician burden. This may involve beta testing to demonstrate how developers and implementers can adhere to differing policies across health systems. For app-based PC CDS, content can be optimized for wider patient populations; for example, through the addition of plain language, elements of personalization, and more specific text content to help patients understand the instructions provided by PC CDS.[36] Finally, developers can consider optimizing PC CDS for the EHR systems that are most widely used across health systems to streamline the path to adoption and scaling, since a greater number of healthcare facilities will be familiar with the system.[30]

Address EHR Limitations. Projects provided several recommendations to address EHR limitations when scaling PC CDS. First, using interoperability standards such as SMART on FHIR, USCDI common data elements, and CDS Hooks can facilitate integration into EHRs across systems.[15] EHR developers should support all FHIR resources frequently used by PC CDS. In addition, developers can make PC CDS available in a variety of formats (e.g., EHR-integrated, web-based, mobile app-integrated) as a workaround to unavoidable EHR limitations. Finally, future projects should ensure implementation teams have EHR integration expertise, including working knowledge of the FHIR standard, to facilitate seamless integration. Maintaining a developer on the team after the project ends to address additional EHR integration concerns may be beneficial for future scaling. If in-house

expertise is not possible, collaborations with outside consultants and developers for assistance may be necessary.

Explore Cost Considerations. To address cost challenges relating to PC CDS, additional funding mechanisms and approaches for aligning PC CDS with value-based care programs can be explored to support PC CDS in the long term. Additionally, private-public partnerships (e.g., with EHR developers) may provide an opportunity to support PC CDS deployment and maintenance across systems. However, developers may charge a fee to use the PC CDS. Finally, implementation teams can consider cloud-based implementation of PC CDS, which would lower costs by outsourcing sustainability and PC CDS maintenance.

5. Conclusion

This case study report serves as a repository of insights gathered from nine AHRQ PC CDS projects, poised to facilitate wider adoption, implementation, and scaling of PC CDS. Across these projects, challenges spanning various domains, including codesign, interoperability, resource expertise and availability, integration, and use, were encountered and addressed using thoughtful solutions. The methodologies employed by these projects to navigate and mitigate such challenges offer pragmatic guidance to future PC CDS developers and implementers, enhancing their ability to surmount similar hurdles effectively.

Leveraging the rich experiences and lessons learned from these projects, stakeholders in the PC CDS ecosystem can strategically anticipate, address, and overcome challenges, thereby accelerating the deployment of PC CDS tools across diverse healthcare settings. These instances underscore the complexity inherent in aligning PC CDS with diverse healthcare settings and patient populations and preferences. Such challenges highlight the need for robust strategies to reconcile disparate interpretations of clinical guidelines, fostering consensus among clinicians and streamlining the development and implementation of effective PC CDS. Through collaborative efforts and iterative refinement, PC CDS stakeholders can navigate these intricacies, ultimately advancing the integration of evidence-based decision support tools into clinical practice to enhance patient care and outcomes.

In light of these findings, this report identifies actionable recommendations and delineates areas for future research aimed at addressing enduring barriers hindering the broader integration of PC CDS into the delivery of person-centered care. By focusing on collaborative efforts to implement these recommendations and advance research in identified areas, we can propel the evolution and dissemination of PC CDS, and transition into truly patient-centered healthcare paradigms. As PC CDS continues to evolve and innovate, it holds immense promise in empowering patients, enhancing clinical decision making, and ultimately improving health outcomes. Through sustained commitment to innovation, collaboration, and evidence-based practice, the vision of patient-centered care can be fully realized, with PC CDS serving as a cornerstone in this transformative journey.

Appendix A. Project Profiles for Case Studies

A.1 Adapting, Scaling, and Spreading an Algorithmic Asthma Mobile Intervention to Promote Patient-Reported Outcomes Within Primary Care Settings (ASTHMAXcel PRO)

Objective: Adapt, test, and refine a mobile app, ASTHMAXcel PRO, to facilitate patient self-management of asthma and support shared decision making using patient-reported outcomes (PROs). The project conducted a randomized control trial (RCT) at three primary care sites to compare ASTHMAXcel PRO to usual care.

Health Issue: The Bronx has disproportionately high rates of asthma and the highest rate of asthma-related mortality in New York. This is attributable to several factors including poor healthcare access, lack of knowledge about proper medication use, and challenges patients face following medication regimens.

Health Issue: Asthma
PC CDS Factors: • *Knowledge:* Uses asthma guideline recommendations • *Patient Data:* Gathers PROs and PGHD • *Delivery:* Directly engages patients through a mobile app to provide medication reminders, guidelines-based asthma education, and behavioral support • *Use:* Facilitates patient and clinician shared decision making and patient self-management
Technology Intervention: Mobile app, clinician-facing dashboard
Intervention Setting: Primary care clinics

PC CDS Solution: ASTHMAXcel PRO is a publicly available, patient-facing app comprising guidelines-based asthma educational content, medication reminders, motivational messaging, and check-in messages to collect PROs and other patient-generated health data (PGHD). The app incorporates gamification through virtual coins, virtual trophies, and virtual leaderboards to incentivize patients to use the app. The app was developed using a virtual cohort study design.[37] The project iteratively refined ASTHMAXcel PRO through participatory design sessions with patients and clinicians. Prior to the RCT, the project conducted participatory design sessions[38] as well as field testing for 4 weeks, followed by formative and summative evaluations. The platform includes a web-based administrative dashboard where clinicians can schedule notifications and view aggregated data (e.g., usage information, self-assessment responses).

Project Results: Based on participatory design sessions, the project added more educational content for medication side effects in the app and enhanced the ability to track symptoms and medications. During field testing, patients found the app to be informative, helpful, and easy to use and understand. Patients suggested adding a search function to the app and the ability to take notes in the app. The project found that the ability to make iterative refinements to the app was linked to increased user satisfaction and app acceptance. Use of the app during the RCT was linked to improvements in asthma control and asthma knowledge, as well as decreased asthma-related hospitalizations. The project has subsequently scaled the app to other conditions, including diabetes[39] and chronic obstructive pulmonary disorder, as well as other care settings such as specialty care asthma centers, emergency departments, and inpatient medicine.

Resources:

- **AHRQ Project Page:** https://digital.ahrq.gov/ahrq-funded-projects/adapting-scaling-and-spreading-algorithmic-asthma-mobile-intervention-promote
- **Final Report:** https://digital.ahrq.gov/sites/default/files/docs/citation/r18hs025645-jariwal-final-report-2022.pdf
- **Journal publications:**
  - Wedel N, Zinger N, Singh AK, Kaur S, Njeze O, Cosar E, Mowrey W, Green S, Reznik M, Feldman J, Su Z, Ansari A, Elrington C, Mathur M, Zheng K, Jariwala SP. ASTHMAXcel PRO patient satisfaction and usability field testing. *J Asthma*. 2024 Jan 16:1-10. doi: 10.1080/02770903.2024.2304615. Epub ahead of print. PMID: 38226774.
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  - Njeze O, Hsia B, Singh A, Cosar E, Kaur S, Jariwala S. The impact of education on health literacy of asthmatics in the Bronx. *Journal of Allergy and Clinical Immunology*. 2021 Feb 1;147(2):AB121.
  - Singh A, Njeze O, Cosar E, Kaur S, Hsia B, Jariwala S. The ASTHMAXcel pro mobile application for adult patients: Evaluating user satisfaction and adoption. *Journal of Allergy and Clinical Immunology*. 2021 Feb 1;147(2):AB49.
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A.2 A Direct-to-Patient Alert for Glycated Hemoglobin Screening Using Prediction Modeling and Mobile Health (mHealth)

Objective: Develop and evaluate a direct-to-patient PC CDS tool to improve the early identification of patients with hyperglycemia. The PC CDS text message intervention texts patients at high risk for abnormal glucose levels and offers them an option to test for hyperglycemia, a potential indicator of type 2 diabetes (T2D).

Health Issue: Approximately one-quarter of adult T2D cases go undiagnosed. T2D, characterized by elevated glucose levels, can result in serious complications and medical costs when left untreated. Diabetic screening consists of a hemoglobin A1c (HbA1c), or blood sugar level test, but despite current guidelines, many patients go unscreened. The project previously developed an HbA1c calculator to predict which patients without previous symptoms of diabetes or high blood sugar would have elevated HbA1c.

Health Issue: Type 2 Diabetes
PC CDS Factors: *Knowledge:* HbA1c calculator based on American Diabetes Association and U.S. Preventive Services Taskforce screening recommendations *Patient Data:* Predicted HbA1c levels using patient serum HbA1c test data. *Delivery:* Engages patients via text messaging alerting about screening eligibility. *Use:* Recommends patients for screening and orders HbA1c tests if patient agrees to screen for risk of diabetes.
Technology Intervention: Text Messaging
Intervention Setting: Primary care outpatient clinic

PC CDS Solution: One way to increase screening is to alert clinicians about which patients are at risk for hyperglycemia, as identified by the A1c risk calculator. To mitigate the potential for alert fatigue that may result from clinician-facing alerts, the project developed a direct-to-patient intervention to text at-risk patients to offer them screening. Patients' EHRs were queried weekly via a SQL process to determine which patients were eligible, and the A1c risk calculator determined which of these patients were at high risk for hyperglycemia and thus, eligible for screening. Lab results were then shared with both the patient and their clinician.

Project Results: The research team demonstrated the technical feasibility of a text-based direct-to-patient PC CDS solution is possible. Messages were sent to 500 individuals, but the majority either opted out or did not respond. Tests were ordered on 40 patients, 13 completed the test, and one individual was found to have elevated HbA1c levels. The project determined that low engagement was attributable to the COVID-19 pandemic, patient reluctance to respond to texts due to the prevalence of spam messages, and a patient-expressed desire to have their physicians involved in the screening. The findings suggest that patients accept text messages that alert them to a higher risk for elevated HbA1c but need clarification of the new processes in which they are asked to engage. Future research is necessary to determine whether these text messages lead to meaningful health behaviors in practice and whether this could apply to other opportunities.

Resources:

- **AHRQ Project Page**: https://digital.ahrq.gov/ahrq-funded-projects/direct-patient-alert-glycated-hemoglobin-screening-using-prediction-modeling
- **Final Report**: https://digital.ahrq.gov/sites/default/files/docs/citation/r21hs026803-wells-final-report-2022.pdf
- **Journal Publication:** Lenoir KM, Sandberg JC, Miller DP, Wells BJ. Patient perspectives on a targeted text messaging campaign to encourage screening for diabetes: Qualitative study. JMIR Form Res. 2023 Jan 17;7:e41011. doi: 10.2196/41011. PMID: 36649056; PMCID: PMC9890353.

A.3 Clinical Decision Support for Chronic Pain Management (CDS4CPM)*

Objective: Adapt, deploy, and evaluate an interoperable SMART on FHIR app, CDS4CPM, that reuses the Pain Manager Summary application by adding a patient-facing CDS component to gather patient-reported outcomes (PROs). The clinician-facing PainManager app supports shared decision making between patients and clinicians regarding chronic pain treatment plans.

Health Issue: Overuse, misuse, and abuse of prescription opioid medications are major factors contributing to the rise of opioid overdose rates in the past decade. PC CDS systems can consolidate patient information provided by patients regarding pain information and preferences to assist clinicians and patients in shared decision making discussions.

PC CDS Solution: CDS4CPM consists of two components: a patient-facing CDS app called MyPAIN and a clinician-facing application integrated in the EHR called PainManager. MyPAIN collects and transmits

Health Issue: Chronic pain
PC CDS Factors: • *Knowledge:* Aligns recommendations with Centers for Disease Control and Prevention (CDC) guidelines for prescribing opioids for chronic pain • *Patient Data:* Consolidates patient-specific data and PROs into a dashboard within the EHR • *Delivery:* Patient-facing MyPAIN app and clinician-facing PainManager app • *Use:* Supports shared decision making between clinician and patient
Technology Intervention: Patient-facing app, clinician-facing app
Intervention Setting: Primary care clinics

PROs to the clinician, provides the patient with relevant educational content, and incorporates the patient's information into the clinical encounter through the EHR to support shared decision making about pain management treatment recommendations. PainManager provides recommendations (aligned with CDC guidelines), contextual information, and alerts to clinicians based on the patient-submitted PROs, patient comorbidities, and other test results.

Project Results*: The research leveraged Health Level 7 (HL7) Fast Healthcare Interoperability Resources (FHIR) standards and builds upon resources available on CDS Connect, such as the Pain Management Summary. The project explored methodologies to display the potential risk from the patient's opioid use versus the benefit of daily functional activities. Additionally, this research identified gaps for future work on using externally generated patient data with information in the patient's EHR. It developed implementation guides and reusable, shareable PC CDS knowledge artifacts suitable for public posting on CDS Connect or other platforms. Evaluation of these shared decision making tools included assessing the impact and lessons learned during the development, implementation, and dissemination phases of the project.

Resources:

- **AHRQ Project Page:** https://digital.ahrq.gov/ahrq-funded-projects/clinical-decision-support-chronic-pain-management-rti

*Project results are not yet publicly available

A.4 Enabling Shared Decision Making to Reduce Harm from Drug Interactions: An End-to-End Demonstration (DDInteract)

Objective: Design and evaluate a patient-centered drug-drug interaction (DDI) CDS dashboard, called DDInteract. DDInteract enables decision support for potential DDI and facilitates shared decision making around the risks of different treatment options.

Health Issue: DDIs contribute to a significant share of adverse drug events, with some leading to hospitalization or death. While prior efforts have attempted to minimize the risk of DDIs by creating PC CDS tools that perform DDI checking, many alerts are often overridden by clinicians. Patients' involvement in the process could play a role in preventing DDIs, but patients are not typically engaged in shared decision making around the risks for DDIs.

PC CDS Solution: DDInteract was developed as an EHR-based SMART on FHIR app using CDS Hooks to support shared decision making around potential anticoagulant DDIs between warfarin and nonsteroidal anti-inflammatory drugs

Health Issue: Drug-drug interactions
PC CDS Factors: • *Knowledge:* A PC CDS dashboard allowing interaction with contextual CDS knowledge artifacts using CDS Connect • *Patient Data*: Patient risk profile integrates with EHR workflow • *Delivery*: App in EHR accessed by clinicians • *Use*: Shared decision making
Technology Intervention: SMART on FHIR app
Intervention Setting: Outpatient clinics with anticoagulation services

(NSAIDs). The project conducted user-centered design and usability assessments to inform iterative development and evaluate DDInteract via simulated encounters with physician/patient dyads randomly assigned to the usual standard of care or DDInteract.

DDInteract consists of a patient-specific risk profile (which accounted for current medications, history of prior gastrointestinal bleeds, and other risk factors), a visual risk calculator, a patient education section, and a decision tree to assist clinicians with structuring the shared decision making conversation.

Project Results: Overall, both patients and clinicians provided positive feedback on DDInteract. The usability assessment found that patient knowledge of warfarin-NSAID DDI varied, but all patient participants in the usability assessment appreciated the ability to see DDInteract while engaging with their clinician. Patients felt the tool empowered them to make decisions aligned with their preferences and expressed an interest in being able to view educational materials outside of the clinical encounter. Clinicians perceived DDInteract as helpful, effective, and efficient. Clinicians appreciated the risk calculator and the ability to move between the risk factors and the treatment options. However, clinicians were uncertain how the tool would fit into the clinical workflow.

As a result of patient feedback, the project made several changes to the tool, including adding non-medication treatment options, the ability to choose more than one non-NSAID treatment, educational material available outside of the app, and an after-visit summary. Based on the clinician feedback, the project simplified the visibility of patient information within the app to simplify clinician access and reduce the time needed to find patient education information within the tool.

Finally, while DDInteract was not designed for use outside of the clinical encounter, the project recommended that future research should allow patients to reference the tool outside of the clinical encounter to help with education and treatment adherence.

Resources:

- **AHRQ Project Page**: https://digital.ahrq.gov/ahrq-funded-projects/enabling-shared-decision-making-reduce-harm-drug-interactions-end-end
- **Final Report**: https://digital.ahrq.gov/sites/default/files/docs/citation/u18hs027099-malone-final-report-2022.pdf
- **Journal Publications**:
  - Reese TJ, Del Fiol G, Morgan K, Hurwitz JT, Kawamoto K, Gomez-Lumbreras A, Brown ML, Thiess H, Vazquez SR, Nelson SD, Boyce R, Malone D. A Shared Decision-making Tool for Drug Interactions Between Warfarin and Nonsteroidal Anti-inflammatory Drugs: Design and Usability Study. JMIR Hum Factors. 2021 Oct 26;8(4):e28618. doi: 10.2196/28618. PMID: 34698649; PMCID: PMC8579222.
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- **Implementation Guide**: HL7 Clinical Decision Support Workgroup. Potential Drug-Drug Interaction (PDDI) CDS IG; Implementation Guide; HL7, Balloted September, 2020.

A.5 Patient Outcomes Reporting for Timely Assessments of Life with Depression: PORTAL-Depression

Objective: Integrate the Computerized Adaptive Test for Mental Health (CAT-MH™), a computer-adapted test validated to assess mental health symptoms, including depression, into the patient portal and evaluate if portal-based screening improves depression screening rates and health outcomes compared to the usual standard of care.

Health Issue: Major depressive disorder (MDD) is a leading cause of disability in the United States. In primary care, depression screenings are conducted during clinic visits with patients. However, shorter durations of each visit can limit the clinician's ability to conduct screenings, particularly for patients with multiple health issues and competing priorities during clinic visits. In addition, patients may be unlikely to attend their primary care appointments or even schedule an appointment even if their symptoms indicate they should receive screening. More timely screenings and patient monitoring could be facilitated by digital health strategies that share results with clinicians regardless of whether patients schedule an appointment to be screened.

Health Issue: Major Depressive Disorder
PC CDS Factors: • *Knowledge*: Follows the U.S. Preventive Services Task Force screening guidelines for depression in adults and uses validated patient-reported outcome assessment CAT-MH • *Patient Data*: Gathers patient-reported symptoms of depression to inform clinical monitoring of at-risk patients • *Delivery:* Questionnaire administered in the patient portal and results stored in EHR for the clinician • *Use*: Patients screened for depression using an adaptive algorithm-based tool via the patient portal
Technology Intervention: Patient Portal
Intervention Setting: Primary Care

PC CDS Solution: The project implemented a system where the patient receives an email notification to log into their patient portal to complete the CAT-MH. Patients with an active patient portal account were randomized into two arms based on whether they had previously attended an appointment in primary care in the past 3 years. Reminders to complete the CAT-MH were sent bimonthly to patients with an active patient portal account for up to 6 months; if patients did not respond to reminders, new invitations were repeated until a patient indicated MDD remission or nonresponse to three invitations. Patients' results were stored in the EHR, and positive results were sent to the patient's primary care clinician's in-basket for review. After review, patients who did not already have a scheduled appointment were referred to a social worker for follow up.

Project Results: Patients who received and completed the patient portal depression screening had higher screening (43% versus 33%) and monitoring (59% versus 18%) rates, compared with those in the usual-care group. The project also found that patients screened via the portal were more likely to report depression symptoms compared to those receiving usual care. These findings suggest portal-based screening represents an opportunity to screen patients that may otherwise be missed but that need timely treatment and monitoring.

Rates of adoption also varied by patient characteristics, including race and insurance. Potential barriers to completing the portal-based screening included access to a web-enabled device to complete the screening, comfort level with web-based technology and devices, concerns about confidentiality, and perceived stigma surrounding mental health issues. More tailored portal messages might increase response rates, as well as larger efforts to encourage portal use.

Resources:

- **AHRQ Project Page:** https://digital.ahrq.gov/ahrq-funded-projects/patient-outcomes-reporting-timely-assessments-life-depression-portal-depression
- **Final Report:** https://digital.ahrq.gov/sites/default/files/docs/citation/u18hs026151-laiteerapong-final-report-2022.pdf
- **Journal Publications**:
  - Staab EM, Franco MI, Zhu M, Wan W, Gibbons RD, Vinci LM, Beckman N, Yohanna D, Laiteerapong N. Population health management approach to depression symptom monitoring in primary care via patient portal: A randomized controlled trial. Am J Med Qual. 2023 Jul-Aug 01;38(4):188-195. doi: 10.1097/JMQ.0000000000000126. Epub 2023 Jun 15. PMID: 37314235.
  - Franco MI, Staab EM, Zhu M, Knitter A, Wan W, Gibbons R, Vinci L, Shah S, Yohanna D, Beckman N, Laiteerapong N. Pragmatic clinical trial of population health, portal-based depression screening: The PORTAL-depression study. J Gen Intern Med. 2022 Sep 20:1–8. doi: 10.1007/s11606-022-07779-9. Epub ahead of print. PMID: 36127535; PMCID: PMC9488885.

A.6 Scalable Decision Support and Shared Decision Making for Lung Cancer Screening

Objective: Adapt an existing standalone shared decision making tool for lung cancer screening, DecisionPrecision, into a sharable, standards-based PC CDS called DecisionPrecision+ that can be integrated into clinical workflows in different EHRs. Evaluate the impact of DecisionPrecision+ and disseminate the tool to increase the use of appropriate lung cancer screening.

Health Issue: Lung cancer, a leading cause of death in the United States, necessitates screening to reduce lung cancer mortality rates through early detection. However, there is significant patient-level variation in the balance of expected benefits versus harm from screening. Currently, CDS tools to aid shared decision making for lung cancer screening are not integrated into the EHR, which can limit access. To address this need, this project developed an EHR-integrated shared decision making tool for lung cancer screening called DecisionPrecision+ that incorporates the U.S. Preventive Services Task Force guidelines.

Health Issue: Lung Cancer
PC CDS Factors: • *Knowledge*: A shared decision making PC CDS tool incorporating best practices and evidence-based guidelines for cancer screening • *Patient Data:* Incorporates patient-specific lung cancer risk factor information from the EHR • *Delivery:* App integrated in the EHR • *Use:* Tool promotes shared decision making by describing benefits and risks of lung cancer screening
Technology Intervention: SMART on FHIR app
Intervention Setting: Primary care & pulmonary clinics

PC CDS Solution: The project developed DecisionPrecision+ app using SMART on FHIR framework to integrate this PC CDS tool seamlessly into the clinical workflow within the EHR. The app provides individualized risk assessments based on risk factors such as age, smoking history (e.g., packs per day, years smoked, and pack years), and comorbidities (e.g., history of cancer, heart attack, hypertension). In the first phase of a two-phase clinical trial, the project developed and integrated clinician-facing prompts in the EHR to indicate a patient's eligibility for screening and to remind the clinician to conduct shared decision making with the patient. In the second phase, the project integrated a patient-facing reminder into the patient portal with recommendations to discuss lung cancer screening with their clinicians or, if they had already decided to undergo screening, to obtain the screening test at recommended intervals.

Project Results: DecisionPrecision+ was successfully integrated into two different EHR systems, and implementations are underway at multiple health systems including academic health systems, community health systems, and the Veteran's Administration. In the two-phase clinical trial, 22.8 percent of eligible individuals (278 out of 1219) were screened with low-dose computed tomography (LDCT) in phase 1 (clinician-facing interventions) and 23.7 percent of eligible individuals (298 of 1255) were screened with LDCT in phase 2 (clinician-facing interventions and patient-reminders). The DecisionPrecision+ app was used for 140 individuals in phase 1 and 168 individuals in phase 2. DecisionPrecision+ is now offered as a free tool that can be downloaded and used at any health system that supports SMART on FHIR apps.

Resources:

- **AHRQ Project Page**: https://digital.ahrq.gov/ahrq-funded-projects/scalable-decision-support-and-shared-decisionmaking-lung-cancer-screening
- **Final Report**: https://digital.ahrq.gov/sites/default/files/docs/citation/r18hs026198-kawamoto-final-report-2022.pdf
- **Journal Publications**:
  - Reese TJ, Schlechter CR, Potter LN, Kawamoto K, del Fiol G, Lam CY, et al. Evaluation of Revised US Preventive Services Task Force Lung Cancer Screening Guideline Among Women and Racial/Ethnic Minority Populations. *JAMA Netw Open*. 2021 Jan 12;4(1):e2033769. Available from: https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2774854.
  - Strasberg HR, Rhodes B, del Fiol G, Jenders RA, Haug PJ, Kawamoto K. Contemporary clinical decision support standards using Health Level Seven International Fast Healthcare Interoperability Resources. *J Am Med Inform Assoc* . 2021 Aug 1;28(8):1796–806. Available from: https://pubmed.ncbi.nlm.nih.gov/34100949/.
  - Kawamoto K, Kukhareva PV, Weir C, Flynn MC, Nanjo CJ, Martin DK, et al. Establishing a multidisciplinary initiative for interoperable electronic health record innovations at an academic medical center. *JAMIA Open*. 2021 Jul 31;4(3):ooab041. Available from: https://academic.oup.com/jamiaopen/article/4/3/ooab041/6333015.
  - Reese TJ, Schlechter CR, Kramer H, Kukhareva P, Weir CR, del Fiol G, et al. Implementing lung cancer screening in primary care: needs assessment and implementation strategy design. *Transl Behav Med*. 2022 Aug 16;12(2):187– 97. Available from: https://pubmed.ncbi.nlm.nih.gov/34424342/.
  - Kukhareva P V, Weir C, Del Fiol G, Aarons GA, Taft TY, Schlechter CR, et al. Evaluation in Life Cycle of Information Technology (ELICIT) framework: Supporting the innovation life cycle from business case assessment to summative evaluation. *J Biomed Inform*. 2022 Mar 1;127(1532–0480):104014.
  - Kukhareva P, Caverly T, Li H, Katki H, Cheung L, Reese T, et al. Inaccuracies in electronic health records smoking data and a potential approach to address resulting underestimation in determining lung cancer screening eligibility. *J Am Med Inform Assoc*. 2022 Apr 13;29(5):779–88.
  - Kukhareva PV, Li H, Caverly TJ, Del Fiol G, Fagerlin A, Butler JM, Hess R, Zhang Y, Taft T, Flynn MC, Reddy C, Martin DK, Warner IA, Rodriguez-Loya S, Warner PB, Kawamoto K. Implementation of Lung Cancer Screening in Primary Care and Pulmonary Clinics: Pragmatic Clinical Trial of Electronic Health Record-Integrated Everyday Shared Decision-Making Tool and Clinician-Facing Prompts. *Chest*. 2023 Nov;164(5):1325-1338. doi: 10.1016/j.chest.2023.04.040. Epub 2023 May 3. PMID: 37142092; PMCID: PMC10792294.
  - Kukhareva PV, Li H, Caverly TJ, Fagerlin A, Del Fiol G, Hess R, Zhang Y, Butler JM, Schlechter C, Flynn M, Reddy C, Choi J, Balbin C, Warner IA, Warner PB, Nanjo C, Kawamoto K. Lung Cancer Screening Before and After a Multifaceted Electronic Health Record Intervention**.** *JAMA Network Open*. 2024; 7(6):e2415383. Doi:10.1001/jamanetworkopen.2024.15383

A.7 Scaling Interoperable Clinical Decision Support for Patient-Centered Chronic Pain Care (MyPAIN & PainManager)

Objective: Tailor, implement, and evaluate two AHRQ interoperable CDS tools, MyPAIN and PainManager, to support shared decision making processes used in chronic pain management and improve patient care and health outcomes.

Health Issue: Efforts to address opioid use disorder and overdose have led to a decline in opioid prescribing. However, this has led to concerns for patients with chronic pain impacted by changes to prescribing practices. Clinicians stand to benefit from tools that assist with making prescribing choices that balance risks and benefits of myriad treatment options available for chronic pain. To help ensure patients receive the right treatment that considers patients' health history and preferences, clinicians should incorporate shared decision making. PC CDS tools can facilitate this shared decision making process for both patients and clinicians.

Health Issue: Chronic Pain
PC CDS Factors: • *Knowledge:* Uses evidence-based chronic pain management treatment guidelines to assist in pain care planning. • *Patient Data:* Incorporates patient-reported data on pain and physical function. • *Delivery:* Integrates a patient-facing app within the patient portal. • *Use:* Promotes shared decision making between clinicians and patients by aiding in treatment plan selection.
Technology Intervention: EHR dashboard; Patient-facing app
Intervention Setting: Primary care clinics

PC CDS Solution: The project used existing CDS for chronic pain management: MyPAIN, a patient-facing CDS, and PainManager, an EHR-integrated dashboard application. The project conducted focus groups, workgroups, and usability assessments with multidisciplinary teams, including patient collaborators, to tailor both tools to the implementation sites. The project plans to integrate the PC CDS into eight clinics at University of Florida Health and evaluate barriers and facilitators to further scaling to other systems with different EHRs.

Project Results: The project is ongoing and research results are forthcoming. Methods for the research are as follows: the project will first tailor the functionality and user interface of the existing PainManager tool through a series of interviews and design sessions with both patients and primary care clinicians. They will then implement the tool in EHRs across eight clinics within the OneFlorida Clinical Research Consortium system to support shared decision making for pain treatment. In a randomized staggered rollout approach, the PC CDS implementation will consist of training, technical assistance, and workflow assessments. The project will conduct a mixed-methods study and evaluate the implementation process by assessing adaptation, feasibility, and contextual factors. The project expects the tailored implementation support will increase PC CDS adoption and shared decision making, leading to improved chronic pain management and patient outcomes. These anticipated outcomes will inform the importance of tailored implementation and the benefits of technology to improve care for chronic pain.

Resources:

- AHRQ Project Page: https://digital.ahrq.gov/ahrq-funded-projects/scaling-interoperable-clinical-decision-support-patient-centered-chronic-pain-care#nav-research-story
- Final Report: Forthcoming
- Journal Publication (Study Protocol): Salloum RG, Bilello L, Bian J, Diiulio J, Paz LG, Gurka MJ, Gutierrez M, Hurley RW, Jones RE, Martinez-Wittinghan F, Marcial L, Masri G, McDonnell C, Militello LG, Modave F, Nguyen K, Rhodes B, Siler K, Willis D, Harle CA. Study protocol for a type III hybrid effectiveness-implementation trial to evaluate scaling interoperable clinical decision support for patient-centered chronic pain management in primary care. Implement Sci. 2022 Jul 15;17(1):44. doi: 10.1186/s13012-022-01217-4. PMID: 35841043; PMCID: PMC9287973. Available at https://pubmed.ncbi.nlm.nih.gov/35841043/

A.8 Shareable, Interoperable Clinical Decision Support for Older Adults: Advancing Fall Assessment and Prevention Patient-Centered Outcomes Research Findings Into Diverse Primary Care Practices (ASPIRE)

Objective: Develop, refine, and test shareable, interoperable fall prevention PC CDS using AHRQ's CDS Connect Authoring Tool and the HL7 CQL standard. Subsequently implement and evaluate the PC CDS tool in an urban and rural primary care clinic.

Health Issue: Older adults, who are at highest risk for falls, need to receive appropriate interventions, education, and referrals from their primary care clinicians to address fall risk factors. However, clinicians do not routinely ask at-risk patients about falls or their associated risk factors. Prior research also shows that patients who experience falls are unlikely to address further fall prevention in primary care settings, making the need for fall prevention and effective care plans more important.

Health Issue: Fall Prevention
PC CDS Factors: • *Knowledge:* Used evidence-based decision rules to support fall risk assessment in primary care • *Patient Data:* Used patient fall-risk screening data • *Delivery:* Implemented a clinician-facing EHR app that provided printable handouts for patients • *Use:* Shared care plan collaboration tool to address fall risk factors
Technology Intervention: Clinician-facing EHR app
Intervention Setting: Rural and urban primary care clinics

PC CDS Solution: The project developed a shareable, interoperable, decision support tool for fall risk assessment and prevention, Advancing Fall ASsessment and Prevention PatIent-Centered Outcomes REsearch Findings into Diverse Primary Care Practices (ASPIRE). ASPIRE supports primary care clinicians in developing care plans that include evidence-based fall prevention strategies and engaging patients in shared decision making discussions. ASPIRE generates fall prevention recommendations based on patients' risk factors associated with mobility, osteoporosis, and fall risk-increasing drugs. The fall prevention recommendations presented to the clinician include exercise/mobility improvement, fall risk increasing drug deprescribing, and osteoporosis management tasks and evidence-based talking points for patient education. Clinicians

also have the option to print handouts for patients. The project conducted formative and summative usability sessions with clinicians and patient-actors to develop ASPIRE before implementing it in two primary care clinics.

Project Results: Usability was rated above average, and time-on-task decreased significantly between the first and second scenarios, indicating good learnability. However, acceptability data were more mixed, with some recommendations being consistently accepted while others were adopted less frequently.

Overall, implementation of ASPIRE was successful, and clinicians agreed that the tool helped engage patients in fall prevention. Clinicians in rural settings reported being able to find the tool easily in their EHR, but urban clinicians expressed more difficulty locating the tool within their respective EHR. When clinicians were able to access the tool, they spent approximately 4 to 5 minutes using the tool. Clinicians most frequently used the exercise/mobility recommendations. The project also found that of clinicians who accessed the tool, they did not always accept the decision support presented to them. However, time was a barrier to use since clinicians needed to address multiple health issues with older patients other than fall prevention. Clinicians also noted that some steps such as copying notes to the after-visit summary and entering recommended orders took extra time to complete because they were not fully automated.

Resources:

- **AHRQ Project Page:** https://digital.ahrq.gov/ahrq-funded-projects/shareable-interoperable-clinical-decision-support-older-adults-advancing-fall
- **Final Report:** https://digital.ahrq.gov/sites/default/files/docs/citation/u18hs027557-dykes-final-report-2022.pdf
- **Journal Publications:**
  - Shear K, Rice H, Garabedian PM, Bjarnadottir R, Lathum N, Horgas AL, Harle CA, Dykes PC, Lucero R. Usability Testing of an Interoperable Computerized Clinical Decision Support Tool for Fall Risk Management in Primary Care. *Appl Clin Inform*. 2023 Mar;14(2):212-226.
  - Shear K, Horgas AL, Lucero R. Experts' Perspectives on Use of Fast Healthcare Interoperable Resources for Computerized Clinical Decision Support. *Comput Inform Nurs*. 2023 Oct 1;41(10):752-758.
  - Shear K, Rice H, Garabedian PM, Bjarnadottir R, Lathum N, Horgas AL, Harle CA, Dykes PC, Lucero R. Management of Fall Risk Among Older Adults in Diverse Primary Care Settings. *J Appl Gerontol*. 2023 Nov;42(11):2219-2232.
  - Schentrup D, Middlemas A, Shear K, Bjarnadottir RI, Lucero RJ. Fall risk management using clinical decision support in a rural nursing-led primary care practice. *J Am Assoc Nurse Pract*. 2022 Aug 1;34(8):1033-1038.
  - Rice H, Garabedian PM, Shear K, Bjarnadottir RI, Burns Z, Latham NK, Schentrup D, Lucero RJ, Dykes PC. Clinical decision support for fall prevention: Defining end-user needs. *Appl Clin Inform*. 2022 May;13(3):647-655.

A.9 Translating Hypertension Guidelines into Practice: Development of Interoperable Clinical Decision Support (COACH)

Objective: Translate current hypertension treatment guidelines in clinical quality language (CQL) query modules, build CDS artifacts using the CDS Connect Authoring Tool, and build a FHIR standards-based application which fosters shared decision making and provides guidance to patients and clinicians for blood pressure management.

Health Issue: Clinical care of patients with high blood pressure (HBP) faces several challenges including: 1) low patient engagement due to lack of awareness of elevated blood pressure (BP) or failure to follow home monitoring guidelines, 2) conflicting treatment guidelines, and 3) insufficient CDS tools to aid clinical decision making for treatment recommendations. Patient-facing PC CDS that is designed in accordance with the 5 Rights of CDS and that encourages patient goal setting can promote patient engagement and involvement in their care while also providing their clinician with key health information to improve shared decision making.

PC CDS Solution: The project produced an implementation guide which encoded the clinical guidelines as logic using CQL. The team also developed an EHR-integrated PC CDS tool, Collaboration Oriented Approach for Controlling HBP (COACH), which can retrieve patient demographics, BP readings and goals, and current medications from the patient's medical record and display it in the EHR for the user. The tool can be launched from either within the EHR or the patient's Epic MyChart. The tool displays a set of recommendations for the patient which could include goal setting, counseling, or contacting the patient's care team. Patients can also enter BP readings, view their current medications, and see whether they are following their prescribed BP monitoring protocol. The study team conducted interviews and surveys with patients to gather input on usability, and clinicians were presented with different patient personas and recommendations to gather feedback on the tool's logic pathways.

Health Issue: Hypertension
PC CDS Factors: • *Knowledge*: Used 71 recommendations from clinical practice guidelines to develop decision logic. • *Patient Data*: Incorporated patient's BP history, patients' BP goals, medications, prior adverse drug events, and recommendations based on patient's data and clinical guidelines. • *Delivery*: Patient-facing CDS for HBP management • *Use*: Engage patients in controlling HBP
Technology Intervention: Patient portal app, EHR-based dashboard
Intervention Setting: Primary care

Project Results: Patients viewed self-monitoring and control of BP through PC CDS applications favorably, and many who completed home monitoring indicated a preference for the tool to include a more complete view of their information (e.g., BP history, clinician-endorsed goals, possible pharmacologic interventions). Patients indicated high levels of trust in their clinicians' recommendations. Patient survey results also indicated they were willing to act on information presented in the tool. The survey results demonstrated that patients placed a high priority on BP management and that PC CDS can be used to better engage patients in shared decision making.

Clinicians' acceptance of at least one of the guideline's recommendations ranged from 65 percent for pharmacologic recommendations, to 70 percent for those related to diagnosis and monitoring, to 100 percent for non-pharmacologic treatments. However, non-pharmacologic recommendations required more patient input than pharmacologic recommendations, and diagnosis and monitoring was burdened by unreliable BP measurements and the reliance on patients to do self-monitoring. The project reported that the instances when clinicians chose to deviate from the clinical recommendations was a result of variation between the established guidance and the specific patient characteristics (such as comorbidities, treatment adherence, or social need), and clinicians opted to deviate from clinical guidelines rather than gather more input from the patient.

The project also found that many ICD-10-CM codes were infrequently or never used. For example, BP management goals were uncoded, limiting the ability to personalize the PC CDS for individual patients. Non-pharmacologic interventions also had limited mapping in the EHR, and alerts would fire on approximately 10 percent of patients, possibly leading to alert fatigue. The project determined that these results demonstrate the importance of prior data quality and logic testing to prevent clinician alert fatigue.

Resources:

- **AHRQ Project Page**: https://digital.ahrq.gov/ahrq-funded-projects/translating-hypertension-guidelines-practice-development-interoperable-clinical
- **Final Report**: https://digital.ahrq.gov/sites/default/files/docs/citation/u18hs026849-dorr-final-report-2022.pdf
- **Implementation Guide**: OHSU Hypertension IG Home Page. Oregon Health and Science University. 2020. Available at: https://build.fhir.org/ig/OHSUCMP/htnu18ig/index.html
- **Journal Articles**:
    - Dorr D, D'Autremont C, Richardson JE, Bobo M, Terndrup C, Dunne MJ, Cheng A, Rope R. Patient-facing clinical decision support for high blood pressure control: Patient survey. *JMIR Cardio*. 2023 Jan 23;7:e39490. doi: 10.2196/39490. PMID: 36689260.
    - Dorr DA, Richardson JE, Bobo M, D'Autremont C, Rope R, Dunne MJ, Kassakian SZ, Samal L. Provider perspectives on patient- and provider-facing high blood pressure clinical decision support. *Appl Clin Inform*. 2022 Oct;13(5):1131-1140. doi: 10.1055/a-1926-0199. Epub 2022 Aug 17. PMID: 35977714; PMCID: PMC9713301.
    - Dorr DA, D'Autremont C, Pizzimenti C, Weiskopf N, Rope R, Kassakian S, Richardson JE, McClure R, Eisenberg F. Assessing data adequacy for high blood pressure clinical decision support: A quantitative analysis. Appl Clin Inform. 2021 Aug;12(4):710-720. doi: 10.1055/s-0041-1732401. Epub 2021 Aug 4. PMID: 34348408; PMCID: PMC8354347.

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