CDS Innovation Collaborative

An Overview of Standards for Patient-Centered Clinical Decision Support

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. Consistent standards are essential to ensure PC CDS is accessible wherever and whenever clinicians and patients prefer to receive it, and in a manner that is easy for both groups to understand and act upon in both clinical and nonclinical settings.

The Agency for Healthcare Research and Quality (AHRQ) Clinical Decision Support Innovation Collaborative (CDSiC) Standards and Regulatory Frameworks Workgroup produced an Environmental Scan that assessed the current landscape of standards and regulatory frameworks of PC CDS to determine gaps, challenges, and opportunities. The scan mapped the findings related to PC CDS standards to eight stages of the PC CDS technical landscape, as defined by a previous AHRQ initiative.[1]

Below are available standards and future opportunities for each stage. These opportunities will require collaboration between electronic health record (EHR) developers, CDS content developers, and healthcare organizations. Federal agencies, standards-development organizations, and professional medical societies must work in partnership to encourage adoption and consistent use of standards.

PC CDS Technical Landscape Stage and Available Standards	Current State	Future Directions
Stage 1: Standards for Translating Clinical Guidelines into PC CDS. **Fast Healthcare Interoperability Resources** (FHIR®) Clinical Reasoning Module • Clinical Quality Language (CQL) • GELLO • Arden Syntax	• Limited collaboration between CDS artifact and guideline developers. CQL can support standardized representation of clinical knowledge into CDS artifacts. • FHIR Clinical Guidelines Implementation Guide (CPG-IG) can provide a standardized approach to knowledge translation.	• 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. • Engage guideline developers to support further development and adoption of the CPG-IG.
Stage 2: Standards for Managing Data Provenance. FHIR Provenance • Provenance Ontology • United States Core Data for Interoperability (USCDI)	• FHIR Provenance can support the representation and tracking of data provenance of different data sources. • 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.	• 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 data. • Develop standards that allow for representation and interpretation of the UDIs associated with medical devices.
Stage 3: Patient-Generated Health Data (PGHD) Standards. Logical Observation Identifiers, Names, and Codes (LOINC) • SNOMED Clinical Terms (SNOMED CT)	• LOINC and SNOMED CT have limited PGHD coverage. • Information regarding coverage of patient-report outcomes (PROs) and other types of patient-generated or patient-reported data in standard terminologies is limited. • Developers may be able to leverage the Health Level Seven (HL7®) FHIR PRO Implementation Guide.	• Assess current coverage for PGHD and PRO terms in LOINC and SNOMED CT. • Promote use of FHIR-based, standardized patient-facing apps to collect PROs. • Generate evidence on how PGHD standards can improve healthcare and health outcomes. • Examine methods for verifying PGHD to ensure PC CDS safety and appropriateness.

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Stage 4: Standard PC CDS Insertion Points. FHIR Clinical Reasoning Module • CDS Hooks • HL7 Infobutton • FHIR Subscription Resource	• CDS Hooks can be paired with other standards, such as Substitutable Medical Applications, Reusable Technologies (SMART) on FHIR or FHIR Clinical Reasoning to facilitate PC CDS. • FHIR Subscription resource can be used to trigger CDS in response to changes in data in a FHIR server.	• 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. • Promote adoption of standardized, automated clinical workflows.
Stage 5: Standards for Non-clinical Patient-Centered Data. LOINC • SNOMED CT • FHIR Questionnaire Response Resource • ICD-10-CM • Current Procedural Terminology •US Core Goal Profile • CarePlan FHIR resource	• Mechanisms to standardize patient-preference and social determinants of health (SDOH) data and integrate these data into the clinical workflow are limited. • The Gravity Project is advancing both terminology and data exchange standards for SDOH.	• 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. • Examine use of the Gravity Project's FHIR implementation guide to support SDOH data exchange for PC CDS.
Stage 6: Integration of PGHD into EHRs. Institute of Electrical and Electronics Engineers 1752 • USCDI	• PGHD collected through PC CDS apps are typically stored and reviewed outside the EHR. • SMART on FHIR application 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.	• 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. • Examine use of frameworks such as SMART Markers to support PGHD integration for PC CDS.
Stage 7: CDS-Focused APIs. USCDI	• API developers' adoption of FHIR standards varies. • FHIR APIs offer limited support for writing information to the EHR database.	• 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 development.
Stage 8: APIs for Bulk Data Export to Inform PCOR. HL7 Bulk Data Access (Flat FHIR) API	Standards are emerging; the SMART/HL7 Bulk Data Access (Flat FHIR) API supports bulk data export.	• 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.
Additional Opportunities for PC CDS Standards	• 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 to medical records.	

Endnotes

1. Dullabh PM, Desai PJ, Gordon JR, et al. Standards and Regulatory Frameworks Workgroup: Environmental Scan. https://cdsic.ahrq.gov/sites/default/files/2023-05/FINALSRFLevel1EnvironmentalScan1.pdf.