Standards and Regulatory Frameworks Workgroup: Environmental Scan

Agency for Healthcare Research and Quality
5600 Fishers Lane
Rockville, MD 20857
www.ahrq.gov

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Prepared by:
Prashila M. Dullabh, MD, FAMIA
Priyanka J. Desai, PhD, MSPH
Janna R. Gordon, PhD
Desirae Leaphart, MPH
Kala S. Wilson, PhD
Rachel L. Richesson, PhD, MPH, FACMI
Aziz Boxwala, MD, PhD, FACMI
CDSiC Standards and Regulatory Frameworks Workgroup

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PURPOSE

The CDS Innovation Collaborative (CDSiC) Standards and Regulatory Frameworks Workgroup is charged with identifying, monitoring, and promoting standards for the development of patient-centered clinical decision support (PC CDS) and examining the current state of the regulatory environment. The Workgroup is comprised of 13 experts and stakeholders representing a diversity of perspectives within the CDS community. This environmental scan is intended to be used by the broader CDS community to advance the use of standards for PC CDS. The CDSiC will also use the scan to inform product development under its Stakeholder and Community Outreach Center Workgroups and for projects developed through its Innovation Center.

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Contributors: CDSiC Standards and Regulatory Frameworks Workgroup

Members of the Standards and Regulatory Frameworks Workgroup who contributed to this report are listed below.

Name	Affiliation
Guilherme Del Fiol, MD, PhD	University of Utah
James Doyle	Epic
Floyd Eisenberg, MD, MPH	iParsimony
Sonja Fulmer, PhD	FDA
Evelyn Gallego, MBA, MPH, CPHIMS	EMI Advisors
Robert Jenders, MD, MS, FACP, FACMI	University of California Los Angeles
Lawrence McKnight, MD, MS	Oracle Cerner
Daniella Meeker, PhD	Yale School of Medicine
Chris Moesel	MITRE
Bryn Rhodes	Alphora
Alissa Russ, PhD	Purdue University
Howard Strasberg, MD	Walters Kluwer Health

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Executive Summary

Patient-centered clinical decision support (PC CDS) provides innovative ways to ensure patients, caregivers, and care teams have patient-specific, evidence-based clinical guidance to inform healthcare decision making. Particularly, PC CDS that incorporates patient-generated health data (PGHD) or other patient-centered data (e.g., patient preferences and social determinants of health [SDOH]) enhances patient and clinician decision making by providing a fuller picture of a patient's needs, preferences, health, and social risk factors. PC CDS will have the most impact when these data can be integrated into electronic health records (EHRs) and other digital health technologies to support patient engagement—to produce clinical recommendations that account for unique patient needs and preferences. To achieve this vision, PC CDS must be accessible wherever and whenever clinicians and patients prefer to receive it, in a manner that is easy for both groups to understand and act upon in both clinical and nonclinical settings.

This environmental scan assesses the current landscape of standards and regulatory frameworks for PC CDS to determine gaps, challenges, and opportunities to advance PC CDS. Based on the scan's findings, the report provides an action plan of opportunities to address gaps and challenges in the current PC CDS landscape. The intended audiences for this document are clinicians, CDS researchers, CDS content developers, EHR developers, app developers, device and wearable manufacturers, health IT standards developers, policymakers, patients/caregivers, and payers.

Methods

The environmental scan pursued three high-level objectives relevant to PC CDS: 1) examine the current state of standards and regulatory frameworks; 2) identify salient gaps, opportunities, and challenges; and 3) develop an action plan. The CDS Innovation Collaborative (CDSiC) team first conducted a scoping review of the peer-reviewed and gray literature relevant to PC CDS standards and regulatory frameworks. Key informant interviews (KIIs) supplemented the literature review findings to fill gaps in the literature and to gather perspectives on future directions for PC CDS. The team then analyzed qualitative data and validated opportunities for the field with the CDSiC Standards and Regulatory Frameworks Workgroup.

An Action Plan for Moving Forward

After reviewing 190 publications and resources, the team documented standards, initiatives, and resources that shape the technical landscape for PC CDS (Appendix B); and laws, frameworks, initiatives, and guidance documents that inform the regulatory landscape (Appendix C).

The Technical Landscape for PC CDS

We mapped the findings related to PC CDS standards to the eight stages of the PC CDS technical landscape.[1] The eight stages are used here to describe 40 opportunities in the form of an action plan that can be used by varied stakeholders in the CDS community to advance the field of PC CDS.

Stage 1: Standards for Translating Clinical Guidelines into PC CDS. Development of PC CDS requires translating clinical guidelines into knowledge artifacts. The Fast Healthcare Interoperability Resources (FHIR®) Clinical Guidelines Implementation Guide (CPG-IG) can provide a standardized approach to knowledge translation, while the Clinical Quality Language (CQL) can support standardized representation of clinical knowledge into CDS artifacts. Emerging standards, such as those from the Business Process Management+ (BPM+) initiative, can support coordinated workflows for decision making among patients and all members of their care team. We identified six opportunities for advancement at this stage:

- Develop guidance on how CDS artifact developers can work with guideline developers when building PC CDS artifacts.
- Promote specification of standards and systematic approaches to translating guidelines into CDS artifacts.
- Promote adoption of CQL by EHR developers, who have relied historically on proprietary standards.
- Recognize the need for standard approaches and shared resources to aggregate granular codes used locally by health systems to capture clinical data into the broad categories used in clinical practice guidelines.
- Support further development and adoption of the CPG-IG, and engage guideline developers to support its adoption.
- Recognize the need for standardized representation of workflow, and further examine emerging standards such as BPM+.

These opportunities will require collaboration between EHR developers, CDS content developers, and healthcare organizations to standardize methods for systematic approaches to translating guidelines into formal representation. Federal agencies, standards-development organizations, and professional medical societies must work in partnership to encourage adoption and consistent use of standards across medical specialties.

Stage 2: Standards for Managing Data Provenance. To trust the data that drive PC CDS, clinicians and patients alike must be able to consistently and reliably identify the source of those data (i.e., data provenance). Standards such as FHIR Provenance can support the representation and tracking of provenance data from different data sources. Efforts such as the Food and Drug Administration's unique device identification (UDI) policy, which requires medical devices to have a human- and machine-readable identification number, will help with the provenance of device data. We identified three opportunities for this stage based on the current state of standards:

[1] Dullabh P, Heaney-Huls K, Lobach DF, et al. The technical landscape for patient-centered CDS: progress, gaps, and challenges. J Am Med Inform Assoc. 2022 May 11;29(6):1101-1105.

- Consider initiatives to highlight the importance of data provenance, further awareness and adoption of FHIR Provenance, and evaluate FHIR Provenance in the context of PC CDS.
- Engage patients to further develop the FHIR Provenance standard to address the use of patient-provided and patient-generated data.
- Develop provenance standards that allow for representation and interpretation of the UDIs associated with medical devices, as well as the tracking of data tied to specific UDIs.

Advancing data provenance standards will require coordinated efforts from standards-development organizations to both develop new standards and encourage the use of existing standards such as FHIR Provenance. Federal agencies may play a role in highlighting the importance of data provenance through national initiatives. EHR developers, app developers, and wearable and device manufacturers will need to support the adoption of these standards.

Stage 3: PGHD Standards. Terminology standards such as Logical Observation Identifiers Names and Codes (LOINC) and SNOMED Clinical Terms (SNOMED CT) currently have limited PGHD coverage. Coverage of patient-reported outcomes (PROs) and other types of patient-generated or patient-reported data in standard terminologies is currently unknown, which makes it difficult to prioritize further code development for PRO data elements. To promote the use of PROs in PC CDS, developers may be able to leverage the Health Level Seven (HL7®) FHIR PRO Implementation Guide. We identified eight opportunities for this stage based on the current state of standards:

- Conduct research to assess current coverage for PGHD and PRO terms in standardized controlled coding systems such as LOINC and SNOMED CT.
- Where gaps exist, advocate for greater coverage of PGHD concepts as well as PRO measures in standard terminologies such as LOINC and SNOMED CT.
- For both PGHD and PROs, develop consumer-friendly extensions of terminology standards.
- Develop a shared taxonomy of different types of PGHD that can support systematic approaches to developing standards and guidance documents for different types of PC CDS.
- Promote use of FHIR-based, standardized patient-facing apps to collect PROs.
- Support PC CDS developers' adoption and use of the PRO FHIR Implementation Guide.
- Support research, including pilot projects, to generate evidence on how PGHD standards can improve healthcare and health outcomes.
- Examine methods for verifying PGHD (e.g., through linkages to complementary information in the EHR) to ensure PC CDS safety and appropriateness.

Terminology standards-development organizations need to lead the development and use of PGHD standards; however, these efforts must include patients and patient representatives to ensure that patients' needs and preferences are addressed. These efforts will also require coordination with device and wearable manufacturers and app developers, with additional support from EHR developers, health systems, and Federal funding agencies, which can incentivize research related to PGHD.

Stage 4: Standard PC CDS Insertion Points. Appropriate CDS insertion points are crucial to provide effective CDS because the clinician may ignore, or the patient may deem irrelevant, poorly timed CDS prompts. HL7's CDS Hooks specification and the FHIR Subscription resource provide a promising avenue forward. The current state of the field leads to five opportunities for advancement at this stage:

- Promote adoption of CDS Hooks and FHIR Subscription within EHRs.
- Increase the number and granularity of possible CDS insertion points in the EHR.
- Adapt CDS Hooks and FHIR Subscription to support trigger logic from patient interaction events.
- Facilitate the use of CDS Hooks for population health management approaches.
- Promote adoption of standardized, automated clinical workflows, such as through BPM+.

These opportunities will require that standards-development organizations address the limitations of current standards. Furthermore, the adoption of existing and new standards for PC CDS insertion points is unlikely to advance without the support of EHR developers.

Stage 5: Standards for Nonclinical Patient-Centered Data. The field needs to further develop mechanisms to standardize patient-preference and SDOH data, as well as to integrate these data into the clinical workflow. The Gravity Project is advancing both terminology and data exchange standards for SDOH, including developing a FHIR implementation guide. The current state of the field leads to four opportunities at this stage:

- Support further informatics research to understand how to standardize and use patient preferences in PC CDS and shared decision making.
- Develop terminology standards to capture the full range of patient preferences needed to support clinical recommendations.
- Promote the Gravity Project's data elements for including SDOH in PC CDS and examine use of the Gravity Project's FHIR implementation guide to support SDOH data exchange for PC CDS.
- Explore how other initiatives can mirror the Gravity Project's practices for data steward engagement.

Standards-development organizations—working in conjunction with patients and patient representatives—will need to drive opportunities to standardize patient-preference data.

Stage 6: Integration of PGHD into EHRs. Much of the PGHD collected through PC CDS apps are stored and reviewed outside the EHR, which makes it difficult to review these data in the clinical workflow. Substitutable Medical Applications, Reusable Technologies (SMART) on FHIR programming interfaces (APIs) and the SMART Markers software framework support the sharing of PGHD and the integration of PGHD from devices into the clinical workflow. We identified three opportunities for this stage based on the current state of standards:

- Invest in research that examines capabilities to leverage current standards to support PGHD integration into the EHR.
- Support development of new standards for PGHD data integration based on patient and clinician input regarding what types of data and data sources are most critical for full EHR integration.
- Examine use of frameworks such as SMART Markers to support PGHD integration for PC CDS.

Health systems can promote new standards for PGHD integration by prioritizing PGHD use in clinical care and advocating for the adoption of these standards by EHR developers. The adoption of PGHD integration standards among EHR developers will be essential for advancing the integration of PGHD in the clinical setting.

Stage 7: CDS-Focused APIs. FHIR-based APIs can support PGHD sharing and integration; however, API developers' adoption of FHIR standards varies, and FHIR APIs often do not support writing information to the EHR database. We identified three opportunities for this stage based on the current state of standards:

- Promote development of FHIR-based APIs that support data exchange to inform PC CDS.
- Focus new FHIR-based API development on patient data access and write capabilities, and engage patients in developing these APIs.
- Develop the FHIR resources that are most needed for common types of PGHD and PC CDS.

For these opportunities, standards-development organizations will need to develop standards that allow data to be written back to the EHR, while EHR developers will need to adopt and implement these standards. Furthermore, health systems must work with patients and clinicians to develop processes for using PGHD to inform clinical care.

Stage 8: APIs for Bulk Data Export to Inform PCOR. A critical step in the PC CDS development lifecycle is the aggregation of patient-level data across patient populations. Aggregation of EHR data supports research (e.g., retrospective data analyses) and can be used to support clinical decision making (i.e., aggregating data at the point of care). Standards are emerging; the SMART/HL7 Bulk Data Access (Flat FHIR) API, for example, supports bulk data export. We identified five opportunities for this stage based on the current state of standards:

- Differentiate use cases for using bulk data (e.g., informing research and data aggregation for point-of-care decision making).
- Develop greater granularity in the Bulk FHIR specification.
- Explore relationships between Bulk FHIR and other standards like CQL and CDS Hooks.
- Encourage research sponsors to require use of the FHIR Bulk Data Access API.
- Examine the potential of common data models to support bulk data export for PC CDS.

For these opportunities, standards-development organizations will need to provide additional resources and guidance to recognize the potential of bulk data export. EHR developers, researchers, Federal agencies, and payers will have an important role in supporting the development of use cases and adoption and implementation of these standards

Additional Opportunities for PC CDS Standards. Additional considerations that transcend specific stages within the PC CDS technical landscape speak to the need for 1) a robust technical infrastructure to ensure that PC CDS is more easily deployed for patients and incorporated into clinical workflows, and 2) collaboration among the larger community of CDS stakeholders, including standards-development organizations and CDS developers to address challenges that broadly impact PC CDS. We identified five opportunities based on the current state of the technical landscape:

- Develop additional technical infrastructure to support PGHD collection and PC CDS tools using Android-based devices to match the capabilities of iOS-devices such as that of the FHIR-compatible Apple HealthKit.
- Support advancement of standardized processes for curating PGHD data.
- Specify and promote common approaches for modeling terminologies and coding within FHIR resources.
- Consider avenues for greater dissemination of information about standards across the broader PC CDS community.
- Promote use of standards to enable patient oversight of proxy access.

The Federal Landscape

Multiple Federal agencies provide guidance on CDS and have supported its adoption and use. Additional opportunities to advance PC CDS center around multistakeholder efforts between the public and private sectors, as follows:

Patient Trust, Transparency, and Safety. Evolving Federal efforts to engage patients and ensure transparency appear to be at the forefront of regulation pertaining to PC CDS. A multistakeholder effort, including patients, can develop a patient safety framework for PC CDS app development to ensure these tools achieve better quality of patient care.

Artificial Intelligence (AI) Ethics Frameworks. Ethics frameworks are becoming more prominent, particularly related to the ethics of using AI to process PGHD and different forms of patient-reported data. An established and widely adopted ethical and safety framework to guide PC CDS app development can ensure patient data are secure and remain within a patient's control when moving from patients' devices or EHRs to third-party apps. The AI Ethics Framework by the Office of the Director of National Intelligence provides AI ethics principles intended to provide guidance on whether and how to develop and use AI to process PGHD and communicate with clinicians or third-party applications.

Codes of Conduct for PC CDS App Development. An abundance of apps currently provides patients and clinicians information about patients' health that could inform healthcare decisions. Multistakeholder efforts, including both public and private sectors, can be convened to develop a coordinated set of fundamental principles for PC CDS developers to adhere to, including an emphasis on improving patient trust and transparency, healthcare equity, and healthcare quality.

Interoperability. With the advent of multiple patient apps, it is important to ensure interoperability so PC CDS apps can integrate with healthcare IT systems used by clinicians. The public and private sector should continue to promote interoperability and employ quality improvement initiatives around such efforts.

Conclusion

The standards and regulatory landscape for PC CDS is evolving to meet new opportunities and challenges presented by broad consumer adoption of mobile technology and healthcare systems' transformation toward whole-person, value-based care. While significant progress has been made to date, additional standards are needed to guide the representation, verification, and integration of

patient-contributed data into both clinician- and patient-facing PC CDS tools. Furthermore, regulatory efforts are under way to ensure patient trust and safety, promote patient data access and privacy, improve interoperability, and address challenges related to the emerging use of AI in clinical care. Given that the regulatory landscape influences the adoption and use of CDS standards and tools, CDS regulations and standards will need to evolve in parallel to optimally advance PC CDS development and adoption. This environmental scan provides suggestions for a path forward to removing current barriers to PC CDS, addressing emerging challenges, and fully embracing the potential of PC CDS.

1. Introduction

Patient-centered clinical decision support (PC CDS) proposes innovative ways to ensure patient-specific, evidence-based clinical guidance is delivered to the appropriate recipients. PC CDS must be accessible wherever and whenever clinicians and patients prefer to receive it, and in a manner that is easy for them to understand and act upon in both clinical and nonclinical settings. PC CDS incorporating patient-generated health data (PGHD) or other patient-centered data (e.g., patient preferences and social determinants of health [SDOH]) has immense potential to enhance patient and clinician decision making by drawing upon patient-specific data to improve patient-clinician communication and facilitate shared decision making. PC CDS will have the most impact when these data can be integrated within the electronic health record (EHR) to reduce clinician burden, support patient engagement, and produce clinical recommendations.

This environmental scan assesses the current landscape of PC CDS standards and regulatory frameworks, culminating in opportunities that form an action plan for addressing barriers in the current PC CDS landscape.

1.1 Background

The healthcare ecosystem is in an unprecedented transition in how it approaches care, payment, and research. Ideally, this transition gives rise to a learning health system that provides value-based, whole-person care that results in positive patient outcomes and addresses systemic issues like bias, racism, and disparities in healthcare and outcomes.[1] To make this vision a reality, clinicians and patients must have access to computable, up-to-date, evidence-based recommendations consistent with the Clinical Decision Support (CDS) Five Rights (the right information, to the right person, in the right format, through the right channel, at the right time in the workflow)[2] and FAIR (findable, accessible, interoperable, reusable) principles,[3] free from biases in data and algorithms that risk perpetuating healthcare inequalities.

Ensuring patient and clinician access to the most up-to-date recommendations will require additional development of the CDS infrastructure to render it more sharable, scalable, and standards-based, and to introduce greater consistency in translating guidelines into computable formats. The discipline and practice of CDS have evolved significantly in recent years. The emergence of Health Level Seven (HL7®) Fast Healthcare Interoperability Resources (FHIR®)—as well as standards such as Clinical Quality Language (CQL), CDS Hooks, and Substitutable Medical Applications, Reusable Technologies (SMART) on FHIR—are beginning to reduce CDS deployment and integration barriers.

Advancing the utility of PC CDS will also require a research agenda to better understand what constitutes the “right” places, times, channels, and formats for CDS implementation.[4] Consumers' increased use of mobile technologies and broadband internet has placed CDS directly in the hands of patients, allowing them to become more engaged participants in their own healthcare. Other technological advancements, such as artificial intelligence (AI) and machine learning, offer new opportunities to deliver PC CDS. For example, existing AI-based CDS software is being deployed throughout healthcare systems to analyze data related to family history, lifestyle changes, and laboratory results; identify at-risk patients; manage diseases; and support patient goals and preferences.[5] This software also supports other preventive and diagnostic measures, such as analyzing

heart rhythms from wearables or other devices to detect conditions such as atrial fibrillation or other abnormalities.[5,6] A supportive regulatory landscape that reinforces and promotes PC CDS adoption and use is also needed to realize the quintuple aim of improving population health, enhancing patients' care experience, reducing costs, reducing healthcare worker burnout, and advancing health equity.[7,8]

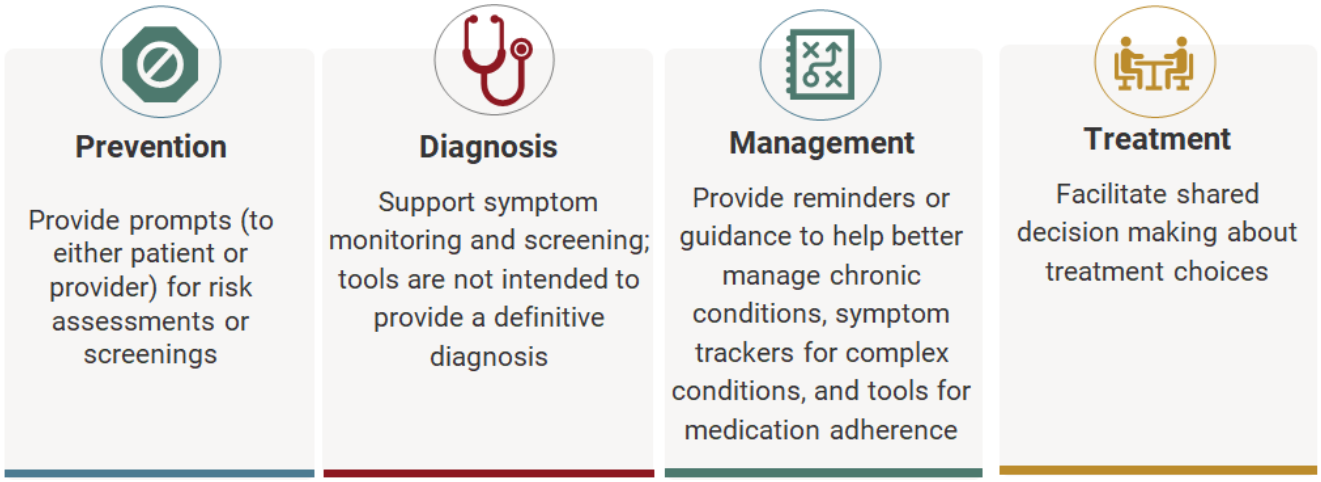
1.2 Defining PC CDS

PC CDS is defined as "tools that significantly incorporate patient-centered factors related to knowledge, data, delivery, and use."[9] In PC CDS, these factors are reflected on a continuum indicating the degree to which they focus on patient needs and experiences. Under this definition, *knowledge* is based on comparative effectiveness research or patient-centered outcomes research (PCOR) that incorporates meaningful outcomes for patients. These meaningful outcomes are derived from *data* generated directly from patients, such as PGHD, patient-reported outcomes (PROs), and/or nonclinical patient-centric data. The *delivery* of PC CDS entails directly engaging patients and caregivers via apps or patient portals across a range of settings. Finally, this patient engagement establishes the *use* of PC CDS by supporting direct patient or caregiver involvement and applying decision support as part of a shared decision making process.

1.3 Use Cases for PC CDS

PC CDS can support care teams in four areas—preventing disease, diagnosing a patient through monitoring and screening, managing a patient's condition through reminders or guidance, or facilitating shared decision making with the patient for a treatment plan (**Exhibit 1**),[9] as briefly elaborated below with use cases and examples. Many of the projects described below were funded by the Agency for Healthcare Research and Quality (AHRQ).

Exhibit 1. Current Uses of PC CDS



1.3.1 Prevention

PC CDS tools designed to address disease prevention typically involve providing prompts to patients and/or clinicians for screenings and risk assessments. Tools may include online or app-based calculators or questionnaires that provide personalized risk scores or screening recommendations

based on patient health information and demographic characteristics. For example, Decision Precision+ is a standards-based shared decision making tool for lung cancer screening.[10] Using patient demographic and health data (e.g., patient conditions, family member history, observations) from the EHR, the tool provides a personalized risk assessment and recommendations regarding lung cancer screening. This information can then be used for shared decision making about screening between patients and clinicians.[11]

1.3.2 Diagnosis

PC CDS tools can support clinicians in making diagnoses by monitoring signs and symptoms. However, these tools are not designed to provide a definitive diagnosis. Per the Food and Drug Administration (FDA), a medical diagnosis must come from a clinician, not a device (for further discussion of the regulatory landscape for CDS, see section 3.2.1).[12] CDS tools that support clinicians in making diagnoses cover a range of conditions and clinical areas, such as breast cancer, head injuries,[13] and cardiovascular disease.[14] Over the course of the COVID-19 pandemic, several CDS tools were developed to help clinicians track and assess symptoms to diagnose patients with COVID-19 and determine disease severity.[15,16] CDS developers are also exploring the use of machine learning—a type of AI that allows systems to draw inferences from data—for decision support to help predict clinical complications and outcomes for COVID-19 patients.[17]

1.3.3 Management

PC CDS is often used to manage chronic diseases and conditions like diabetes, hypertension, chronic kidney disease, and cardiovascular disease.[18] These tools may draw upon patient-provided data (e.g., daily at-home blood sugar or blood pressure readings) and/or laboratory values (e.g., hemoglobin A1C readings) to determine the need for decision support. For example, CDS interventions focused on diabetes management may provide patient-specific recommendations based on patient laboratory values. These tools can incorporate specific health and self-management goals (e.g., complete daily blood sugar readings and exercise for 30 minutes per day) as part of the recommendations.[19] PC CDS may also be used to manage acute conditions. Recently, CDS tools have facilitated remote patient monitoring during the COVID-19 pandemic. A PC CDS tool, piloted at Yale New Haven Health System as part of AHRQ's PCOR CDS: Current State and Future Directions Project, collected PGHD about COVID-19 symptoms via a remote patient monitoring app. These data, collected daily, helped clinicians and care coordinators monitor COVID-19 remotely and provide guidance about symptom management.[20,21]

1.3.4 Treatment

PC CDS can be used to facilitate decision making about treatment across a range of diseases and conditions. In particular, PC CDS can facilitate shared decision making about treatment options among patients, caregivers, and care teams, and support patients in weighing the benefits and risks of treatment options. Although a common use for PC CDS within this context is shared decision making about cancer treatments,[22,23,24,25] PC CDS can be used to support shared decision making across a range of conditions and diseases. CDS developers and researchers are also exploring innovative methods, such as AI, to generate treatment recommendations for individuals with chronic diseases.[26] In

addition to selecting treatment options, PC CDS can be used to facilitate discussions about treatment options and avoid potential side effects or drug interactions.[27,28] For example, the DDInteract app was designed to help patients and clinicians avoid the risk of gastrointestinal bleeding for patients taking both warfarin, a blood thinner, and a nonsteroidal anti-inflammatory drug.[28,29] Based on patient EHR data, the app calculates a risk score for gastrointestinal bleeding.

1.4 Roadmap of Report

This report provides key findings and gaps in the current PC CDS standards and regulatory environment, as well as recommendations that form an action plan for the future. Chapter 2, *Methods*, details the environmental scan process—including the primary research questions, organizing framework, and approaches used for the literature review and key informant interviews (KIIs). Chapter 3, *Key Findings: The Landscape of PC CDS,* organizes the findings for standards according to the eight stages in the PC CDS technical landscape and presents an analysis of the Federal landscape. The report ends with Chapter 4, *Discussion: An Action Plan for Moving Forward*, which discusses opportunities that should be embraced to attain a promising future for PC CDS.

2. Methods

The environmental scan pursued three high-level objectives relevant to PC CDS: 1) examine the current state of standards and regulatory frameworks; 2) identify salient gaps, opportunities, and challenges; and 3) develop an action plan. The CDS Innovation Collaborative (CDSiC) team conducted a scoping review of the peer-reviewed and gray literature relevant to PC CDS standards and regulatory frameworks. Key informant interviews (KIIs) supplemented the literature review findings to fill gaps in the literature and to gather perspectives on future directions for PC CDS. The team analyzed qualitative data and validated opportunities for the field with the CDSiC Standards and Regulatory Frameworks Workgroup. These methods are briefly expanded below (see **Appendix A** for detail).

2.1 Scoping Review

The environmental scan was built on a previous Horizon Scan of the PC CDS landscape.[30] Given that the previous scan captured much of the published literature related to standards, the team conducted a targeted scoping review to capture peer-reviewed and gray literature (including regulatory frameworks and guidance documents) published from 2019 through June 2022. To identify additional peer-reviewed literature, team members searched PubMed. To access gray literature, they searched Google and Google Scholar, targeting specific websites and resources such as Healthcare Information and Management Systems Society (HIMSS),[31] the Office of the National Coordinator for Health Information Technology (ONC),[32] HL7 FHIR,[33] Open mHealth,[34] and HL7 white papers.[35]

The initial peer-reviewed literature search yielded 123 articles from PubMed. The team conducted two levels of screening—a title/abstract and a full-text review. At each level, team members assessed whether the reviewed records appeared to meet the eligibility criteria (**Appendix A**) and assigned one of the following codes: 1) *eligible*, 2) *ineligible*, or 3) *uncertain*. Forty-nine records deemed *eligible* or *uncertain* at the title/abstract level were screened again at the full-text review. Following full-text screening, 22 peer-reviewed articles were included in our scan. An additional 36 peer-reviewed articles

were shared by colleagues or identified through supplemental PubMed and hand searches. In addition, 132 gray literature resources (i.e., webpages, guidance documents, white papers, reports) were identified by Workgroup members, through Google searches, and by directly searching relevant websites. In total, the scan included 190 publications and resources: 58 from the published literature, and 132 from the gray literature.

2.2 Key Informant Interviews

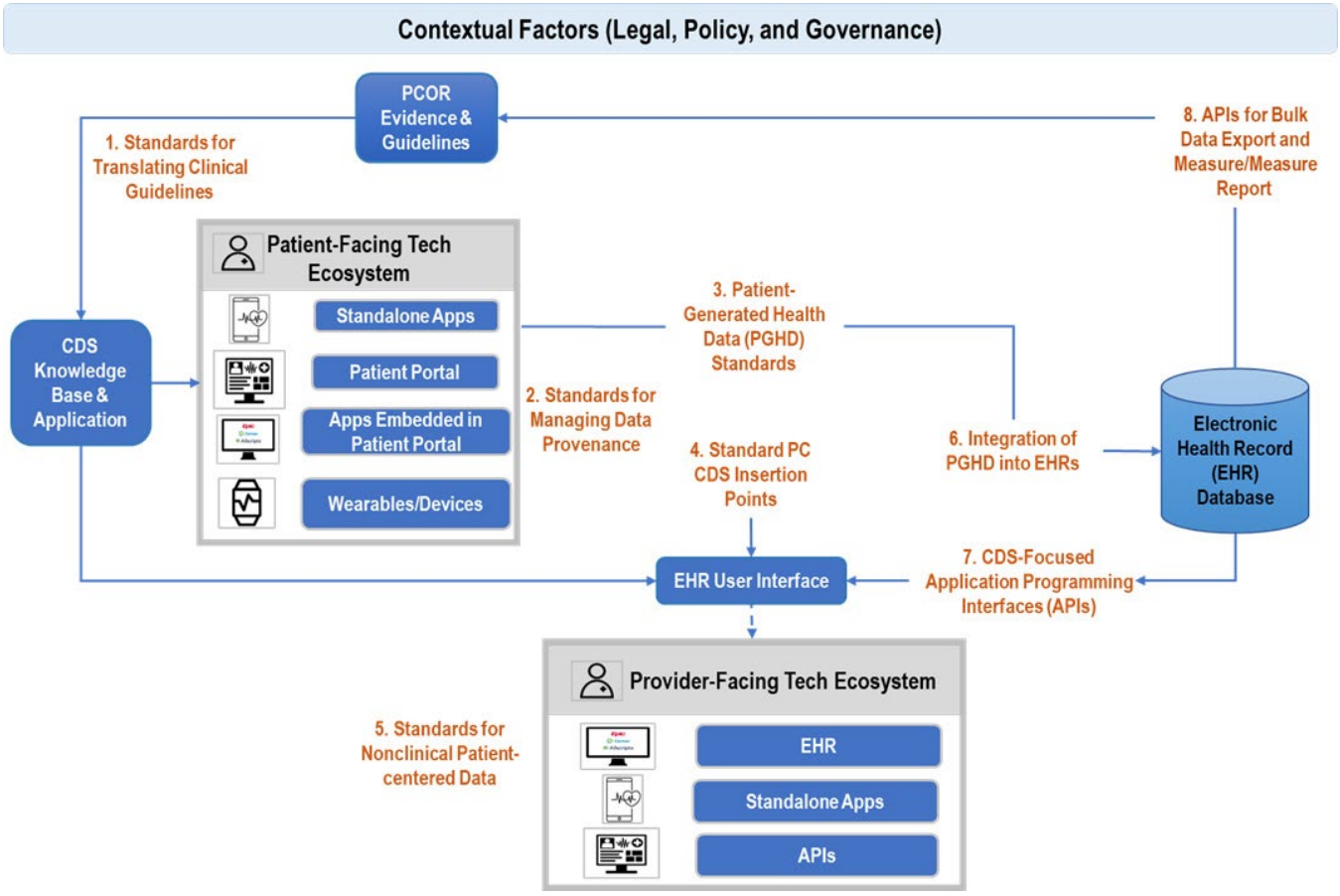
KIIs gathered additional perspectives on the facilitators, challenges, current and future standards for PC CDS, and future directions for PC CDS research and initiatives. Between July and September 2022, the team interviewed nine key informants who were experts in diverse disciplines related to PC CDS, organized into six main categories: CDS artifact developers (n=1), standards developers (n=1), informaticians (n=4), app developers (n=1), and representatives from patient groups or advocacy organizations (n=2).

Semistructured discussion guides for each stakeholder type allowed the interviewer to steer the conversation toward the key informant's expertise. Each interview was conducted via Zoom, audio recorded, and lasted approximately 60 minutes. Transcript-style notes were created for each interview to support analysis.

2.3 Analysis and Synthesis

To assess PC CDS standards, the team used an analytic framework depicting the technical landscape for PC CDS, which provides a comprehensive view of the various stages of the PC CDS lifecycle (**Exhibit 2**).[30] Using this analytic framework enabled analysis of standards-related findings for PC CDS functioning as a rubric for organizing the findings that emerged from the published and gray literature and KIIs. The team used an inductive approach to analyze the themes within and across interviews to map the findings to the technical landscape. Finally, the team validated the current standards and regulatory landscape and opportunities for the field with the CDSiC Standards and Regulatory Frameworks Workgroup.

Exhibit 2. Technical Landscape for PC CDS



Ratings of adoption for standards and implementation guides were adapted from the 2022 ONC Interoperability Standards Advisory (ONC ISA) (**Exhibit 3**).[36] ONC ISA defines adoption as "a standard or implementation specification that is being used in health information technology (IT) in the field by end users to address the specific interoperability need."

Exhibit 3. ONC ISA Adoption Levels

Scale Ratings	Indicated Adoption Level
●●●●●	High or widespread adoption
●●●●○	Medium-high adoption
●●●○○	Medium adoption
●●○○○	Low-medium adoption
●○○○○	Low adoption
"Feedback Requested"	Does not have a known status for the current level of adoption in healthcare within the United States

For the regulatory landscape, the team organized guidance and frameworks by Federal agencies to identify key actors that impact PC CDS, and potential gaps in existing guidance.

3. Key Findings: The Landscape for PC CDS

Across the technical landscape, we identified a range of relevant standards, initiatives, and resources for PC CDS, as well as gaps in adoption and use of existing standards and areas where new standards are needed. Across the regulatory landscape, we identified multiple Federal agencies that provide guidance on CDS use and adoption, including ONC, Centers for Medicare & Medicaid Services (CMS), AHRQ, Centers for Disease Control and Prevention (CDC), and FDA. Findings are in the sections that follow (see **Appendix B** for a summary of standards, initiatives, and resources and **Appendix C** for a summary of regulatory frameworks).

3.1 PC CDS Standards

This section organizes the findings within the following eight stages of the PC CDS technical landscape[30]: 1) standards for translating clinical guidelines into PC CDS, 2) standards for managing data provenance, 3) PGHD standards, 4) standard PC CDS insertion points, 5) standards for nonclinical patient-centered data, 6) integration of PGHD into EHRs, 7) CDS-focused application programming interfaces (APIs), and 8) APIs for bulk data export to inform PCOR. This section also discusses additional considerations for PC CDS standards that transcend discrete stages in the technical landscape.

3.1.1 Standards for Translating Clinical Guidelines into PC CDS

Standards for translating clinical guidelines into PC CDS are essential for incorporating evidence-based guidelines into PC CDS tools. Inclusion/exclusion criteria, decision rules, and recommendations must be represented in computable and portable formats to enable broader and more rapid dissemination of evidence-based PC CDS tools across patient engagement applications (apps), healthcare systems, and health IT systems.[30]

A promising approach to the systematic translation of scientific knowledge into PC CDS involves the use of a multilayered framework for structuring guideline recommendations.[37] The first layer is narrative text developed by guideline authors to communicate evidence and recommended policies. The second layer is semistructured, organized text that provides recommendations for implementing the guidelines in PC CDS. The third layer comprises structured, coded knowledge artifacts that define all elements needed for CDS in a standard, sharable representation. The last layer comprises executable, coded knowledge artifacts that are localized and interpretable by a particular clinical IT system for the purpose of CDS.

Current state, gaps, and challenges for standards for translating clinical guidelines into PC CDS

Multiple standards are designed to encourage translation of clinical guidelines into sharable knowledge artifacts that can be incorporated into PC CDS tools. The main standard currently available is the FHIR Clinical Reasoning module.[38] FHIR's Clinical Reasoning Module provides resources (such as PlanDefinition) to represent and share clinical knowledge artifacts, such as CDS rules and clinical protocols. FHIR Clinical Reasoning also supports the use of questionnaires, which enables the exchange of patient-contributed information that can be integrated into PC CDS tools.

Clinical Quality Language. FHIR Clinical Reasoning leverages CQL, a standardized, FHIR-compatible expression language.[39] CQL is a standard for representing clinical knowledge (e.g., guidelines and recommendations) in both human and computable formats. While CQL provides the flexibility for use with different data models, compatibility with FHIR resources has been its major requirement during its development. This distinguishes CQL from prior efforts to develop standard expression language for CDS logic (e.g., GELLO and Arden Syntax)[40] and makes it a leading candidate for translating clinical guidelines as FHIR adoption increases. The Clinical Reasoning module facilitates the exchange of CQL knowledge artifacts that can be incorporated into computable PC CDS tools.

According to the 2022 ONC ISA, adoption of the Clinical Reasoning module is low-to-medium,[36] and adoption of CQL to facilitate sharable CDS is medium-to-high. However, for providing patient-specific assessments and recommendations, the 2022 ONC ISA characterizes adoption of CQL as medium. Recent examples of CQL adoption include the AHRQ CDS Connect Authoring Tool and Repository, which support artifact developers in producing knowledge artifacts in CQL.[41] While not specifically a CDS use case, CMS has adopted CQL as the standard for electronic clinical quality reporting measures used for several different quality reporting programs.[42]

> *[CQL] is a language that is mature enough now to make building and scaling much easier….How do we build infrastructure tools and platforms with the initial upfront investment that makes the rest of the scaling much easier and faster? CQL was the right tool for the job. It's designed to build CDS…. The challenge with CQL is it is not yet fully mature and not used routinely across the world for CDS, especially for rules engines…The companies building rules engines are using a whole range of typically proprietary software tools from various countries. They are interested in what they can do by converting to CQL.…*
>
> *When we started pushing CQL and the related standards, they [EHR developers] already had invested in whatever tech platform they were on…they had many years of legacy code. There was not much expertise to help them—they had to figure out how to learn it themselves.* - **CDS Artifact Developer**

Consistent with the literature, key informants noted that, at present, CQL is largely used for disseminating quality measures rather than CDS knowledge artifacts.[40] In addition, key informants cited limited adoption by EHR developers, who still tend to use proprietary software tools for their rules engines and do not provide tools for translating CQL to their native formats. EHR developers may not feel compelled to prioritize native support of CQL until knowledge artifact developers create a sufficient critical mass of CQL content. Developers may be similarly hesitant to create new CQL content until more EHR developers adopt CQL. Even so, increasing the representation of clinical guidelines and knowledge in CQL may support EHR developers in rewriting CDS logic inside their products, thus smoothing the transition to native CQL rules engines in the future.

Key informants also identified other specific challenges for CQL. They noted that, at present, the standard may not be mature enough for broad-scale adoption, and that while CQL rules engines operate quickly, executing APIs to retrieve patient data (evaluated by the CQL expressions) often requires significant processing time to access data from a remote server, which has negative implications for scalability (e.g., retrieving data from EHRs of smaller practices that may have limited computational resources or slower internet connection speeds). Finally, key informants revealed that currently, only a limited number of CQL experts exist to assist with CQL dissemination and adoption.

Emerging Standards. Other emerging standards promoting dissemination of sharable knowledge artifacts include FHIR Resources for Evidence-Based Medicine (EBMonFHIR)[43] and BPM+ Health.[44] The HL7 EBMonFHIR project provides a standard for exchanging clinical research evidence and clinical practice guidelines. The project was initiated in 2018, with development accelerating quickly due to the clinical information needs posed by the COVID-19 pandemic. In addition, the Fast Evidence Interoperability Resources (FEvIR) Platform, a tool developed by the leader of the EBMonFHIR project, promotes uptake of FHIR standards for evidence-based knowledge.[45] FevIR provides developers with numerous tools to build and view scientific knowledge as standards-based, computable HL7 resources that can be used in authoring PC CDS knowledge artifacts.[46] Since EBMonFHIR is a new and emerging standard, it is not yet included in the 2022 ONC ISA report.

BPM+ is a community initiative launched in 2019 to apply business process management (BPM) standards to clinical care workflows and processes, with the goal of promoting sharable evidence-based guidelines and care pathways.[44] BPM+ enables creation of automated clinical pathways that can be disseminated to institutions. BPM+ standards are complementary with existing standards such as FHIR and CQL. BPM+ care pathways and clinical workflows can enable coordination among multiple stakeholders (e.g., patient, primary care and specialist physicians, community-based healthcare professionals) in decision making and in ensuring the decision is enacted reliably.

> *To me, the most important gap right now is the complete lack—other than what we are advocating for in the BPM+ Health world—of any process automation standards across healthcare. Healthcare is not an encounter; healthcare is not an event. Healthcare is long-ranging, hopefully cost-contained, keeping people out of hospitals and executing best practices over time, in an agile learning health system fashion. You know, the fact that it still takes 17 years of the latest clinical best practices to make it into clinical care…* - **Informatician**

FHIR Implementation Guides. Implementation guides are also available to aid PC CDS developers in applying a standardized approach to knowledge translation. The FHIR Clinical Guidelines Implementation Guide (CPG-IG) assists developers in creating computable and accurate representations of clinical guidelines while minimizing duplicative efforts.[47] The CPG-IG specification was borne out of CDC's Adapting Clinical Guidelines for the Digital Age initiative, which aimed to identify more efficient and reliable approaches to translate clinical information into digital products.[48] To date, the 2022 ONC ISA characterizes CPG-IG adoption as low-medium, and its use has largely been in federally funded projects.[36,49]

Other HL7 Standards. Key informants also identified legacy standards used to represent knowledge artifacts, including GELLO[50] and Arden Syntax.[51] Both are HL7 standards, but neither was designed for use with a standard data model. GELLO was released in 2003 to represent clinical guidelines, specify decision criteria, and facilitate the sharing of decision logic.[52] Although Arden Syntax has been in use for more than three decades, CDS knowledge artifacts created using Arden Syntax historically have not been portable across EHRs due to Arden Syntax's reliance on proprietary mechanisms for data retrieval (i.e., the "curly braces problem"). However, Arden Syntax 3.0 is now in development and will incorporate FHIR to improve interoperability.[53] This could facilitate adoption of PC CDS tools in those health IT systems that use Arden Syntax. GELLO and Arden Syntax currently have limited adoption and are largely viewed as legacy standards.

Other Considerations. For PC CDS tools to leverage sharable knowledge artifacts, software developers and health systems must be able to aggregate granularly coded data into the broad conceptual groups represented in clinical guidelines. For example, different vendors and healthcare systems may use different diagnostic codes to represent whether a given patient has type 2 diabetes or has tests or treatments indicative of the condition. These various codes need to be combined into a single group of codes that all represent type 2 diabetes, which can be achieved using value sets[54] or computable phenotype definitions.[55] Projects like the Value Set Authority Center (VSAC),[56] Phenotype Knowledge Base (PheKB),[57] and Hexodes[58] are working to make logic to aggregate different detailed codes into broad categories.

3.1.2 Standards for Managing Data Provenance

Patients and their caregivers contribute numerous types of health data, both within and outside the clinical setting. The HL7 Patient Empowerment Workgroup has documented these data types, which include patient demographics, health history, family health history, medication information, patients' request for corrections in the medical record, symptoms, biometric tracking, lifestyle tracking (e.g., diet, sleep, physical activity), PROs, treatment goals and preferences, and healthcare data the patient acquires that can be shared with other health organizations.[59] These data can be solicited by the healthcare team (i.e., data clinicians have asked a patient to track, such as sleep, blood pressure, or blood glucose) or be unsolicited (i.e., data individuals collect to understand and manage their own health). These data can also come from a variety of sources, such as remote monitoring devices (e.g., wearables, implants, or mobile health apps), questionnaires or prompts (e.g., health histories, PRO measures), and previous clinical settings.[59,60]

Patient-contributed data provide critical information about patients' health conditions, lifestyles, goals, and priorities: all information that can be used by PC CDS tools to provide personalized care. To date, however, few healthcare systems have been able to capture the origin (provenance) of these data. Lack of information about where the data originated makes using these data for PC CDS challenging. If clinicians know and trust the source of data, they may be more inclined to use those data for PC CDS. If patients know and trust the source of data, they may be more inclined to use recommendations from PC CDS tools. To integrate patient-provided data into CDS, standards are needed to consistently and reliably identify the source of data.

> *One of the things that I have seen a lot of times is the black box—you do not know what happened with the data or where it came from, until it came to you. And therefore, it is less trustworthy in that regard.* - **Informatician**

Current state, gaps, and challenges for standards for managing data provenance

The standards landscape for data provenance is still in its infancy. Overall, FHIR resources have varying support for representing provenance information. For example, the Observation resource allows associating an Observation data instance with a Device resource.[61] The FHIR Provenance resource, developed using the World Wide Web Consortium's (W3C's) Provenance Ontology (PROV-O), is the only major healthcare standard currently available to support the representation and tracking of

provenance data from different data sources. Limited provenance information is included in the US Core FHIR Implementation Guide. In addition, developing regulations hold some promise of progress.

PROV-O. Released in 2013, PROV-O is part of the PROV family of documents that define the components needed to facilitate the interoperable exchange of provenance information.[62] PROV-O provides a set of classes, properties, and restrictions developers can use to represent, exchange, and integrate provenance information across heterogenous systems and contexts. PROV-O was used by HL7 FHIR to create the FHIR Provenance resource.[63] FHIR Provenance tracks information about the activity that created, edited, or deleted a resource. FHIR Provenance allows for encoding activities involving different agents—including practitioners, organizations, devices, the patient, and people related to the patient (i.e., relatives or friends). This allows for the integration of patient-contributed data into clinician-facing health IT systems, while enabling PC CDS to account for potential differences between data gathered in the clinic and data gathered remotely (e.g., measurement error in home versus clinic blood pressure monitoring). Adoption of FHIR Provenance for representing data provenance has not yet been established by the ONC ISA.[36]

> *Provenance should be a much richer resource than it is. For example, I have collected my data, and then I forward them to a specialist so that they have access to my data. Provenance, currently as it's defined in the standards, doesn't have anything about the trail that that data has come from.*
>
> *If you do provenance right, you can tell whether it's still the same data that came from a clinical setting and passed through the patient without being changed, or whether the person has made changes. And that felt like an important distinction because we didn't want data that is held in the custody of patients to be dismissed as not equivalent to the same data that they might get from physician to physician or organization to organization transfer* - **Patient Representative**

FHIR Implementation Guides. The US Core FHIR Implementation Guide facilitates consistency around how and what patient data are accessed, as well as security standards used to authenticate, authorize, and audit data access.[64] The specifications are based on the United States Core Data for Interoperability (USCDI), a standardized set of health data elements that support interoperability and information exchange.[65] Provenance is included in the US Core FHIR Implementation Guide. However, per the current USCDI (version 3.0), the US Core Provenance only includes metadata pertaining to the Authoring Organization and Time Stamp.[66,67] This does not allow data to be attributed to an individual outside the health system (e.g., data contributed by patients or caregivers).[59]

Ongoing Initiatives. The regulatory landscape may also impact the need for data provenance standards. In July 2022, FDA posted final guidance for its unique device identification (UDI) policy.[68] When fully implemented, this UDI system will require every medical device to have a human- and machine-readable identification number. This information can be used to inform PC CDS rules that can accommodate PGHD from different medical devices. Provenance standards will need to allow for the representation and interpretation of UDIs and tracking of data tied to specific UDIs. To ensure data quality, there will also need to be mechanisms for ensuring consistency of UDI data for third-party manufacturers or resellers of medical devices.

3.1.3 Patient-Generated Health Data Standards

PGHD are "health-related data created, recorded, or gathered by or from patients (or family members or other caregivers) to help address a health concern."[69] PGHD include health history, treatment history, biometric data, symptoms, and lifestyle factors. These data are often collected via devices and mobile applications outside the clinical setting, such as through biometric monitoring (e.g., monitoring of sleep, oximetry, weight, heart rate, blood glucose, blood pressure, physical activity) and patient reporting of symptoms, treatments, and lifestyle factors (e.g., mood, psychological stress, smoking behavior).[70,71]

Incorporating PGHD collection into routine clinical care enables development of tailored PC CDS based on patient-driven insights gleaned from patients' everyday lives. These data can improve the prevention, diagnosis, and management of emergent and chronic diseases.[70] Industry-wide standards are needed for the capture and representation of PGHD data. These standards will allow for development of PC CDS tools that can integrate various PGHD elements, including data from different smartphones, apps, and medical devices.

> *Lots of the things that generate the opportunities for PC CDS are because patients are actually feeding data in. They're tracking their meals or exercise or they're wearing an Apple Watch or they're logging peak flows; they're doing things that are generating data. And yet we don't tend to take that data and use it to personalize the guidance we provide. For example, "we've noticed that, on the weeks when you report X in your exercise, or Y in your food tracking, you're actually losing more weight or reporting better sleep"… and that sort of insight-driven stuff is a form of PC CDS that is based on the intersection between where the population is and where the individual is, and using both to actually provide feedback and insights.* - **Patient Representative**

Current state, gaps, and challenges for PGHD standards

Standardized Terminologies. Standardized capture of PGHD is an emerging area. The Logical Observation Identifiers, Names, and Codes (LOINC) and SNOMED Clinical Terms (SNOMED CT) coding systems currently have limited coverage of PGHD data, but many PGHD concepts are within the scope of LOINC and SNOMED CT and can be accommodated by their conceptual models.[72,73] For example, LOINC can accommodate answers to patient-directed queries (e.g., "what type of pain do you experience with your headache?"[74]) as well as summary metrics from patient-facing applications (e.g., total steps) or devices (e.g., average blood glucose level, highest glucose value in the past week). LOINC also established a panel that contains biometric observations from wearable devices specifically—including heart rate, body temperature, blood pressure, and activity level[75]—and provides terminology for dietary intake and sleep duration.[76,77] Similarly, SNOMED CT provides codes for symptoms and vital signs (e.g., heart rate, glucose monitoring) that can be applied to PGHD. Both the LOINC and SNOMED CT standards-development organizations have mechanisms that enable users to submit requests for new terms.[78,79]

Although LOINC and SNOMED CT will likely be able to accommodate the representation of a broad range of PGHD concepts in the future, the adoption of LOINC and SNOMED CT for PGHD currently varies across developers, and the translation of PGHD from languages other than English is extremely limited.[70] Furthermore, there is limited coverage of standard terms for health consumers, who may use

different vocabulary in communicating health information (e.g., use of “pain killer” vs. “analgesic”).[80] The 2022 ONC ISA ratings for adoption of SNOMED CT and LOINC range from low to high depending on the type of observation (e.g., low adoption for representing patient health concerns, functional status, and alcohol use; high adoption for representing tobacco use).[36]

Ongoing Initiatives. Open mHealth, a mobile health initiative, aims to enable developers to standardize data from various mHealth data sources (e.g., wearable devices, mobile apps) to promote interoperability with EHR and external care platforms. Open mHealth has coverage of different types of PGHD—including blood pressure, sleep (e.g., duration, time to sleep onset, number of awakenings), physical activity (e.g., pace, duration, distance, intensity), blood glucose, body temperature, medication adherence, and heart rate.[81] We were not able to find any specific information on the adoption of Open mHealth, but key informants noted that Open mHealth is actively working on developing more standards for representing PGHD and on mapping these to FHIR. Key informants also highlighted that Open mHealth is complementary with HL7 FHIR, allowing for the mapping of Open mHealth data elements to FHIR resources.

CardinalKit, available for both iOS and Android, is an open-source framework to assist app developers in creating interoperable digital health tools. CardinalKit provides features such as survey generation, adherence monitoring, and collection of health and movement data from smartphones and other Bluetooth-enabled devices, all represented using Open mHealth and HL7 FHIR standards.[82]

> *[There are] no requirements that anybody who's building those apps or tools is storing it in the same standardized format used in clinical settings. There’s certainly an overlap between data that people might share about themselves and clinical data; there isn't a reliable assumption that data that you're getting from an app or device that's in your custody as a consumer device is actually going to have interoperable data with your readings in a clinic so that you could really look at it over time with those caveats.* - **Patient Representative**

Gaps in PGHD Standardization. Due to the emerging nature of PGHD data capture and use, several gaps in data standardization remain. One key informant noted that, although many medical devices collect the same data (e.g., blood glucose), different manufacturers code and store data in different ways, which precludes development of PC CDS that can be applied across different brands. Another key informant noted that there are currently no requirements for consumer-facing applications to store data in standardized ways that allow PGHD to be interoperable with clinical data. Thus, app developers currently have little incentive to use standards-based methods for data capture.

Key informants also described challenges in understanding “time persistence” associated with PGHD from devices (i.e., what happened, when, and for how long). To date, continuous data (e.g., monitoring that occurs every 10 seconds) has been difficult to represent using existing standards. Furthermore, key informants noted that there are some PGHD metrics for which there is no standard coding available, such as physical activity (e.g., swimming strokes, cycling cadence). Informants noted that these data need to be mapped to a standard to be useful for PC CDS. Key informants also stated that mapping free text (e.g., text entered about symptoms) to a standard is a current challenge, and recommended use of FHIR implementation guides and profiles for this purpose.

You see a similar pattern with patient-generated data then as well, there are things that just do not traditionally fit into the FHIR model, and then have to be shoehorned into resources that were not bespoke for that. And then using semantic standards to kind of lay a context on top of that. A lot of that is kind of developer's choice. And when you give that level of developer's choice, the level of standard of the data starts to erode. - **Informatician**

Patient-Reported Outcomes

While under the umbrella of patient-contributed data, PROs are distinct from PGHD in that PRO data are generated through standardized questionnaires or surveys that gather information about the patient experience, such as quality of life and function.[83] Furthermore, these data are often solicited directly by the care team. In the context of PC CDS, these data can inform clinical recommendations and shared decision making discussions between patient and clinician.

A wide range of PRO measures can be collected to inform healthcare decision making,[84] with terminology standards for some measures further developed than others. LOINC currently has coverage for PRO domains spanning behavioral health, cardiology, dermatology, orthopedics, neurology, physical activity, and pediatrics, including the Patient Reported Outcomes Measurement Information System (PROMIS).[85,86] However, LOINC does not cover the full range of PROs that may be measured across different specialties or conditions.

Challenges Related to PRO Standardization. The coverage of PROs in standard terminologies (e.g., LOINC) is currently unknown, which makes it difficult to prioritize further code development for PRO data elements. Having no standard ontology for capturing PRO data makes it challenging to share measurements across institutions and obtain generalizable, population-level data.[87] Standard approaches to integrating PROs into PC CDS are also lacking. While some EHRs, like Epic, allow for the native mapping to terminology standards for instruments that have LOINC codes, including codes from items from standardized instruments and PROMIS measures, integrating PRO data into the EHR remains a challenge.[88]

FHIR PRO Implementation Guide and Related Initiatives. To promote the use of PROs in PC CDS, developers may also be able to leverage the HL7 FHIR PRO Implementation Guide.[89] Developed through the AHRQ and ONC-led project, Advancing the Collection and Use of PROs through Health IT,[90] this implementation guide focuses on the capture and exchange of PRO data using the FHIR data model. This guide, which is currently in draft status, is not supported by any EHR system, to our knowledge.[91] However, recent initiatives have used the FHIR PRO Implementation Guide to develop FHIR-based mobile apps for collecting PRO data.[92] Pilot testing has found that PRO data collected from standardized apps can be successfully integrated into a range of EHRs. Using interoperability standards in user-facing apps may support the further collection and integration of PROs across health systems.

3.1.4 Standard PC CDS Insertion Points

CDS insertion points designate when PC CDS can be delivered in a workflow, thus dictating where CDS tools can be triggered in applications to provide clinical guidance and facilitate shared decision making. To date, there is no standardized approach to designating insertion points for PC CDS, which limits the extent to which CDS can be deployed at the appropriate time to the appropriate recipient to facilitate patient-centered care. Appropriate CDS insertion points are crucial for providing effective CDS, because poorly timed CDS prompts may be ignored by the clinician and/or deemed irrelevant by the patient. However, HL7's CDS Hooks specification and the FHIR Subscription resource provide a promising avenue forward for this need.

PC CDS Use Case: Selecting Treatment While Preventing Drug-Drug Interactions
The DDInteract app uses CDS Hooks to integrate the decision support tool within the EHR workflow. The CDS Hooks service requests additional patient data from the EHR's FHIR server. If the CDS Hooks service detects increased risk of gastrointestinal bleeding, it returns this information back to the EHR as an app card with a link to DDInteract. DDInteract retrieves patient data from the EHR's FHIR server and calculates a risk profile.

Current state, gaps, and challenges for standard PC CDS Insertion Points

HL7 Standards. CDS Hooks are used to trigger CDS in response to user actions in the EHR, such as when a new patient record is opened or new orders are entered. CDS Hooks can be paired with other standards, such as SMART on FHIR or FHIR Clinical Reasoning, to facilitate PC CDS. For example, CDS Hooks was recently used to suggest relevant SMART on FHIR medical calculator applications to physicians on chart entry, based on patient characteristics and health data. Physicians who received these CDS Hooks prompts were more than twice as likely to use the medical calculators as physicians who did not receive the prompts.[93]

While CDS Hooks have been developed to trigger CDS in the workflow,[94] implementation of this standard and its various hooks (i.e., workflow triggering points) has been only partial. Most vendors limit these integration points, only enabling a hook in response to the opening of a patient's chart.[95] This limits the ability of PC CDS developers to integrate CDS in response to other care team actions (e.g., ordering labs), or to provide patient-facing CDS in response to patient-provided data input (e.g., completing a survey in a patient portal). Key informants noted that CDS Hooks has not yet been used to enable patient-facing CDS.

> *A lot of clinical decision support is hand-coded, or it works only on this system, and so on. CDS Hooks is much more generic—as long as you have a FHIR server that allows you to access the data in the way that a CDS Hooks app wants it, then you are portable. You know, you can put this into the Epic App Store and that is great. So, I call it the "democratization" of clinical decision support.* - **Informatician**

CDS Hooks have recently been used in population health management approaches that identify and engage specific patient subgroups that meet criteria for certain preventive or treatment measures (e.g., genetic screening due to familial cancer risk).[96,97] In this scenario, CDS Hooks were triggered at

predetermined times, outside a patient-level interaction, rather than being triggered by specific user actions. CDS Hooks were used to evaluate a patient population to determine patients' eligibility for outreach.

Higher adoption of CDS Hooks is needed overall. According to the 2022 ONC ISA, CDS Hooks adoption has been medium for certain purposes (e.g., sharing CDS tools and providing patient-specific assessments and recommendations through CDS) but low for others (e.g., requesting context-specific knowledge from online resources; obtaining patient-specific resources from health IT systems to answer patients' questions).[36] Similar to CDS Hooks for EHRs, the field needs a specification of CDS Hooks for patient events to integrate CDS into patient-facing digital tools like patient portals and apps.

Whereas CDS Hooks typically trigger CDS due to user interaction with an application, the emerging FHIR Subscription resource can be used to trigger CDS in response to changes in data in a FHIR server.[98] Subscriptions allow CDS developers to specify events that should trigger a notification to a PC CDS system to act (e.g., when a lab result is returned in a particular reference range or when a patient reports a new vital sign). The HL7 Infobutton standard can also be used to offer access to patient context-relevant resources inserted into workflow screens in the EHR and in patient portal applications.[99,100]

> *CDS Hooks as a standard is still very functional but still very immature in terms of its adoption across the industry. But it is critical that when we are executing knowledge algorithms against, at this point, now standardized data flows, that we have standardized approaches to executing those knowledge formats.* - **Informatician**

3.1.5 Standards for Nonclinical Patient-Centered Data

Nonclinical, patient-centered data such as patient preferences and social risk factors are increasingly recognized as important to inform patient, caregiver, and care team decision making.[101] Patient-preference data provide insight into what treatment or management options may be best for patients based on their desired goals and outcomes.[102] Social risk-factor data or SDOH data offer information about nonmedical factors that may influence healthcare decisions and health outcomes.[103] A significant challenge in using these types of data in PC CDS is lack of standardized representation of nonclinical, patient-centered data.

> *Way too often in the healthcare system, we tend to do things to patients, instead of with them. Understanding and taking into account patient needs is one of those areas where there's lots of room for improvement.* - **Patient Representative**

Current state, gaps, and challenges for standards for patient-preference data

Patient preferences refer to the "relative desirability or acceptability to patients of specified alternatives or choices among outcomes or other attributes that differ among alternative health interventions."[104] Patient preferences may encompass patient goals in terms of their overall health and lifestyle goals, goals for management of a specific disease or condition, or goals for their healthcare outcomes.[102,105]

Standards for data related to patient preferences is a developing area. Current terminology standards support the limited capture of patient-preference data and patient health goals within the EHR. Both LOINC and SNOMED CT include terminology standards to represent patient goals and preferences under specific circumstances. For example, LOINC terms address limited contexts, such as documenting goals and preferences at the end of life or documenting preferences for caregivers making decisions on behalf of the patient.[106,107] According to the 2022 ONC ISA, adoption of current terminology standards for patient goal and preference data is low.[36]

Critically, developers have not yet established standards that capture the full range of patient preferences relevant to CDS. Standards are needed to represent the full range of preferences that affect clinician recommendations and patient decision making. These include care goals, acceptance of treatment and management options, and preferred decision making styles. In addition, standards do not consider patient preferences across multiple conditions, a critical gap in decision support for patients with multiple chronic conditions.

FHIR Questionnaire Resource and Implementation Guides. While standards for capturing patient-preference data are still developing, the FHIR Questionnaire Resource can be used to capture patient-directed questions, allowing for the representation of questionnaire names and specific questions. The FHIR QuestionnaireResponse Resource can then be used to capture patient responses to these queries.[108]

Key informants noted that FHIR implementation guides and resources focused on care planning may help advance the capture and exchange of patient-preference and goal data in a standardized way. Key informants highlighted three specific FHIR resources: 1) the electronic Long-Term Services and Supports (eLTSS) Implementation Guide, 2) the Multiple Chronic Conditions (MCC) e-Care Plan Project Implementation Guide, and 3) the CarePlan resource:

- The eLTSS Implementation Guide was developed to support the exchange of data gathered during care planning for long-term services and supports.[109] The Implementation Guide includes a Goal Profile derived from the US Core Goal Profile. The US Core Goal Profile sets the minimum required data elements (i.e., status, description, patient, target date) for capturing patient goals.[110] The terminology binding for the goal description is clinician-centered rather than patient-centered.[111]
- The MCC e-Care Plan Project, a joint effort between AHRQ and the National Institutes of Health, is advancing the interoperable collection and exchange of person-centered health and SDOH data across settings.[112] Key informants indicated that the guide would support the capture and exchange of patient preferences and goals as part of care plan development. The Implementation Guide includes a resource profile for minimum data elements for MCC care plan goals.[113]
- As part of the FHIR 4.3.0 specification, the CarePlan FHIR resource includes capturing patient care goals (using the FHIR Goal resource).[114,115] However, these resource elements appear to currently focus on the capture of clinically focused goals the care team sets (e.g., lowering blood glucose, healing a wound within a certain period of time) rather than goals defined by the patient (e.g., walking without a cane, making a trip to see family).[116]

Ongoing Initiatives. Key informants also highlighted the work of initiatives that may help advance the capture of patient-preference data within clinical workflows. Sponsored by CMS, the PACIO Project focuses on advancing interoperable health data exchange between post-acute care (PAC) and other healthcare stakeholders.[117] A key informant shared that the project is capturing some patient-preference data through use of questionnaires for advance directives.

The HL7 Patient Empowerment Workgroup recently completed a 2-year effort to define the concept of patient-contributed data, which includes patient-preference and SDOH data. The Workgroup recently released a white paper that defines the concept of patient-contributed data, explores data governance needs, and assesses the current state of standards. The Workgroup recommended that existing clinical standards, such as care plans, directly include patient-contributed data, including patient-defined goals.[59]

Current state, gaps, and challenges for standards for SDOH data

SDOH are nonmedical factors that affect health, functioning, and quality of life.[118] These include economic stability, education, and neighborhood/environment.[118] Like the landscape for patient-preference data, the landscape for SDOH data standards is evolving.

SDOH Terminology Standards. Terminology standards such as LOINC and SNOMED CT can support the standardized capture of SDOH data. LOINC has established a panel that represents social, psychological, and behavioral health measures.[119] SNOMED CT has nearly 5,000 items relevant to SDOH data capture, with a multiyear plan for adding SDOH content into the clinical terminology.[120] In addition, the International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) has a subset of diagnostic "Z" codes that allow hospitals to identify nonmedical factors that may impact a patient's outcomes,[121,122] and Current Procedural Terminology (CPT) can now capture SDOH data.[123] However, the 2022 ONC ISA indicates that adoption of these standards is either low or unknown.[36] Initiatives like the Gravity Project (described below) are helping advance development and adoption of terminology standards for SDOH data. LOINC terms tend to be modeled as observations or reports from patients that are structured as questions and responses, and SNOMED CT terms are findings (not necessarily associated with, or as a response to, a specified patient-directed question).

Ongoing Initiatives. The Gravity Project is advancing both terminology and data exchange standards for SDOH. Through its terminology workstream, the Gravity Project is identifying coded data elements and associated value sets to represent SDOH data across several domains (e.g., food insecurity, housing instability, stress) in four areas: screening, diagnosis, goal setting, and interventions.[124] These SDOH domains have been added to the USCDI Version 2. Key informants shared that the Gravity Project uses a consensus-based process for identifying and developing data elements that focuses on identifying gaps in what data need to be captured. The Gravity Project then works with coding stewards to make proposed additions as needed to LOINC, SNOMED CT, and ICD codes. The initiative's technical workstream has developed a FHIR implementation guide focused on documenting and exchanging SDOH data.[125] The Gravity Project also includes a pilot workstream validating use of identified terminologies and FHIR implementation guides through real-world testing.[126]

> *I think you must convene whoever is building data concepts and needs to have code submissions, do it within a public collaborative way…[I] think moving forward, the recommendation is, depending on what type of research it is, that you have a mechanism to engage with the coding stewards, and ensuring that you have a consensus-based process for defining the data elements before you present them for new code development.* - **Standards Developer**

The Protocol for Responding to and Assessing Patients' Assets, Risks, and Experiences (PRAPARE) effort focuses on assisting health systems and care teams in collecting standardized SDOH data to improve clinical care. PRAPARE offers an implementation toolkit and standardized EHR templates for various EHR developers, including Epic, Cerner, eClinicalWorks, and Athena.[127,128]

3.1.6 Integration of PGHD into EHRs

PGHD provides critical information about a patient's health and relevant activities outside a clinical setting, which helps clinicians assess care plans and make clinical recommendations.[83] Key informants noted it is important for patients to be able to curate and share their data with their clinicians in a logical and user-friendly way. Integration and use of PGHD in PC CDS is critical, as PGHD can generate better-informed clinical recommendations.

Current state, gaps, and challenges for standards for PGHD data sharing and integration

Currently, accessing PGHD for PC CDS can be cumbersome if health systems lack the technical infrastructure to receive and store patient-submitted data.[129] Much of the PGHD collected through PC CDS apps is stored and reviewed outside the EHR;[130] this makes it difficult to include a review of these data in the clinical workflow.[83]

> *As we look out longer, and I really do think that we should be thinking about, on the one hand, data that individuals are collecting about their own health as something that is going to become commonplace and patterns of exchange of it, and interoperability around it, and standards for it.* - **Patient Representative**

Standards for PGHD integration into EHRs are still developing. There is no widely adopted standard that allows for full integration of PGHD data into the EHR. As discussed above, the US Core FHIR Implementation Guide facilitates consistency around how and what patient data are accessed. In addition, the PRO FHIR Implementation Guide, also discussed above, can aid in PRO data exchange and integration. However, additional standards are needed to support PGHD integration into EHRs. One key informant noted the emerging Institute of Electrical and Electronics Engineers (IEEE) 1752 family of standards, which can be leveraged to capture information meaningful to patients, like sleep and physical activity.[131]

FHIR-based Resources. The FHIR standard has been leveraged to support development of standards-based user interfaces that allow for collecting and sharing patient-provided data. Specifically, FHIR APIs enable the sharing and integration of PGHD from devices into the clinical workflow.[87] For example, Apple HealthKit is currently using FHIR.[132] Epic allows data sharing from the Apple HealthKit to its MyChart app.[70] Another example key informants highlighted was CommonHealth, developed by The Commons Project (TCP), which leverages data interoperability standards such as HL7 FHIR and

SMART Health Cards.[133] CommonHealth was developed to offer functionality analogous to Apple HealthKit in an effort to connect users to their EHR data and give them complete control of how, when, and with whom they share their health data.

The SMART Markers software framework supports development of apps that allow for the exchange of PGHD from patient apps or devices to the point of care.[87] The framework uses a "Request & Report" model that allows clinicians to send PGHD requests to patients via a tablet or EHR app, and patients to respond to these requests using their personal devices.[87]

PC CDS Use Case: Integrating PGHD in the EHR for COVID-19 Management

As part of a pilot, the COVID-19 Tracker app used PGHD to support remote patient monitoring at Yale New Haven Health. Patients enrolled in the program provided data daily, using a questionnaire accessible via their smartphones. The FHIR Observation resource (used with proprietary codes) transmitted the PGHD from the app to the EHR. These data were integrated into EHR-enabled workflows to allow clinicians to check patients' symptoms and data.

Ongoing Initiatives. The literature and conversations with key informants revealed four initiatives that are helping advance the sharing and integration of PGHD:

- AHRQ has developed a comprehensive guide to support the collection, integration, and use of PGHD in ambulatory care settings. The guide focuses on providing evidence-based and practical steps for implementing a PGHD program, including planning, design, launch, and maintenance.[134]
- While not exclusively focused on PGHD, HEART (Health Relationship Trust) profiles leverage existing open standards (e.g., FHIR) to enable patients to determine how their clinical data are shared. HEART also defines an interoperable process for systems to exchange patient-authorized healthcare data.[135]
- Open mHealth supports the collection, storage, and aggregation of PGHD from multiple APIs (e.g., Fitbit, Apple Health) and the sharing of these data within the EHR. The initiative provides open-source code to store, integrate, and visualize data. This includes an implementation guide to interoperate data from FHIR to Open mHealth schemas.[136]
- Supported by Stanford University, CardinalKit provides an open-source framework for digital health applications that collect PGHD, such as physical activity data.[82] The platform, which interfaces with both Apple iOS and Android, represents data based on FHIR standards and the Open mHealth initiative.

3.1.7 CDS-Focused Application Programming Interfaces

APIs support patient and clinician access to health data, as well as the aggregation of health data from different sources (e.g., EHR, patient portal, mobile apps).[137] They represent a key feature of an interoperable health data ecosystem.

Current state, gaps, and challenges for standards for CDS-focused APIs

FHIR-based APIs support access to data for PC CDS; however, adoption of FHIR standards by API developers varies. Only a fraction of EHR apps support the FHIR standard.[138] In addition, the interpretation and implementation of FHIR profiles can differ across and within health systems.[139] Key informants shared that there is ongoing work from the American Medical Informatics Association

(AMIA) and HL7 to identify where FHIR apps have been implemented into care settings. This work may provide a better understanding of the extent to which the FHIR standard has/has not been adopted on a global scale. FHIR adoption will increase as the ONC Cures Act Final Rule requires that certified health IT developers update and provide users with FHIR-based APIs by December 31, 2022.[140,141]

Beyond gaps in adoption of the FHIR standards, challenges relate to API capabilities. Performance can be a challenge, as many requests return large amounts of data (e.g., a high number of lab results), which can take significant processing time. Furthermore, FHIR and proprietary APIs often provide only read capability—this allows information to be received and reviewed from the EHR but does not support writing information to the EHR database.[137] Implementation of the standard APIs for writing data is developing slowly, especially as it relates to patient-facing apps. The HL7 Patient Empowerment Workgroup notes that lack of adoption of standards to write data in EHRs, especially for external patient apps, is a key barrier that must be addressed if patient-contributed data are to be used in clinical care.[59] In discussing the lack of standards in this area, one key informant noted that USCDI data elements focus on read rather than write access.

PC CDS Use Case: FHIR-based APIs for Prevention Screenings

The Decision Precision+ tool is a SMART on FHIR app that pulls patient demographic and health data from the EHR to provide patient-specific recommendations for lung cancer screening. While a standalone tool is available, the University of Utah has developed an EHR-integrated version of the tool.

> *[Most] of the things in the USCDI core are focused on read access as opposed to write access. [If] I'm moving and I've gotten APIs from each of the providers I see, what do I do with it?...So, I take responsibility, I send all this data, and then they may not be able to read it or may not be able to find it at the point that I'm actually there for care. We used to talk about last mile connectivity. It's kind of as if we've gotten to the mailbox at the end of the driveway, but we haven't gotten it into the home or vice versa, in some respects.* - **Patient Representative**

Beyond read-write capability, key informants noted the need for standardized processes that provide transparency in how data are stored in consumer-facing apps. App vetting processes are key to maintaining data safety and security.[137] One key informant suggested providing an app equivalent to a "nutrition label" that provides information about whether the app stores data in a standard way, allows for data interchange, sells data, and allows users to retain data if they leave the app.

Ongoing Initiatives. While not CDS-focused, several initiatives are advancing development and use of FHIR-based APIs. The CARIN Alliance addresses standardization and best practices related to security, data protection, authentication, identity proofing, privacy, user experience, interoperability, and the conformance regime.[142] Previously, the CARIN Alliance Health Plan Workgroup developed an implementation guide to support sharing Medicare claims information with Medicare fee-for-service beneficiaries through FHIR-based APIs.[143] The PACIO project is working to support patient data exchange across healthcare settings through development of use case-driven FHIR APIs.117 To date, the project has developed implementation guides for functional status and cognitive status use cases.

3.1.8 Application Programming Interfaces for Bulk Data Export to Inform PCOR

Key informants noted that, as PC CDS continues to evolve, the need for CDS tools to address decision making at a population level, rather than just at an individual patient level, is increasing. A critical step in the PC CDS development lifecycle is patient-level data aggregation across patient populations. The aggregated EHR data can be used in research (e.g., retrospective data analyses), and then to inform PC CDS. In addition, bulk data can support analysis for population health management.

Current state, gaps, and challenges for standards for bulk data export

Standards for the aggregation of patient-level data are emerging. The HL7 Bulk Data Access (Flat FHIR) API supports export of data for patient populations. Bulk FHIR capabilities are emerging in various FHIR servers, including HAPI-FHIR, Google Cloud Healthcare API, and Epic's EHR.[144,145] To date, the approach to bulk data export lacks granularity, using an 'all-or-none' approach that provides more data than may be relevant for a specific population health management need. This challenge has implications both for efficiency and performance, as well as for patients' privacy.

Common data models, which organize data into a standard format, may provide a pathway for aggregating and standardizing real-world data for bulk data export. However, different common data models exist, which presents challenges when harmonizing data across research networks. ONC previously led an effort to harmonize four common data models: Sentinel, Patient-Centered Outcomes Research Network (PCORnet), Informatics for Integrating Biology & the Bedside (i2b2), and Observational Medical Outcomes Partnership (OMOP).[146] The project developed a FHIR implementation guide that supports mapping observational data into the FHIR format.[147]

Ongoing Initiatives. The Da Vinci project is advancing data sharing between patients and clinicians by leveraging the FHIR standard to support and integrate value-based care data exchange.[148] The project has developed the Data Exchange for Quality Measures Implementation Guide, which focuses on three use cases: medication reconciliation, colorectal cancer screening, and venous thromboembolism prophylaxis.[149]

Stanford University is advancing use of aggregate data at the point of care through its Informatics Consultation Service. This service builds upon the concept of a "Green Button," allowing aggregate data to be used at the point of care. The Green Button approach envisions a function directly within EHRs that aggregates data to support clinician decision making and provide patients with data on patients like them.[150] In 2019, Stanford University launched a pilot study in which users could submit consultation requests and receive a report with a descriptive summary of similar patients in Stanford's clinical data warehouse. The summary included a description of treatment choices made and outcomes observed.[151,152]

3.1.9 Additional Considerations for PC CDS Standards

Conversations with key informants also identified additional opportunities that transcend specific stages within the PC CDS technical landscape. These opportunities speak to the need for a robust technical infrastructure to ensure PC CDS is more easily deployed for patients and incorporated into clinical workflows.

Technology Disparities. As CDS is increasingly placed directly in patients' hands, two key informants noted the potential for disparities or inequities due to the current limitations of the technical landscape. Key informants noted that patient-facing CDS is not currently designed for individuals with older technology like flip phones, thus disproportionately impacting individuals of low socioeconomic status.[153] Another informant raised that the technical infrastructure for Android-based smartphones currently lags compared to Apple iOS-based phones in the ability to aggregate health data from different sources and share health data. As noted above, the Apple HealthKit interfaces with Epic's MyChart. The key informant indicated that there was no comparable FHIR-based API for Android.

Furthermore, significant disparities exist in the adoption of patient engagement tools, such as patient portals, in low-resource settings (e.g., critical access hospitals).[154] This precludes patients from being active participants in their care (e.g., able to view and submit health information, message their care team, or schedule appointments online), which may further disadvantage certain communities and provide additional roadblocks to PC CDS integration and use.

PGHD Aggregation and Visualization. A robust technical infrastructure will be especially critical to support PGHD use in PC CDS and clinical decision making. Wearables and medical devices can capture vast amounts of data (e.g., multiple blood pressure readings or blood glucose readings per day). Even if PGHD are captured and exchanged in a standardized way, challenges remain in aggregating these data and visualizing them in a way that facilitates meaningful discussions between patients and their care teams. Key informants highlighted the need to better represent continuous data (i.e., data streamed at a high frequency, such as blood glucose readings), noting that current standards are insufficient. For example, a device may provide many repeated measures, but the data point important for PC CDS will be a summary, calculated, or derived measure (e.g., average steps per day, most recent value, highest value in the past 7 days). At present, some LOINC codes can be used to represent summary data or calculated or derived data that are often used as outcome measures (e.g., percentage of glucose measurements in range).[155]

> *And, you know, in general, it was just very difficult for clinicians to make sense of what we thought were simple visualizations, and correlations between the wearable data, like the steps and sleep, and disease outcomes. So, there is a lot more work to do and making sure that these data are also easy to digest and a priority for clinicians, who are already very time constrained* - **Informatician**

Variability in Use of Standard Terminologies and FHIR Resources. Standard terminologies (e.g., LOINC, SNOMED CT) alone are insufficient to precisely communicate clinical or scientific meaning; they must be bound to "information models" to fully represent the semantic context—including, for example, different types of data or messaging models that specify data fields or variables. FHIR implies an information model that captures different data elements (e.g., patient characteristics, medication list, health conditions, care plan) in standard categories (i.e., FHIR Resources). However, within each of these FHIR Resources, different terminologies and codes can be used to represent a single concept.[156]

FHIR allows substantial flexibility in the use of standard terminologies and coding systems in its resource. This flexibility has the disadvantage of increasing the likelihood that different sites use terminology differently, and thus capture the same data in different ways,[157] creating challenges for aggregating the data across different sites to inform PCOR, as well as for disseminating interoperable

PC CDS tools. For standards-based FHIR PC CDS applications to scale across many organizations, the field needs additional specificity around the use of terminology within FHIR resources.

Authorization of Proxy Access. Digitization of healthcare increases opportunities for shared decision making and patient engagement with CDS tools. However, many patients look to caregivers, family members, or other trusted individuals for guidance on healthcare and medical decision making. Two key informants highlighted the importance of standards related to data privacy and sharing. One key informant noted that authentication standards are currently insufficient for allowing patients to grant proxy access to their medical records while allowing patients to control what proxies can view or edit. Another key informant shared that a FHIR Permission resource is under development that would allow for the expression of access control rules derived from a FHIR Consent resource, which keeps a record of patient choices related to collection, access, use, and disclosure of healthcare information.[158]

Documenting and Disseminating the Landscape of Standards for PC CDS. The landscape of current standards for PC CDS is wide-ranging and constantly evolving. Two key informants noted that it is difficult to keep track of the availability and maturity of standards for PC CDS, and advocated for increased communication and dissemination by standards organizations. Another key informant highlighted the potential role of AMIA and HIMSS in disseminating resources that provide a broad view of the standards landscape.

3.2 Federal Landscape

Multiple Federal agencies—including ONC, CMS, and FDA—provide regulatory guidance on CDS and support its adoption and use. Additionally, AHRQ and CDC fund CDS-related initiatives, research, and pilots to help advance the use of standards-based CDS within the healthcare system. **Exhibit 4** provides an overview of the Federal landscape for PC CDS, as described in this section.

Exhibit 4. Overview of the PC CDS Federal Landscape

Regulatory Landscape and Guidance			Federal Initiatives	
Office of the National Coordinator for Health Information Technology (ONC) • Principal federal entity that coordinates nationwide health IT efforts • Promotes the adoption of standards-based health IT	**Centers for Medicare & Medicaid Services (CMS)** • Enacted programs that include use of CDS as part of quality improvement activities • Promotes price transparency for healthcare and patient access to their health data	**Food and Drug Administration (FDA)** • Regulates the safety and effectiveness of some medical devices • Established a Digital Health Software Precertification Program to inform a regulatory model for software-based medical devices	**Agency for Healthcare Research and Quality (AHRQ)** • Created a multi-component program to advance PC CDS • Funded the development of standards-based PC CDS tools through grants	**Centers for Disease Control and Prevention (CDC)** • Promotes health IT tools to improve the clinical response to public health emergencies • Funded open-source tools and projects that promote the use of standards-based CDS

3.2.1 Regulatory Landscape and Guidance

This section describes the current Federal rules and regulations that might influence PC CDS development, implementation, and use. The regulatory landscape for CDS continues to evolve with the introduction of new regulations—such as the Coronavirus Aid, Relief, and Economic Security (CARES) Act—that have created a supportive environment for CDS innovations.[159] In addition, the 21st Century Cures Act (signed into law on December 13, 2016) provides Federal guidance on patient trust and transparency that also has implications for PC CDS. Given that the field of PC CDS is emergent, the discussion includes existing guidance documents. Also described are relevant Federal regulations and guidance applicable to PC CDS. **Appendix C** provides full descriptions of the regulations and guidance included in this section.

Office of the National Coordinator for Health Information Technology

ONC is the principal Federal entity that coordinates nationwide health IT efforts. In 2017, ONC collaborated with the National Academy of Medicine (NAM) to engage experts in a series of strategic development activities to gather recommendations for optimizing CDS in support of improved patient care. They published their recommendations in *Optimizing Strategies for Clinical Decision Support*, which identified priorities for action that broadly included: "develop, test, establish, validate and apply CDS standards; encourage CDS adoption, use, and assessment at the delivery system level; and establish a national CDS infrastructure."[160]

The ONC 2020 Cures Act Final Rule. The ONC 2020 Cures Act Final Rule calls for open APIs that are safe, secure, and affordable. The rule focuses on fostering an ecosystem of new applications to provide patients more choices in their care and encourages developers to adopt standards-based APIs. ONC has provided clarification regarding the ONC 2020 Cures Act Final Rule that "encourages health IT developers to use standards to retrieve CDS content."[161]

The rule also includes provisions for the sharing and use of patient data, further promoting collection and use of PGHD, which has implications for its use in PC CDS apps. Additionally, the ONC 2020 Cures Act Final Rule encourages transparency around patient data access and sharing issues within health IT. It also attempts to protect the intellectual property rights of health IT developers, which can prompt further innovation and distribution of PC CDS products.[162]

Centers for Medicare & Medicaid Services

CMS has enacted programs, like Meaningful Use (MU) and Performance Improvement Projects, that include CDS use as part of quality improvement activities. CMS has also been at the forefront of regulations that allow patients to electronically access their health records and are propelling price transparency for healthcare services.

Promoting Interoperability Programs (PIPs). The PIPs consist of three stages. Stage 1 establishes requirements for ensuring patients are provided with electronic copies of their health information. Stage 2 encourages use of certified electronic health record technology (CEHRT) for continuous quality at the point of care. Stage 3—established in the Interoperability and Patient Access Final Rule—focuses on ensuring CEHRT is used to improve health outcomes. One PIP objective for 2020 and 2021 was for eligible professionals to "implement CDS interventions focused on improving performance on high-priority health conditions." This objective called for implementation of five CDS interventions related to

four or more clinical quality measures and for enabling and implementing functionality for drug interaction checks.[163] These align with one of the core components of PC CDS—use of patient data to develop tools for shared decision making. These interventions also promote quality improvement by CDS use.

CMS Interoperability and Patient Access Final Rule. The Interoperability and Patient Access Final Rule ("the final rule") gives patients access to their health information when they need it, in a way they can best use it. The final rule improves interoperability and allows patients to access their health information via standards-based APIs and claims data, using third-party apps of their choice.[164] This may enhance patients' ability to choose between healthcare options that meet their needs. CMS emphasizes that the final rule is only a first step to advance interoperability and patient access.

Appropriate Use Criteria Program (Protecting Access to Medicare Act) of 2014. This program promotes CDS use. Under the provisions of this Act, a clinician is required to consult a qualified CDS mechanism at the time of ordering advanced diagnostic imaging services for Medicare beneficiaries.[165] This type of regulation promotes CDS use among the clinical profession and patients. It has spurred implementation of new CDS approaches within EHR products, such as the ability for EHRs to integrate with external CDS services.[166,167]

Hospital Price Transparency Requirements. CMS finalized hospital price transparency requirements under section 2718(e) of the Public Health Service Act, which requires hospitals to make public their list of standard charges.[168] Key informants discussed price transparency as an important aspect of PC CDS, noting that patients are interested in tools that incorporate the price of care to help decision making. Out-of-pocket costs are an important consideration for many patients; thus, making accurate cost estimates available via APIs can be valuable for PC CDS and shared decision making applications.

Food and Drug Administration

FDA regulates the safety and effectiveness of medical devices, including mobile medical applications that meet the definition of device in section 201(h) of the Federal Food, Drug, and Cosmetic (FD&C) Act. FDA intends to apply its regulatory oversight to only those software functions that are medical devices and whose functionality could pose a risk to a patient's safety if the device were to not function as intended.[12] In addition, certain software functions are excluded from the device definition and are not regulated by FDA as a device, as described in Section 3060 of the 21st Century Cures Act (Cures Act , which amended Section 520(o) of the FD&C Act.[12] Notably, certain CDS software functions are among those excluded from the definition of device by Section 520(o)(1)(E) of the FD&C Act.[169]

Clinical Decision Support Software Guidance. With its recently released guidance in September 2022, FDA has clarified the scope of its oversight for CDS software functions in the guidance document, *Clinical Decision Support Software*.[169] This guidance further clarifies that FDA's existing digital health policies continue to apply to software functions that meet the definition of a medical device. In applying a risk-based approach, FDA does not intend to focus its regulatory oversight on low-risk CDS products, even if they meet the statutory definition of a medical device.[170] FDA focuses on a limited set of CDS that poses higher risks to patients; for example, when the app or device makes a diagnosis or when a device makes treatment decisions without review of a professional intermediary. An example of required FDA clearance is the electrocardiogram app on the Apple Watch, which

measures signs of irregular heartbeat rhythms that may be suggestive of atrial fibrillation.[171] However, there are features of patient-facing devices that provide clinicians and patients insight into cardiac performance and other health indicators (e.g., software functions that help patients self-manage their disease or conditions without providing specific treatment or treatment suggestions, or software that promotes healthy lifestyles) that are not the focus of FDA's oversight.

Food and Drug Administration Safety and Innovation Act (FDASIA). FDA, in collaboration with the Federal Communications Commission and ONC, established the FDASIA Health IT Working Group to develop a risk assessment report in 2014. This report provides strategy and recommendations from the FDASIA Health IT Working Group on an appropriate, risk-based regulatory framework pertaining to health IT. In the report, the FDASIA Health IT Working Group recommended that FDA provide greater clarity related to medical device CDS software and mobile medical apps. The report includes additional strategies and recommendations that set the stage for FDA's current efforts related to CDS.[170]

21st Century Cures Act (Section 1002, FDA Innovation Projects). The Cures Act builds on FDA's ongoing work to incorporate patient perspectives into the development of drugs, biological products, and devices to inform FDA's decision making process. FDA published a work plan and proposed allocation of funding, which includes expanding its participation in national and international standard-setting across all device areas (Section 3053. Recognition of Standards) and implementing a surveillance system for software products exempted from FDA oversight (Section 3060. Clarifying Medical Device Software).[172]

Report on Risks and Benefits to Health of Non-Device Software Functions. Section 3060(b) of the Cures Act requires that Department of Health and Human Services (HHS) publish a report every 2 years that examines any risks and benefits to health associated with the software functions described in Section 520(o)(1) of the FD&C Act, and "provides summary findings regarding the impact of these non-device software functions on patient safety, including best practices to promote safety, education, and competency."[173] The findings of the report, submitted by FDA, detail impacts to patient safety related to use of non-device software, which include certain functions of CDS.

Device Software and Mobile Applications Drafted Guidance. In 2022, FDA updated the guidance document, *Policy for Device Software Functions and Mobile Medical Applications: Guidance for Industry and FDA Staff,* which provides clarity on FDA's approach to regulating device software functions and provides guidance for CDS developers. The guidance also clarifies medical app functions and explains conditions under which FDA oversight is applicable or required.[12]

Digital Health Software Precertification Pilot Program. The advent of smartwatches, health apps, and patient-facing devices (e.g., wearables, sensors) has led to an explosion of apps that provide users with indicators to monitor or measure their health status. FDA has responded to this industry trend by establishing the Digital Health Software Precertification Pilot Program to inform development of a regulatory model for oversight of software-based medical devices. In 2022, FDA issued a report describing key findings of the pilot. The report indicates that rapidly evolving technologies could benefit from a new regulatory paradigm, which would require a legislative change.[174]

3.2.2 Federal Initiatives

Federal agencies such as AHRQ and CDC fund initiatives that support the development and adoption of standards-based PC CDS. These initiatives address steps across the PC CDS development and implementation lifecycle from the translation of evidence into computable guidance to the piloting of PC CDS that integrates PGHD.

Agency for Healthcare Research and Quality

Since 2016, AHRQ has been creating a multicomponent program to fulfill the legislative requirements of the Patient Protection and Affordable Care Act (2010) related to dissemination of PCOR findings through CDS. AHRQ has funded development of standards-based PC CDS tools and real-world pilots to assess the implementation of these tools in practice. Through these projects, AHRQ aims to advance the science of CDS by supporting development of "CDS tools that are shareable, standards-based, publicly available, and patient-centered."[175] **Exhibit 5** summarizes the components of AHRQ's PCOR CDS Initiative; it is not a comprehensive list of AHRQ activities pertaining to PC CDS.

Exhibit 5. Summary of Example AHRQ Initiatives

Initiative Component and Dates	Advancement of PC CDS
PC CDS Learning Network (PCCDS LN) (4/01/2016 – 01/31/2020)	The PCCDS LN galvanized attention to PC CDS by conceptualizing a definition for PC CDS as well as forming workgroups and hosting convenings to advance PC CDS development and use. The six PCCDS LN workgroups and their products promoted incorporation of PCOR findings into clinical practice through CDS, by engaging a wide range of stakeholders, identifying barriers and facilitators to PC CDS use in clinical practice, and helping generate consensus-based recommendations related to building trust in CDS. The PCCDS LN enabled PC CDS for chronic pain management, human-centered design principles for CDS development, and sustainability of a PC CDS-focused "knowledge network."[176]
Patient-Centered Outcomes Research Clinical Decision Support Prototype Development and Dissemination (CDS Connect) (09/12/2016 – 09/11/2019)	AHRQ's CDS Connect Repository is a publicly available, free, web-based platform that hosts CDS artifacts. The repository is usable for a diverse group of stakeholders in designing and developing PC CDS tools.[177]
Quantifying Efficiencies Gained Through Shareable CDS (07/30/2018 – 07/29/2019)	The Quantifying Efficiencies project examined the potential value of sharable CDS, specifically CDS Connect resources, in creating efficiencies in the CDS lifecycle. The project generated lessons learned about CDS development and the value of sharable CDS made available through the CDS Connect Repository.[178]

Initiative Component and Dates	Advancement of PC CDS
Patient-Centered Outcomes Research Clinical Decision Support: Current State and Future Directions (09/30/2019 – 03/31/2023)	AHRQ funded a contract to understand the impact of the overall PCOR CDS Initiative, understand the current state of PC CDS, identify gaps for future research, and disseminate lessons learned to help promote the spread of PCOR findings through CDS to improve care in clinical practice.[179] The evaluation assessed the PCOR CDS Initiative's accomplishments and generated findings related to successes, challenges, and lessons learned to inform future AHRQ CDS program and policy initiatives. The evaluation also explored how AHRQ contributes to the larger field of CDS development.
CDS Demonstration Projects (2019 – ongoing)	The demonstration projects produced standards-based CDS tools that supported shared decision making between patients and their clinicians. These projects generated several important lessons related to developing and implementing standards-based, publicly available CDS.[180]
The Clinical Decision Support Innovation Collaborative (CDSiC) (09/22/2021 – ongoing)	Launched in 2021, the CDSiC is a multistakeholder collaborative of patients, patient advocates, researchers, clinicians, and developers. The CDSiC aims to shape the current and future landscape of CDS by developing products that will help advance PC CDS, as well as resources to support the advancement, testing, implementing, tracking, and measuring of PC CDS in the real world.[181] The CDSiC will produce frameworks, resources, and guidance to advance the field of PC CDS while considering the needs of varying audiences. The CDSiC will also engage in real-world PC CDS measurement and testing to identify best practices and improve PC CDS usability.

In addition to funding these programs, AHRQ continues to provide grants for digital healthcare research, including PC CDS.

Centers for Disease Control and Prevention

CDC has initiatives focused on the modernization of data collection and use to advance patient and population health. Through these initiatives, CDC has funded tools and projects that promote CDS use.

Adapting Clinical Guidelines for the Digital Age (ACG) Initiative. The ACG Initiative ensures evidence-based clinical guidance is easily accessible and aims to reduce the time it takes to apply clinical guidance for patient care by use of health IT standards. Through this initiative, CDC programs are applying standards like FHIR to improve the way clinical guidance is implemented.[48] In 2018, the ACG Initiative convened a multidisciplinary group of over 200 stakeholders to generate ideas for enhancing the efficiency, accuracy, consistency, and accessibility of applying clinical guidance for patient care. Meeting results included ideas for a new FHIR standard to develop computable guidance (i.e., FHIR Clinical Guidelines)[182] and ideas for an evaluation framework for the new FHIR standard.[48]

The Clinical Response through Emerging Technology (CRET) Program. CDC works with ONC on the CRET program, which is an HHS initiative to improve clinical response to emerging public health hazards using EHRs and IT tools and infrastructure.[183] CRET's goal is to provide clinicians with health IT tools (including CDS) that provide nearly real-time updates and best practices to enhance their response to a range of public health hazards.[183,184]

Illustrative Funded Projects. CDC has funded development and piloting of CDS open-source tools, with accompanying guidance, to promote use of standards-based CDS for patient and population health. For example:

- CDC funded development of a standards-based CDS for alcohol screening and intervention. Two CDS tools were piloted in real-world settings. The CDS resources are available in AHRQ's CDS Connect Repository.[185]
- CDC's Opioid Prescribing Electronic CDS tools are supported by most EHR developers and can be used by clinicians and health systems to promote safe opioid prescribing practices.[186]
- CDC's Clinical Decision Support for Immunization project developed CDS and implementation guides for delivering immunization recommendations.[187]

These CDC-funded open-source tools, with accompanying guidance, promote use of standards-based CDS for patient and population health.

3.2.3 Artificial Intelligence

The AI landscape is emergent and evolving as its use becomes increasingly prevalent in healthcare. Below, we provide an overview of AI-focused activities within the Federal landscape. Given that the landscape is continuously evolving, our review is not exhaustive.

PC CDS Use Case: Using AI to Predict COVID-19 Outcomes

As the healthcare system grappled with COVID-19, CDS developers explored the use of AI to help predict outcomes and potential complications for patients hospitalized with COVID-19. For example, a study used machine learning techniques to analyze data from 229 patients to predict ICU admission, intubation, and development of acute respiratory syndrome.

AI is relevant for PGHD or software programs that interact with patients (e.g., a chatbot) and is used for applications that involve treatment recommendations, diagnoses, and patient engagement, among other uses.[188] Natural language processing is another application of AI used in healthcare to transform clinical notes in EHRs to quantifiable data that can be used for research.[189] AI is being explored in PC CDS innovations to provide recommendations to patients and clinicians to facilitate shared decision making; for example, AI researchers have used EHR data to develop a PC CDS tool for diabetes medication choice.[190] CDS developers have also explored AI to predict potential outcomes and complications for patients (see text box example regarding COVID-19 outcomes),[17] to identify patients at risk for specific diagnoses to provide evidence-based recommendations[191] (e.g., developmental surveillance and screening),[192] and to develop recommendations for care plans (e.g., asthma assessment and management).[193] The National Academy of Medicine released a discussion paper in 2022 that further speaks to facilitating provider uptake of AI and the benefits of AI in healthcare for medical diagnosis, including the ability of AI techniques to reduce cognitive burden on providers and enhance care quality.[194]

ONC has done some preliminary work around AI as it relates to CDS tools, including hosting webinars and showcases to advance responsible use of AI in health IT.[195] In 2021, the National AI Initiative Office was established by the National AI Initiative Act of 2020 to ensure continued US leadership in AI research and development, and to lead development and use of trustworthy AI systems in public and private sectors.[195] In 2021, AHRQ issued a request for information on clinical algorithms used in healthcare and evidence on clinical algorithms that may introduce bias into clinical decision making.[196] Also, AHRQ has ongoing work on developing an evidence base for assessing risk of AI-based algorithms.[197] In 2021, FDA hosted the virtual public workshop, "Transparency of Artificial Intelligence/Machine Learning (AI/ML)-enabled Medical Devices," intended to identify considerations for

achieving transparency in AI/ML-enabled medical devices. The workshop also gathered input from stakeholders on recommended information for developers to include in labels and public-facing information for AI/ML-enabled medical devices.[198] The National AI Initiative Office, FDA, and industry have also made efforts to establish a framework for AI, as follows.

The AI Ethics Framework. The National AI Initiative Office developed the AI Ethics Framework in 2020, an ethics guide for United States Intelligence Community personnel on how to procure, design, build, use, protect, consume, and manage AI and related data. The guide provides AI ethics principles on whether and how to develop and use AI. This indirectly affects PC CDS development, as it is relevant for potential AI applications to process PGHD and communicate with clinicians or third-party applications.[199]

AI/Machine Learning-Based Software as a Medical Device Action Plan. The report includes a five-part action plan focusing on AI software as a medical device. One step includes a patient-centered approach to incorporating transparency to patient users of these devices. Additionally, the FDA intends to develop an updated regulatory framework regarding AI and machine learning-based software as a medical device.[200] Originally proposed in a discussion paper by the FDA in 2019,[201] the proposed approach would allow FDA's regulatory oversight to embrace the iterative improvement power of AI and machine learning software as a medical device, while assuring that patient safety is maintained.

AI Risk Management Framework. The National Institute of Standards Technology developed the AI Risk Management Framework (updated in 2022) which is a consensus-driven framework for voluntary use to "address risks in the design, development, use, and evaluation of AI products, services, and systems."[202] This framework promotes trustworthy and responsible AI by providing common language and understanding to manage AI risks.

Blueprint for an AI Bill of Rights. With the increasing use of AI in healthcare and other sectors, the Biden administration called for the Federal Government to address the inequities and biases AI algorithms can introduce;[203] as a result, the White House Office of Science and Technology identified five principles to guide the design, use, and deployment of systems that use AI in the *Blueprint for an AI Bill of Rights*. The five principles include safe and effective systems; algorithmic discrimination protections; data privacy; notice and explanation; and human alternatives, considerations, and fallback.[204]

Ethical concerns regarding AI are important; resolving these concerns will require developing standard approaches. AI algorithms can be biased, for example, if racial and ethnic minority and lower socioeconomic groups are not represented appropriately in the training datasets (e.g., certain patient demographic groups may find that AI algorithms interpret their data inaccurately).[205] Additionally, researchers have articulated challenges in measuring the effectiveness of AI,[206] and patients have noted lack of transparency and, therefore, trust.[207] The evolving area of transparency of AI/machine learning-enabled devices represents a gap in PC CDS that could be further supported by research and standards development.

4. Discussion: An Action Plan for Moving Forward

While PC CDS has made great progress, challenges remain in the PC CDS landscape. The field lacks standards to fully capture, integrate, and use the data needed to develop CDS that is patient-centered (e.g., PROs, PGHD). In addition, determining the sources of these data is crucial to ensure trust and transparency in PC CDS. Addressing these challenges will help advance the adoption, integration, and delivery of PC CDS that is accepted by healthcare stakeholders (including clinicians, patients, and caregivers) and that improves the quality and efficiency of healthcare by adhering to the Five Rights.[2,208]

4.1 Opportunities to Advance PC CDS Standards

This report's analysis of the current state of standards for PC CDS identifies several opportunities for further development. **Exhibit 6** summarizes these opportunities in the form of an action plan to advance standards for PC CDS, as elaborated below.

Exhibit 6. Action Plan to Advance PC CDS Standards

Recommendations
Stage 1: Standards for Translating Clinical Guidelines into PC CDS
• Develop guidance on how CDS artifact developers can work with guideline developers when building PC CDS artifacts. • Promote specification of standards and systematic approaches to translating guidelines into CDS artifacts. • Promote CQL adoption by EHR developers, who have relied historically on proprietary standards. • Recognize the need for standard approaches and shared resources to aggregate granular codes into higher-level concepts used in clinical practice guidelines. • Support further development and adoption of the CPG Implementation Guide; engage guideline developers to support adoption. • Recognize the need for standardized representation of workflow; further examine emerging standards such as BPM+.
Stage 2: Standards for Managing Data Provenance
• Consider initiatives to highlight the importance of data provenance, further the awareness and adoption of FHIR Provenance, and evaluate FHIR Provenance in the context of PC CDS. • Engage patients to further develop FHIR Provenance standard to address the use of patient-provided data. • Develop provenance standards that allow for the representation and interpretation of the UDIs associated with medical devices, as well as tracking of data tied to specific UDIs.
Stage 3: Patient-Generated Health Data (PGHD) Standards
• Conduct research to assess current coverage for PGHD and PRO terms in terminologies like LOINC and SNOMED CT. • Where gaps exist, advocate for greater coverage for PGHD concepts, as well as PRO measures in standard terminologies such as LOINC and SNOMED CT. • For both PGHD and PROs, develop consumer-friendly extensions of terminology standards.

- Develop a shared taxonomy of different types of PGHD that can support systematic approaches to developing standards and guidance documents for different types of PC CDS.
- Promote use of FHIR-based, standardized patient-facing apps to collect PROs.
- Support PC CDS developers' adoption and use of the PRO FHIR Implementation Guide.
- Support research, including pilot projects, to generate evidence on how standards for PGHD can improve healthcare and health outcomes.
- Examine methods for verifying PGHD (e.g., through linkages to complementary information in the EHR) to ensure the safety and appropriateness of PC CDS.

Stage 4: Standard PC CDS Insertion Points

- Promote adoption of CDS Hooks and FHIR Subscription within EHRs.
- Increase the number and granularity of possible CDS insertion points in the EHR.
- Adapt CDS Hooks and FHIR Subscription to support trigger logic from patient interaction events.
- Facilitate use of CDS Hooks and FHIR Subscription for population health management approaches.
- Promote adoption of standardized, automated clinical workflows, such as through BPM+.

Stage 5: Standards for Nonclinical Patient-Centered Data

- Support further informatics research needed to understand how to standardize and use patient preferences in PC CDS and shared decision making.
- Develop terminology standards to capture the full range of patient preferences needed to support clinical recommendations.
- Promote the Gravity Projects' data elements for including SDOH in PC CDS and examine use of the Gravity Project's FHIR implementation guide to support the exchange of SDOH data for PC CDS.
- Explore how other initiatives can mirror the Gravity Project's practices for data steward engagement.

Stage 6: Integration of PGHD into EHRs

- Invest in research that examines capabilities to leverage current standards to support integration of PGHD into the EHR.
- Support development of new standards for PGHD data integration based on patient and clinician input regarding what types of data and data sources are most critical for full EHR integration.
- Examine use of frameworks such as SMART Markers to support the integration of PGHD into PC CDS.

Stage 7: CDS-Focused Application Programming Interfaces

- Promote development of FHIR-based APIs that support data exchange to inform PC CDS.
- Focus new FHIR-based API development on patient data access and write capabilities, and engage patients in the development of these APIs.
- Develop FHIR resources that are most needed for common types of PGHD and PC CDS.

Stage 8: Application Programming Interfaces for Bulk Data Export to Inform PCOR

- Differentiate use cases for using bulk data (e.g., informing research and Green Button to look at accumulation of patient data).
- Develop greater granularity in the Bulk FHIR specification.
- Explore relationships between Bulk FHIR and other standards like CQL and CDS Hooks.
- Encourage research sponsors to require use of the FHIR Bulk Data Access API.
- Examine the potential of common data models to support bulk data export for PC CDS.

Additional Opportunities for PC CDS Standards

- Develop additional technical infrastructure to support PGHD collection and PC CDS tools using Android-based devices.
- Support advancement of standardized processes for curating PGHD data.
- Specify and promote common approaches for modeling terminologies and coding within FHIR resources.
- Consider avenues for greater dissemination of information about standards across the broader PC CDS community.
- Promote use of standards to enable patient oversight of proxy access.

4.1.1 Standards for Translating Clinical Guidelines into PC CDS

Despite the growing availability of data terminology and exchange standards for translating clinical guidelines into computable CDS artifacts, challenges remain. Addressing these challenges will require collaboration between EHR developers, CDS content developers, and healthcare organizations to standardize methods for systematic approaches to translating guidelines into formal representation. Federal agencies, standards-development organizations, and professional medical societies must work in partnership to encourage the adoption and consistent use of standards across medical specialties.

While CQL provides a standard language for knowledge artifacts, it has had limited adoption by EHR developers, who have relied historically on proprietary code to develop CDS artifacts. CQL will need to be more widely adopted to develop sharable CDS artifacts. Development of a prespecified transition plan for both EHR developers and CDS artifact developers may facilitate a stepped transition from proprietary rules engines to CQL. For example, a transition plan can focus on facilitating CQL adoption by constraining the parts of the CQL specification that must be implemented, mirroring the approach of the US Core Implementation Guide. Alternatively, a transition plan can identify high-priority use cases for CQL implementation—in concert with EHR developers and CDS artifact developers—and focus on demonstration projects that illustrate how vendor-based CQL logic can be integrated into EHRs to support those use cases. Furthermore, additional individuals will need to be trained in the use of CQL to promote widespread adoption. Promoting use of tools such as CDS Connect can also assist artifact developers in building CDS artifacts using CQL.[177]

Implementation guides such as CPG-IG are designed to support consistent approaches to translating guidelines, but this guide has not been widely adopted.[36] It will be important to promote awareness and use of CPG-IG to enable creation of computable guidelines that can be used more readily for PC CDS. Efforts to translate guidelines into computable formats should include guideline developers, to ensure the coded guidelines are valid representations of clinical recommendations. Emerging standards such as those from BPM+ may also provide ways to share knowledge artifacts, as well as evidence-based CDS tools and automated workflows.

Standardized approaches and shared resources are needed to aggregate granular codes used within healthcare systems into the higher-level categories used in clinical practice guidelines. This can be achieved by using value sets or computable phenotype definitions. Efforts such as VSAC, PheKB, and PheCodes may provide useful resources for this need.

4.1.2 Standards for Managing Data Provenance

Capturing and tracking data provenance is crucial for the advancement of PC CDS that incorporates patient-contributed data—including patient goals and preferences, PGHD, PROs, and prior health records. Advancing data provenance standards will require coordinated efforts from standards-development organizations to both develop new standards and encourage the use of existing standards such as FHIR Provenance. Federal agencies may play a role in highlighting the importance of data provenance through national initiatives. EHR developers, app developers, and wearable and device manufacturers will need to support the adoption of these standards.

CDS developers should consider use of FHIR Provenance in PC CDS. In addition, US Core Provenance should include "Author" in addition to "Organization" and "Time Stamp" to facilitate provenance for patient-contributed data. Overall, standards developers should engage patients to further develop the FHIR Provenance standard to address the use of patient-contributed data. Identifying and sharing feasible methods for EHR developers to integrate provenance data will likely speed adoption of provenance standards and the use of patient-contributed data in PC CDS.

To support integration of PGHD from medical devices, standards developers should develop provenance standards that allow for the representation and interpretation of UDIs and tracking of data tied to specific UDIs.

4.1.3 Patient-Generated Health Data Standards

Although medical devices, wearables, and mobile apps to help patients monitor and manage their health have proliferated, standardized approaches to labeling and storing these data remain limited. Terminology standards-development organizations will likely be primary stakeholders to lead the development and use of PGHD standards; however, these efforts must include patients and patient representatives to ensure that patients' needs and preferences are addressed. These efforts will also require coordination with device and wearable manufacturers and app developers, with additional support from EHR developers, health systems, and Federal funding agencies, who can incentivize research related to PGHD.

Future work should create a shared taxonomy of different types of PGHD, and assess current coverage for PGHD terms in standard terminologies such as LOINC and SNOMED CT. These findings can be used to determine additional PGHD-related codes needed to incorporate PGHD into PC CDS and clinical care.[30,70] In addition, more research is needed to generate evidence regarding the clinical utility of standards for PGHD. This evidence may help promote greater adoption of PGHD standards and speed use of PGHD from wearables and mobile applications in routine care. As PC CDS is placed increasingly in the hands of patients and caregivers, it will also be critical to develop consumer-friendly extensions of LOINC/SNOMED CT terms for both PGHD and PROs.

For PROs, further work should characterize the percentage of PROs currently covered in standard terminologies, as well as representation of PROs across different specialties (e.g., mental health). Additional terminology standards will be needed to reflect the full range of PRO measures used in clinical care. In addition, future research should focus on integrating standardized PRO data into EHRs for use in PC CDS. The use of FHIR-based, standardized patient-facing apps to collect PROs may be a valuable strategy for ensuring the interoperability of PRO data from the outset.[92]

As the integration of patient-contributed data into shared decision making and clinical care becomes more normative, methods for verifying patient-contributed data (e.g., through linkages to complementary information in the EHR) may also be needed to ensure the safety and appropriateness of PC CDS.[30] This has been a focus of PCORnet, which developed methods to assess the quality of patient-contributed data and compare patient-contributed health data and EHR data.[209,210]

4.1.4 Standard PC CDS Insertion Points

To achieve the Five Rights of CDS, PC CDS tools must align with workflows and be seamlessly integrated into EHRs and patient portals. Standards-development organizations will need to address limitations of current standards in this area. Furthermore, the adoption of existing and new standards for PC CDS insertion points is unlikely to advance without the support of EHR developers.

In addition to promoting the adoption of CDS Hooks and FHIR Subscription, EHR developers should increase the number and granularity of possible standardized CDS insertion points in the EHR. This would allow for more flexible PC CDS that meets the needs of patients at multiple stages within the clinical workflow.

CDS Hooks have historically relied on actions from a care team member. A future avenue for CDS Hooks is using them to trigger logic from patient-interaction events, as opposed to triggering only from EHR events (e.g., opening a patient's record), as is currently available. Patient portals and third-party patient-facing apps may be an optimal place to embed CDS Hooks services. Additional hooks can be proposed through the HL7 Standards Process.[211] The FHIR Subscription resource may also be leveraged for patient-facing CDS.

Greater adoption of FHIR Subscription can increase CDS trigger points, including trigger points that do not rely on user interaction within the workflow (e.g., CDS triggered when a laboratory result is returned). The field must also recognize the need for standardized representation of workflow (and integration of PC CDS into workflows) and further examine emerging standards, such as BPM+, that promote workflow automation. Finally, use of CDS Hooks for population health management is a promising avenue for PC CDS that can engage large cohorts of patients at once (i.e., population-level CDS); however, scale-up will require expansion of the CDS Hooks specification to support population-level CDS. FHIR Subscription may also allow for population-level CDS, whereby cohorts of patients are subscribed if they meet certain criteria (e.g., a family history of cancer denoted in the EHR).

4.1.5 Standards for Nonclinical Patient-Centered Data

Nonclinical patient-centered data, such as patient preferences and SDOH, are increasingly important for healthcare decision making.[101] Standards-development organizations—working in conjunction with patients and patient representatives—will need to drive efforts to standardize patient-preference data. These efforts should develop and promote terminology standards that capture the full range of patient preferences needed to support clinical recommendations—including care goals, acceptance of treatment and management options, and preferred decision-making styles. New efforts should also consider patient preferences across multiple conditions, especially for those patients managing multiple chronic conditions.[212]

Furthermore, Federal agencies can promote the use of patient-preference and SDOH data in routine clinical care by supporting informatics research that focuses on standardizing and using patient preferences in PC CDS and shared decision making. EHR developers and app developers will also need to prioritize the capture of interoperable patient-centered data.

The Gravity Project also provides a pathway for advancing the development and adoption of SDOH terminology and data exchange standards.[124] Encouraging widespread adoption and use of standards emerging from the initiative will be critical; PC CDS developers seeking to leverage SDOH as part of decision support should align their activities with the Gravity Project's outputs. Future PC CDS efforts should examine standard terminologies for food security, housing stability and quality, and transportation access across the different uses of PC CDS (e.g., prevention, diagnosis, treatment, management) to advance the standardization of SDOH data. In addition, CDS developers should examine the extent to which the project's SDOH Clinical Care implementation guide can support the exchange of SDOH data for PC CDS.

The Gravity Project's activities may also provide a model for engaging data stewards and standards-development organizations. Key informants shared that the project engages multiple stakeholders in a consensus-based process to identify needs and develop standards and established consistent communication processes with data stewards. Other PC CDS standards initiatives may want to adopt a similar approach.

4.1.6 Standards for PGHD Integration into EHRs

PGHD are increasingly important for healthcare decision making, as they provide a fuller picture of a patient's health outside the clinical setting. However, the clinical utility of PGHD is limited, given the lack of PGHD collection, transfer, and tracking standards.[30,213]

To address this challenge, funders should invest in additional research that examines capabilities to leverage current standards to support full integration of PGHD into the EHR and should support the development of new standards. Future PC CDS research should also examine the use of existing frameworks, such as SMART Markers, to support the integration of PGHD for PC CDS.[87]

However, these frameworks alone will not be sufficient to address current gaps in PGHD standards. Standards-development organizations will need to spearhead new efforts to develop PGHD data-integration standards. These efforts should engage patients and clinicians to understand what types of data, and from which sources, are most critical for full EHR integration. It will also be important to understand patient and clinician preferences for PGHD visualization. Health systems can promote new standards for PGHD integration by prioritizing PGHD use in clinical care and advocating for the adoption of these standards by EHR developers. The adoption of PGHD integration standards among EHR developers will be essential for advancing the integration of PGHD in the clinical setting.

4.1.7 CDS-Focused Application Programming Interfaces

The provisions under the final rule for the 21st Century Cures Act will help advance the development and use of FHIR-based APIs.[141] To address current challenges, standards-development organizations will need to develop standards that allow data to be written back to the EHR, while EHR developers will

need to adopt and implement these standards. Furthermore, health systems must work with patients and clinicians to develop processes for using this type of data to inform clinical care.

CDS developers and funders should continue to support the development of FHIR-based APIs that support data exchange to inform PC CDS. There may also be a need to develop new FHIR resources to support APIs that aggregate and share PGHD for PC CDS.

CDS that is patient-centered should support patient participation in healthcare decision making. Consequently, new FHIR-based API development should focus on facilitating patient data access. As PGHD, SDOH, and other patient-provided data become increasingly important for clinical decision making, it is critical that FHIR APIs have write capability to store these data.[59] EHR developers should invest in FHIR-based APIs with both read and write capabilities. Furthermore, developers should engage patients in the development of new APIs.

4.1.8 Application Programming Interfaces for Bulk Data Export to Inform PCOR

Bulk data is an evolving area that will become increasingly important as the field looks to develop PC CDS that addresses needs at a population level. Standards-development organizations will need to provide additional resources and guidance to recognize the potential of bulk data export. As standards for bulk data export evolve, it will be important to differentiate use cases for bulk data (e.g., informing research and a “Green Button” to look at accumulation of patient data). EHR developers, researchers, Federal agencies, and payers will have an important role in supporting the development of these use cases, and adoption and implementation of these standards. To encourage adoption of existing standards and resources, research sponsors should be incentivized to require use of the Bulk Data API. Finally, there may be opportunities to leverage efforts to harmonize common data models to support standardization of real-world data to inform PC CDS.

4.1.9 Additional Opportunities for PC CDS Standards

Advancing PC CDS will also require that the larger community of CDS stakeholders, including standards-development organizations and CDS developers, address challenges that broadly impact the PC CDS technical landscape.

First, to mitigate potential disparities in the availability of patient-facing PC CDS tools and collection of PGHD, additional infrastructure is needed that supports Android-based mobile devices and addresses barriers to technology access—such as limited availability of broadband internet and smartphones among low socioeconomic status and rural communities.[214] In addition, there must be a standardized process to curate PGHD data to assess data provenance and quality, and ensure data are in a human- and/or machine-readable format that can ultimately be used by patients and clinicians for shared decision making.

To enable scaling of interoperable PC CDS tools, it is important to address the ambiguity and variation that currently exist around the use of standard terminologies in FHIR resources. Creating and promoting the use of FHIR Implementation Guides can provide the needed clarity. Additionally, while PC CDS tools and logic may use a specified coding system or value set of eligible codes, no single authoritative library of value sets exists. The National Library of Medicine VSAC hosts value sets used in Clinical Quality Measures, many of which might be used to support CDS applications.[56] To date,

however, it is not clear how many value sets are relevant to PC CDS specifically, or if CDS developers routinely contribute to VSAC. Furthermore, while the National Library of Medicine hosts the repository, it does not actively curate the content received from CMS or other organizations. Future work in this area is needed to identify and host value sets relevant to PC CDS, specify approaches (e.g., CQL) for using code systems within FHIR resources, and assist standards developers and users (e.g., health systems) in using common approaches for modeling terminologies within FHIR and in the representation of clinical knowledge.

Finally, standards need to be further developed and broadly adopted to allow patients to provide other trusted individuals (e.g., family, friends) with proxy access to their medical records, while still allowing for patient oversight of what is accessed or edited.

4.2 Additional Opportunities to Advance PC CDS

Evolving efforts to engage patients and ensure transparency appear to be at the forefront of current policy efforts in health IT. Multistakeholder efforts from both the public and private sectors could coalesce to develop a streamlined set of basic principles for the development of PC CDS that ensures patient trust and safety and clinician uptake. With the emergence of new technologies like AI, further development of AI ethics frameworks and guiding principles is needed to ensure AI is trustworthy, transparent, and bias-free.[199] **Exhibit 7** outlines additional opportunities to advance PC CDS, mostly centered around multistakeholder efforts between the public and private sectors.

Exhibit 7. Opportunities to Advance PC CDS

Current State	Future Needs
Patient Trust, Transparency, and Safety. Regulatory efforts to engage patients and ensure transparency are evolving and appear to be at the forefront of regulation pertaining to PC CDS.	There can be a multistakeholder effort, including patients, to develop a patient safety framework for PC CDS app development to ensure these tools achieve better patient care quality.
AI Ethics Frameworks. Ethics frameworks are coming to prominence, particularly related to the ethics of using AI to process PGHD and different forms of patient-reported data.	An established and widely adopted ethical and safety framework to guide PC CDS app development can ensure patient data are secure and remain within the patients' control when moving from the patients' devices or EHRs to third-party apps. The AI Ethics Framework by the Office of the Director of National Intelligence provides AI ethics principles intended to guide whether and how to develop and use AI to process PGHD and communicate with clinicians or third-party applications.[199] The evolving area of transparency of AI/ML-enabled devices can be further supported by research and standards development.
Codes of Conduct for PC CDS App Development. Currently, an abundance of apps provides patients and clinicians information about the patient's health that could inform healthcare decisions.	Multistakeholder efforts, including both the public and private sectors, can be convened to develop a coordinated set of fundamental principles to adhere to regarding development of PC CDS—including an emphasis on improving patient trust and transparency, healthcare equity, and healthcare quality.

Current State	Future Needs
Interoperability. With the advent of multiple patient apps, it is important to ensure interoperability so that PC CDS apps are able to integrate with healthcare IT systems used by clinicians.	Public and private sector efforts should continue to promote interoperability and employ quality improvement efforts around such efforts.

4.3. Conclusion

The standards and regulatory landscape for PC CDS is evolving to meet new opportunities and challenges presented by broad consumer adoption of mobile technology and healthcare systems' transformation toward whole-person, value-based care. While significant progress has been made to date, additional standards are needed to guide the representation, verification, and integration of patient-contributed data into both clinician- and patient-facing PC CDS tools. Furthermore, regulatory efforts are under way to ensure patient trust and safety, promote patient data access and privacy, improve interoperability, and address challenges related to the emerging use of AI in clinical care. This environmental scan provides suggestions for a path forward to removing current barriers to PC CDS, addressing emerging challenges, and fully embracing the potential of PC CDS.

Appendix A. Expanded Methods

Exhibit A1. Environmental Scan Research Questions

High-Level Goals	Research Questions
Examine current state of standards and regulatory frameworks	1. What is the current state of standards (i.e., knowledge management, vocabulary, and exchange standards) relevant to PC CDS, and what are the gaps? What new standards are in development? 2. What is the current state of adoption of PC CDS standards? 3. What is the current state of regulatory frameworks for PC CDS, and where are there gaps in the regulatory frameworks?
Identify salient gaps, opportunities, and challenges	4. What are the current challenges in identifying and using different types of standards in PC CDS? 5. What are the opportunities for addressing the gaps and challenges in standards and regulatory frameworks?
Identify recommendations and develop an action plan	6. What critical activities related to standards development and adoption will support PC CDS development in the short (< 5 years), medium (5-10 years), and long term (> 10 years)?

Exhibit A2. Key search terms for environmental scan

Search Terms for PubMed Search	
decision support systems, clinical/standards"[MeSH Major Topic] OR ("decision support systems, clinical"[MeSH Terms] OR "clinical decision making"[MeSH Terms] OR "clinical decision support"[Title/Abstract] OR "clinical decision rules"[MeSH Terms] OR "clinical decision rules"[MeSH Terms]	
AND	
"patient generated health data"[MeSH Terms] OR "patient reported outcome measures"[MeSH Terms] OR "patient preference"[MeSH Terms] OR "patient generated health data"[Title/Abstract] OR "patient-reported outcomes"[Title/Abstract] OR "patient preferences"[Title/Abstract] OR "patient goals"[Title/Abstract] OR "social determinants of health"[MeSH Terms] OR "social determinants of health"[Title/Abstract] OR "shared decision making"[Title/Abstract] OR "patient centered"[Title/Abstract] OR "patient centered care"[MeSH Terms] OR "patient-facing"[Text Word])	
AND	
Standards Search:	*Regulatory Frameworks Search:*
"artificial intelligence/standards"[MeSH Terms] OR "Fast Healthcare Interoperability Resources"[Text Word] OR "FHIR"[Text Word] OR "CQL"[Text Word] OR "CDS Hooks"[Text Word] OR "SNOMED"[Text Word] OR "LOINC"[Text Word] OR "interoperability"[Title/Abstract] OR "standards"[Title/Abstract])) OR ("decision support systems, clinical"[MeSH Terms] AND "standards"[Title/Abstract])	"government regulation"[MeSH Terms] OR "regulation"[Title/Abstract] OR "law"[Title/Abstract] OR "FDA"[Text Word] OR "promoting interoperability program"[Text Word] OR "CURES Act"[Text Word] OR "information blocking"[Text Word] OR "decision support systems, clinical/legislation and jurisprudence"[MeSH Terms] OR "decision support systems, clinical/ethics"[MeSH Terms] OR "privacy"[Title/Abstract] OR "security"[Title/Abstract]) OR ("decision support systems, clinical"[MeSH Terms] AND ("government regulation"[MeSH Terms] OR "regulation"[Title/Abstract] OR "law"[Title/Abstract] OR "FDA"[Text Word] OR "promoting interoperability program"[Text Word] OR "CURES Act"[Text Word] OR "information blocking"[Text Word] OR "decision support systems, clinical/legislation and jurisprudence"[MeSH Terms] OR "decision support systems, clinical/ethics"[MeSH Terms] OR "privacy"[Title/Abstract] OR "security"[Title/Abstract])

AND
2019/01/01:2022/12/31[Date - Publication]

Exhibit A3. Inclusion and Exclusion Criteria

Inclusion Criteria	Exclusion Criteria
• Published/developed in 2019 or later • Focuses on the use of clinical decision support (CDS) in the United States • Peer-reviewed literature including literature reviews, qualitative studies, implementation studies, viewpoints, and commentaries or: • Gray literature including reports, policy statements, white papers, conference proceedings, agency initiatives, and infographics • Relevant to patient-centered CDS interventions: targeted to patients or caregivers or created from Patient-Centered Outcomes Research (PCOR) and designed to facilitate shared decision making or target treatment based on patient-specific health data • Discusses technical standards and/or implementation guidance relevant to developing, implementing, and supporting PC CDS, including facilitation of data exchange and interoperability, standards related to sharing knowledge artifacts, artificial intelligence, machine learning, and/or standardization of specific terminologies or vocabularies that are germane to PC CDS such as patient preferences, social determinants of health, or patient-reported outcomes and/or: • Discusses legal regulatory frameworks or guidance documents relevant to operationalizing PC CDS as related to data exchange and interoperability, privacy and security, artificial intelligence, machine learning, and/or digital health applications or mobile medical devices	• Does not address a clinical decision support intervention or technologies that could be applied to improve PC CDS • Does not include human patients (e.g., veterinary studies; algorithms or clinician-focused tools that do not involve some element of patient interaction) • Blog, book, news article, discussion forum, webinar

Appendix B. Standards, Implementation Guides, Software, and Initiatives

Standard	Stage(s)	Relevance to PC CDS
FHIR Clinical Reasoning Module	1,4	The FHIR Clinical Reasoning Module enables the exchange of patient-contributed information that can be integrated into PC CDS tools.
Clinical Quality Language (CQL)	1	CQL is a standardized, FHIR-compatible expression language for representing clinical knowledge (e.g., guidelines and recommendations) in both human and computable formats.
GELLO	1	GELLO represents clinical guidelines, specifies decision criteria, and facilitates the sharing of decision logic.
Arden Syntax	1	Arden Syntax is being developed into Arden Syntax 3.0 and will incorporate FHIR to improve interoperability, which could facilitate the adoption of PC CDS tools in those health IT systems that use Arden Syntax.
FHIR Provenance	2	FHIR Provenance allows for the integration of patient-contributed data into clinician-facing health IT systems, while enabling PC CDS to account for potential differences between data gathered in the clinic and data gathered remotely.
Provenance Ontology (PROV-O)	2	PROV-O provides a set of classes, properties, and restrictions that can be used by developers to represent, exchange, and integrate provenance information across heterogenous systems and contexts.
United States Core Data for Interoperability (USCDI)	2	USCDI is a standardized set of health data elements that support interoperability and information exchange.
Logical Observation Identifiers, Names, and Codes (LOINC)	3,5	LOINC can accommodate answers to patient-directed queries as well as summary measures from patient-facing applications or devices. LOINC also provides terminology for dietary intake, sleep duration, patient preferences and goals.
SNOMED CT	3,5	SNOMED CT provides codes for symptoms and vital signs (e.g., heart rate, glucose monitoring) that can be applied to PGHD, as well as patient preferences and goals.
CDS Hooks	4	CDS Hooks are used to trigger CDS in response to user actions in the EHR, such as when a new patient record is opened or new orders are entered, and can be paired with other standards, such as SMART on FHIR or FHIR Clinical Reasoning, to facilitate PC CDS.
HL7 Infobutton	4	Infobuttons can be used to offer access to patient context-relevant resources and can be inserted in various workflow screens in the EHR and in patient portal applications.

Standard	Stage(s)	Relevance to PC CDS
FHIR Subscription Resource	4	The FHIR Subscription allows CDS developers to specify events that should trigger a user notification and enable another system to act. Notifications can be sent to users via email, text messaging, or FHIR messaging service.
FHIR Questionnaire Resource	5	The FHIR Questionnaire Resource is used to capture patient-directed questions, allowing for the representation of questionnaire names and specific questions.
FHIR QuestionnaireResponse Resource	5	The FHIR QuestionnaireResponse Resource is used subsequently to the FHIR Questionnaire Resource to capture patient responses to those queries.
ICD-10-CM	5	ICD-10-CM provides a subset of diagnostic “Z” codes that allow hospitals to identify nonmedical factors that may impact a patient’s outcomes.
Current Procedural Terminology (CPT)	5	CPT provides the ability to capture SDOH data to identify nonclinical factors to facilitate PC CDS.
US Core Goal Profile	5	The US Core Goal Profile sets the minimum required data elements (i.e., status, description, patient, target date) for capturing patient goals.
The CarePlan FHIR resource	5	The CarePlan FHIR resource includes the capture of goals related to patient care (using the FHIR Goal resource), as part of the FHIR 4.3.0 specification.
IEEE 1752	6	IEEE 1752 is a set of family standards enabling the description, exchange, sharing, and use of mHealth data including 1752.1 (sleep and physical activity data), and 1752.2 (cardiovascular, respiratory, and metabolic data).
The United States Core Data for Interoperability (USCDI)	6,7	The USCDI is a standardized set of health data elements that support interoperability and information exchange, which served as the basis for the US Core FHIR Implementation Guide specifications.
HL7 Bulk Data Access (Flat FHIR) API	8	Flat FHIR supports export of data for populations of patients.

Implementation Guides	Stage(s)	Relevance to PC CDS
FHIR Clinical Guidelines Implementation Guide (CPG-IG)	1	CPG-IG seeks to assist developers in creating computable and accurate representations of clinical guidelines while minimizing duplicative efforts.
US Core FHIR Implementation Guide	2, 6	The US Core FHIR Implementation Guide facilitates consistency around how and what patient data are accessed, as well as security standards used to authenticate, authorize, and audit data access.
HL7 FHIR PRO Implementation Guide.	3	The HL7 FHIR PRO Implementation Guide focuses on the capture and exchange of PRO data using the FHIR data model.
The electronic Long-Term Services and Supports (eLTSS) Implementation Guide	5	The eLTSS Implementation Guide supports the exchange of data gathered during care planning for long-term services and supports and includes a Goal Profile derived from the US Core Goal Profile.

Implementation Guides	Stage(s)	Relevance to PC CDS
The Multiple Chronic Conditions (MCC) e-Care Plan Project Implementation Guide	5	The MCC e-Care Plan Project Implementation Guide is a joint effort between AHRQ and the National Institutes of Health, which advances the interoperable collection and exchange of person-centered health and SDOH data across settings.
Data Exchange for Quality Measures Implementation Guide	8	The Data Exchange for Quality Measures Implementation Guide was developed by the Da Vinci project and focuses on three use cases: medication reconciliation, colorectal cancer screening, and venous thromboembolism prophylaxis to advance data sharing.

APIs, Software, and Platforms	Stage(s)	Relevance to PC CDS
Fast Evidence Interoperability Resources (FEvIR) Platform	1	FEvIR provides developers with numerous tools to build and view scientific knowledge as standards-based, computable HL7 resources that can be used to create PC CDS.
SMART on FHIR APIs	6,7	SMART on FHIR APIs enable the sharing of PGHD and the integration of PGHD from devices into the clinical workflow.
CommonHealth	6	CommonHealth leverages data interoperability standards such as HL7 FHIR and SMART Health Cards to offer functionality analogous to Apple HealthKit in an effort to connect users to their EHR data and give them complete control of how, when, and with whom they share their health data.
Apple HealthKit	6	Apple HealthKit is a FHIR-based API that allows for the aggregation of PGHD from various sources and the integration of this data into the EHR.
SMART Markers Software Framework	6	The SMART Markers Software Framework supports the development of apps that allow for the exchange of PGHD from patient apps or devices to the point of care.

Initiatives	Stage(s)	Relevance to PC CDS
HL7 Evidence-Based Medicine (EBM) on FHIR	1	The HL7 EBMonFHIR project provides a standard for exchanging clinical research evidence and clinical practice guidelines.
BPM+ Health	1,4	BPM+ Health allows for the creation and dissemination of automated clinical pathways across institutions and are complementary with existing standards such as FHIR and CQL.
Adapting Clinical Guidelines for the Digital Age	1	Adapting Clinical Guidelines for the Digital Age aims to identify more efficient and reliable approaches to translate clinical information into digital products.
Open mHealth	3,6	Open mHealth enables developers to standardize data from various mHealth data sources (e.g., wearable devices, mobile apps) to promote interoperability with EHR and external care platforms.

Initiatives	Stage(s)	Relevance to PC CDS
CardinalKit	3,6	CardinalKit is an open-source framework to assist app developers in creating interoperable digital health tools and features such as survey generation, adherence monitoring, and collection of health and movement data (e.g., PGHD) from smartphones and other Bluetooth-enabled devices.
The PACIO Project	5,7	The PACIO Project focuses on advancing interoperable health data exchange between post-acute care and other healthcare stakeholders.
The Gravity Project	5	The Gravity Project advances both terminology and data exchange standards for SDOH.
Protocol for Responding to and Assessing Patients' Assets, Risks, and Experiences (PRAPARE)	5	PRAPARE focuses on assisting health systems and care teams to collect standardized SDOH data to improve clinical care.
HEART (Health Relationship Trust) profiles	6	HEART leverages existing open standards (e.g., FHIR) to enable patients to determine how their clinical data are shared.
CARIN Alliance	7	The CARIN Alliance Health Plan Workgroup developed an implementation guide to support the sharing of Medicare claims information with Medicare fee-for-service beneficiaries through FHIR-based APIs.
The Da Vinci project	8	The Da Vinci project advances data sharing between patients and clinicians by leveraging the FHIR standard to support and integrate value-based care data exchange.
The Green Button approach	8	The Green Button approach envisions a function directly within EHRs that aggregates data to support clinician decision making and to provide patients with data on patients who are like them.

Appendix C. Regulatory Frameworks

Federal Agency or Department	Regulation or Guidance	Overview
ONC	ONC Cures Act Final Rule (45 CFR 170; 45 CFR 171)	The ONC Cures Act Final Rule calls for open APIs that are safe, secure, and affordable. These APIs support innovation in the marketplace for health IT and app developers.[215]
CMS	CMS Interoperability and Patient Access Final Rule	The Interoperability and Patient Access Final Rule (CMS-9115-F) gives patients access to their health information when they need it and in a way they can best use it.[216]
CMS	Promoting Interoperability Programs	The Promoting Interoperability Programs encourages eligible professionals and health systems to adopt, implement, upgrade, and demonstrate meaningful use of certified electronic health record technology (CEHRT).[163]
CMS	Appropriate Use Criteria Program (Protecting Access to Medicare Act) of 2014	The Protecting Access to Medicare Act (PAMA) of 2014, Section 218(b) established a program to increase the rate of appropriate advanced diagnostic imaging services for Medicare beneficiaries.[165]
CMS	Hospital Price Transparency	CMS finalized hospital price transparency requirements under section 2718(e) of the Public Health Service Act, which requires hospitals to publish their list of standard charges.[168]
FDA	Section 3060(a) of the 21st Century Cures Act	Section 3060(a) of the 21st Century Cures Act (Cures Act), amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) to exclude certain medical software functions from the definition of device. It describes the statutory framework for what functions are considered non-device CDS software.[217]
FDA	21st Century Cures Act (Section 1002, FDA Innovation Projects)	Section 1002 of the 21st Century Cures Act is designed to help accelerate medical product development and bring new innovations and advances to patients faster and more efficiently.[218]
FDA	Policy for Device Software Functions and Mobile Medical Applications: Guidance for Industry and FDA staff	“Policy for Device Software Functions and Mobile Medical Applications: Guidance for Industry and FDA staff” describes FDA's regulatory approach to CDS software functions. The agency's approach includes recent changes to the FD&C Act made by the 21st Century Cures Act, which amended section 520 and excludes certain software functions from the device definition.[12]
FDA	Food and Drug Administration Safety and Innovation Act (FDSIA) risk assessment report (Section 618 of the FDASIA, Public Law 112-144)	Section 618 of the Food and Drug Administration Safety and Innovation Act requires that FDA, in consultation with ONC and the Federal Communications Commission (FCC), develop and post on their respective websites "a report that contains a proposed strategy and recommendations on an appropriate, risk-based regulatory framework pertaining to health information technology, including mobile medical applications, that promotes innovation, protects patient safety, and avoids regulatory duplication."[170]

Federal Agency or Department	Regulation or Guidance	Overview
FDA	Clinical Decision Support Software: Guidance for Industry and Food and Drug Administration Staff	The Clinical Decision Support Software Guidance for Industry and FDA Staff was updated and finalized in September 2022. In this guidance, FDA clarified the scope of its oversight for CDS software functions.[169] This guidance further clarifies that FDA's existing digital health policies continue to apply to software functions that meet the definition of a medical device.
FDA	Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD) Action Plan.	The Action Plan was developed by FDA in 2021; the proposed approach in the report allows FDA's regulatory oversight to embrace the iterative improvement power of AI and machine learning software as a medical device, while assuring that patient safety is maintained.[200]
Office of the Director of National Intelligence	AI Ethics Framework by the Office of the Director of National Intelligence	This AI Ethics Framework is an ethics guide for United States Intelligence Community personnel on how to procure, design, build, use, protect, consume, and manage AI and related data.[199]

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