Standards and Regulatory Frameworks Workgroup: Improving Interoperability of Patient Apps With the Health IT Ecosystem

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PURPOSE

The Clinical Decision Support 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 14 experts and stakeholders representing a diversity of perspectives within the CDS community. This report 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 report to inform product development under its Stakeholder and Community Outreach Center Workgroups and for projects developed through its Innovation Center.

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Executive Summary

The healthcare mobile application (app) market is expanding at a rapid pace. As the number, maturity, and quality of health-related apps grow and healthcare organizations evaluate them for use in "digital health formularies," clinicians are increasingly recommending and prescribing apps to help patients manage clinical conditions. Apps can collect a variety of data about the health of patients—including vital signs, patient-reported outcomes, behaviors, preferences, and values—that can be shared with care teams to inform patient-centered care and support clinical decision making.

Currently, gaps in interoperability limit the clinical utility of apps and their ability to inform patient-centered clinical decision support (PC CDS). Without integration across systems and technologies, patient data collected by apps remain sequestered in the app or in portals separate from clinician health information technology (IT) systems and workflows. This separation can lead to increased time and cognitive burden for clinicians and inappropriate PC CDS guidance based on incomplete or outdated information.

This report pursued four objectives related to understanding and improving patient app interoperability: 1) develop a model of an integrated PC CDS ecosystem with associated data flows, 2) create an index of key interoperability scenarios and requirements for integration, 3) examine the landscape of relevant standards and salient gaps, and 4) identify opportunities to achieve patient app interoperability and develop an action plan. Given the focus on data interoperability between apps and clinician health IT systems, the content of the report applies to apps that are prescribed by clinicians or recommended by health systems, rather than apps selected by patients and used without clinician participation or health system authorization.

The intended audiences for this document are policymakers, electronic health record (EHR) developers, app developers, device and wearable manufacturers, clinicians and health systems, CDS researchers, CDS content developers, health IT standards developers, payers, and patients and their caregivers.

Methods

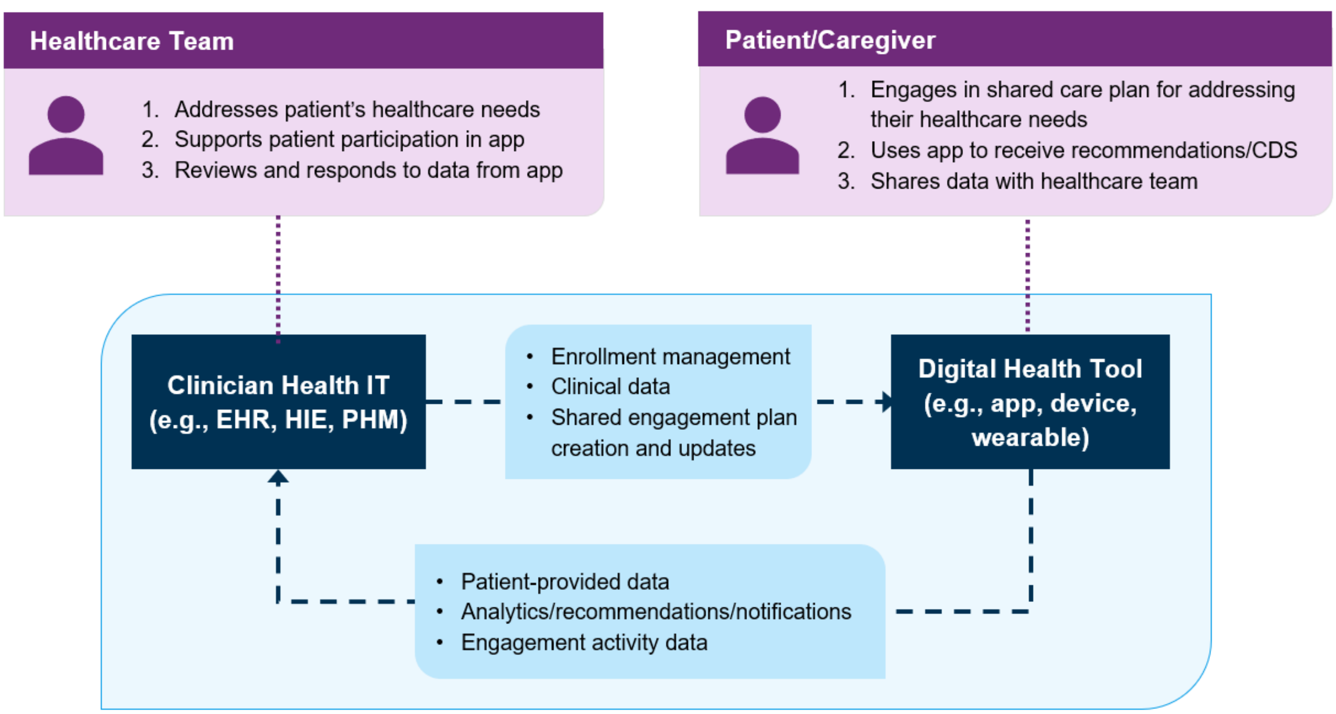
The Clinical Decision Support Innovation Collaborative (CDSiC) team synthesized information from three sources: a targeted literature review of the peer-reviewed and grey literature to characterize applicable work in patient app integration, as well as available standards; key informant interviews (KIIs) with CDS experts to understand the current state of patient app interoperability, as well as needs, challenges, and opportunities; and review and input from the CDSiC Standards and Regulatory Frameworks Workgroup.

An Action Plan for the Integrated PC CDS Ecosystem

Achieving interoperability between patient apps and the health IT ecosystem (e.g., health information exchanges, personal health data platforms, population health management tools) requires designing systems and technologies that permit the exchange of different types of data relevant to managing, interpreting, and acting on app data. The Integrated PC CDS Ecosystem (Exhibit ES.1) illustrates the flow of data across technologies in an interoperable ecosystem, focusing on patient-facing technologies that are prescribed, recommended, or monitored by a clinician or healthcare organization to manage a patient's healthcare. It represents the optimal exchange of information—and the activities this enables—when systems and technologies are integrated.

Within the Ecosystem, patients, caregivers, and healthcare teams can monitor patient health and make healthcare decisions, facilitated by the regular exchange of data between patient-facing digital health technologies and clinician-facing health IT systems. Furthermore, the Ecosystem may apply to a single episode of care (e.g., preparation for a surgery) or it may be established to address a chronic condition (e.g., diabetes) over time. In all cases, clinician- and patient-facing technologies are integrated such that users and systems have access to the combined data from either system to fulfill their responsibilities. Underpinning the system are common standards that facilitate data exchange across the different technologies involved. Examples of the types of data exchanged between the health IT system and patient app include data related to enrolling the patient in the app, clinical data, the app engagement plan, patient-provided data (including data related to patient preferences, values, and treatment decisions stemming from shared decision making), analytics, recommendations, alerts, and data on patient engagement with the app.

Exhibit ES.1. Integrated PC CDS Ecosystem



Note: Dashed lines indicate data flows; dotted lines indicate user interaction with the Ecosystem.

EHR = Electronic Health Record; HIE = Health Information Exchange; PHM = Population Health Management

Next, we identified a set of key interoperability scenarios for integrating apps into the health IT ecosystem, focusing on the EHR as an essential first step. There are five key interoperability scenarios: 1) managing patient enrollment in the app, 2) healthcare team review of data from the app, 3) integrated PC CDS and population-level analytics based on app and EHR data, 4) notifying the healthcare team, and 5) notifying the patient (Exhibit ES.2).

Exhibit ES.2. Five Key Patient App-EHR Interoperability Scenarios

Managing Enrollment

The EHR should be able to communicate with the app about patient enrollment and unenrollment.

Healthcare Team Review of Data

The healthcare team must be able to monitor patient-provided data entered in the app—ideally combined with EHR data in an integrated view—to make informed decisions.

Integrated PC CDS and Population-Level Analytics

Incorporating data from both the patient app and EHR into CDS logic will yield more relevant PC CDS and support population health and quality reporting.

Notifying Healthcare Team

Apps may need to notify the healthcare team regarding clinically significant events, patient questions, and lack of patient engagement with the app.

Notifying Patients

Interoperability is required for the app to communicate with the patient about their care plan or upcoming appointments outside of the app, such as through the EHR's patient portal.

For each interoperability scenario, we summarize interoperability requirements, available standards for integration, and opportunities for the CDS community to overcome current challenges to app interoperability and advance the use of patient apps in PC CDS.

Scenario 1: Managing Patient Enrollment. The first requirement for an integrated ecosystem involves managing patient enrollment in the app. This involves multiple activities, including identifying eligible patients, requesting patient enrollment and customizing the engagement plan, sending the enrollment request to the app, enrolling the patient, and exchanging enrollment updates between the app and EHR. We identified several standards that will facilitate these activities, as well as seven opportunities for this scenario based on the current state of standards.

Existing Standards	Opportunities for Advancing Patient App Interoperability
To identify patients to enroll: • Clinical Quality Language (CQL) • FHIR PlanDefinition • FHIR Subscription • CDS Hooks **To request patient enrollment and customizing engagement plan:** • FHIR Questionnaire • FHIR QuestionnaireResponse • FHIR Parameters • SMART on FHIR **To send enrollment request to app:** • No standard available to exchange enrollment request, although SMART on FHIR could potentially be used to enroll patient **To have app enroll and inform patient:** • FHIR CommunicationRequest **To exchange enrollment status updates** • No standards currently available	• Promote greater implementation of PlanDefinition and CQL to assist with identifying eligible patients for enrollment. • Encourage implementation of FHIR Subscription to trigger identification of eligible patients for enrollment. • Advance implementation and use of CDS Hooks to assist care team with identifying eligible patients for enrollment. • Facilitate dissemination and adoption of standard terminologies and value sets that can be used to standardize patient identification and enrollment procedures and provide guidance for the consistent use of these standards. • Encourage implementation of FHIR CommunicationRequest by EHR developers and healthcare organizations to facilitate the use of CommunicationRequest to correspond with patients about their enrollment. • Modify the Bulk FHIR specification to allow standard, EHR-agnostic queries to allow this standard to be used to identify cohorts of patients eligible for enrollment in a scalable manner. • Develop an implementation guide on communicating enrollment requests and exchanging enrollment status updates between the app and EHR, using existing resources or developing new resource types as needed.

Scenario 2. Healthcare Team Review of Data. The healthcare team must be able to monitor patient-provided data entered in the app—ideally combined with EHR data in an integrated view—to make informed decisions about patient care. This can occur within the EHR, a standards-based "EHR-extender" such as a SMART on FHIR app, or in the app itself (i.e., clinician app portal). We identified a number of standards that can facilitate these activities, as well as three opportunities for this scenario based on the current state of standards.

Existing Standards	Opportunities for Advancing Patient App Interoperability
To view app data in EHR: • FHIR Create APIs for Observation • FHIR QuestionnaireResponse • FHIR Task **To pull EHR data into apps:** • United States Core Data for Interoperability (USCDI) FHIR APIs **To view both EHR and app data in a standards-based EHR-extender** • SMART on FHIR	• Health apps should implement FHIR APIs to provide access to the data they obtain from users, which can be used to create integrated views of app and EHR data using standards-based EHR extenders such as SMART on FHIR. • Develop an implementation guide for patient app data interoperability describing the minimal data elements that should be interoperable between apps and EHRs and identifying how they should be shared. • Promote development and implementation of FHIR APIs that allow write access to EHRs, especially for FHIR Observations and QuestionnaireResponses. These APIs should accept data coded with standard terminologies and provenance metadata.

Scenario 3. Integrated PC CDS and Population-Level Analytics. Apps and EHRs can provide more relevant and accurate PC CDS and population-level analytics by incorporating data from the EHR and the app in CDS logic. We identified several standards that can facilitate these activities, as well as two opportunities for this scenario based on the current state of standards:

Existing Standards	Opportunities for Advancing Patient App Interoperability
For PC CDS: • USCDI FHIR APIs • FHIR Questionnaire and Observation APIs **For population-level analytics:** • Bulk FHIR • CDS Hooks • SMART on FHIR backend service	• Promote additional implementation of the Bulk FHIR API standard. • Bulk FHIR can be used to pull data into repositories for population-level analytics, but the specification needs to support granular queries that are more efficient and that limit receipt of unneeded/unnecessary data.

Scenario 4. Notifying Healthcare Team. Apps may need to notify the healthcare team regarding clinically significant events, patient questions, and/or lack of patient engagement with the app. Although health systems will have their own preferences for designing care team notifications based on urgency and content, there are several standards at present that can be used for this purpose. We identified four opportunities for this scenario based on the current state of standards.

Existing Standards	Opportunities for Advancing Patient App Interoperability
To send a message to the healthcare team: • FHIR CommunicationRequest **To display a dialog/alert when the healthcare team member logs in:** • CDS Hooks **To display a message in a population or patient view:** • FHIR Observation • FHIR Flag • FHIR DetectedIssue*	• Expand the implementation of FHIR CommunicationRequest to allow for standards-based messaging with healthcare team members. • Broaden the implementation and adoption of CDS Hooks to enable display of CDS cards when a healthcare team member opens a chart or performs other action that may require a PC CDS intervention. • Develop an implementation guide on using available standards to notify healthcare teams based on app data or activity. • Explore and test the use of FHIR DetectedIssue for displaying a message in a population or patient view, modifying the resource as needed.

*Standard may require modification prior to use for this purpose

Scenario 5. Notifying Patients. Interoperability is required for the app to communicate with the patient about their care plan or upcoming appointments outside of the app, such as through the EHR's patient portal. This is an emerging area in the PC CDS ecosystem. The FHIR CommunicationRequest can be used to route a message to the patient, either from the app to the EHR, or the EHR to the app. We identified two opportunities for this scenario based on the current state of standards.

Existing Standards	Opportunities for Advancing Patient App Interoperability
• CommunicationRequest	• Expand the implementation of FHIR CommunicationRequest to enable messages to be sent to patients by either the app or the EHR. • Develop new hooks that enable delivery of PC CDS to patients using the CDS Hooks standards (e.g., when patient logs into the portal).

Conclusion

The ecosystem for PC CDS is rapidly evolving. As access to mobile technologies and broadband internet has grown, so has the availability of patient-facing apps authorized by healthcare systems to monitor and manage health conditions, facilitate patient engagement, improve the relevance and value of PC CDS, and support clinical decision making. However, to fully realize the potential of apps, they must be interoperable with the health IT systems that care teams use, particularly EHRs. This report identifies key interoperability scenarios and current standards for patient app integration, as well as opportunities for further advancing the standards landscape to support the interoperability of patient apps with EHRs and health IT systems. These opportunities address three primary needs: 1) additional implementation and adoption of existing standards for patient app interoperability, 2) further modification of current standards to support PC CDS use cases, and 3) new implementation guides to support the consistent use of standards in this domain. This work will require a coordinated effort between app developers and EHR developers, alongside standards developers, Federal funders, health systems, clinicians, and patients and their caregivers.

1. Introduction

The healthcare mobile application (app) market is expanding at a rapid pace. Currently, over 350,000 consumer apps are available related to health and healthcare.[1] Electronic health record (EHR) developers also provide access to hundreds of curated apps for clinicians, patients, and other healthcare stakeholders through dedicated app galleries to support administrative, clinical, care management, and population health functions.[2,3]

As the number, maturity, and quality of apps grow, clinicians are increasingly recommending and prescribing apps to patients to help manage clinical conditions. These apps provide another channel through which patients and clinicians can track patient health, including between routine office visits. Apps can collect a variety of data about the health of patients, including patient-provided data, such as vital sign measurements, patient-reported outcomes (PROs), behaviors, preferences, and values,[4] that can be shared with clinicians to monitor and inform adjustments in patient care. By utilizing apps, patients may be encouraged to be more engaged in their healthcare and healthcare planning, and providers have a more comprehensive view of patients' health and wellbeing, which can inform patient-centered care.[5] Moreover, research demonstrates that when patients are involved in care, they can shape their care and treatment to fit their needs and preferences, ultimately resulting in improved health outcomes.[6]

However, without integration across systems and technologies, patient data collected by apps remain sequestered in the app or in portals separate from clinician health information technology (IT) systems and workflows.[7,8,9] This separation can lead to increased clinician burden and even inappropriate care, if relevant data from the app are excluded from clinical decision support (CDS) systems.[10]

Currently, gaps in interoperability limit the clinical utility of apps and their ability to inform patient-centered clinical decision support (PC CDS). This report describes the technical activities, requirements, and standards needed to support interoperability between patient apps recommended or prescribed by clinicians and EHRs, a necessary first step in improving the integration of patient apps and data with the broader clinician health IT ecosystem. It begins by providing context on the growth and use of apps in healthcare and challenges due to limited interoperability. It then provides a vision of an Integrated PC CDS Ecosystem, a model for how data can flow and be used across clinical teams and patients when technologies are made interoperable. The report then describes the current interoperability landscape, including relevant standards and guidelines that can support integration. The report concludes with recommendations for addressing interoperability barriers and gaps.

The intended audiences for this report are policymakers, EHR developers, app developers, clinicians, health systems, CDS researchers, CDS content developers, health IT standards developers, payers, and patients and their caregivers.

1.1 Background

1.1.1 A Growing App Landscape

Health-related apps serve a range of functions and target clinicians, patients/caregivers, or both. While many health-related apps focus on general wellness and fitness—and are of highly variable quality—a growing number of health-related apps are vetted by healthcare stakeholders and serve specific administrative, management, and disease-specific needs.[1]

One study conducted from December 2019 through December 2020 identified 734 unique apps managed by five major EHR developers.[2] Nearly half of these apps supported administrative functions, such as scheduling, check-in, and billing. Apps also facilitated patient engagement, such as patient education, secure messaging, and satisfaction surveys; care management activities, such as disease management, care planning, patient monitoring, and medication management; and clinical care, such as population health, telehealth, and CDS.[2] Broadly, apps that provide CDS may include guidance to verify if lab tests and medication orders are appropriate, guidance for medication dosing, feedback on biometric measures, and alerts to notify clinicians of clinically significant changes in patient health.[3,11]

Apps are increasingly being developed to address specific diseases.[1] Common medical issues addressed by apps include chronic conditions such as mental health conditions, diabetes, and hypertension and other cardiovascular diseases.[1,12] To support management of these conditions, patient apps can collect a variety of data that can be used in clinical decision making through features such as symptom, biometric, and medication tracking. For example, apps can be used to collect data from devices such as pulse oximeters, blood pressure cuffs, or glucose monitors to monitor heart rate, oxygen saturation, blood pressure, and blood glucose, respectively.[5,13] Apps may also collect data through surveys and questionnaires to track items like patients' mental health status, pain levels, or reactions to a new drug.[5,14] Apps can even be leveraged to gather important contextual information about patients, such as data related to family medical history or social determinants of health (SDOH) like housing, educational, employment, and economic status.[15,16]

As mobile apps for remote monitoring of patient health have proliferated, clinicians have started to "prescribe" apps to patients during clinical encounters, much as they would a medication.[17] A specific category of patient-facing apps is digital therapeutics, which are evidence-based software that can be used to prevent, treat, or manage illness. Some digital therapeutics are delivered in the form of an app that may be prescribed by a clinician, though these specific apps are subject to stringent regulatory oversight.[18,19]

Given the vast number and variable quality of apps available, organizations are putting in place systems and processes to assist clinicians in selecting and prescribing appropriate apps. Major pharmacy benefits management organizations, including Express Scripts and CVS Health, offer healthcare organizations a curated list of vetted patient-facing apps to choose from through digital health formularies, with apps chosen based on qualities such as clinical effectiveness, affordability, usability, and security.[20,21] Some large healthcare systems are developing their own formularies for their clinicians' use as well.[22,23] These formularies tend to offer only a handful of apps but are projected to grow as more apps are vetted and added. Major EHR developers also maintain app marketplaces that offer apps compatible with their EHR platforms, with some overlap across platforms.[3]

1.1.2 A Standards-Based Approach to Interoperability

The potential of healthcare apps lies in their ability to collect data on patient health and relay these data back to patients and clinicians, conceivably with built-in PC CDS, to inform healthcare decision making. To realize this potential, apps must be interoperable with clinical IT systems, particularly EHRs. Improved integration of patient apps could facilitate more sophisticated research, clinical care, and quality reporting based on accurate and more complete assessments of health status.[5,24]

One of the leading standards that can support app interoperability is the Fast Healthcare Interoperability Resources (FHIR®). FHIR allows different systems to efficiently exchange healthcare data in a consistent format.[25] Designed with flexibility and ease of implementation in mind, FHIR comprises a set of modular "Resources." Each Resource corresponds to a type of healthcare data, such as patient, clinician, medication, or insurance claim data, and contains relevant data elements and defines constraints on the data.[26,27] Resources can be used individually or in combination to meet the needs of different use cases.[26]

FHIR also defines specifications for exchanging these resources via an application programming interface (API). FHIR's API-centric integration[28] approach is more aligned with the architecture of modern apps, as compared to the messaging-based integration approaches of prior healthcare standards.[29] FHIR APIs have the potential to enable more complete and timely integration between patient apps and the health IT systems that care teams use. Using APIs, FHIR can enable two-way data exchange between patient health apps and EHRs.[12] FHIR APIs can therefore support integration of app data—and even relevant analyses—into clinician workflows.[30]

Since its development, FHIR adoption has rapidly increased. By 2019, over 80 percent of hospitals and 60 percent of clinicians reportedly used health IT products that supported FHIR.[31] The industry's embrace of FHIR is likely spurred by Federal policy that incentivizes adoption of FHIR APIs: The final rule to implement the 21st Century Cures Act required that federally certified EHRs include APIs aligned with FHIR standards.[2,12] Furthermore, app developers have also started to incorporate FHIR standards in their products.[12] Two recent reviews each identified over 100 FHIR-based apps, with many of these targeting clinicians or patients for clinical care, engagement, or care management purposes.[2,12]

1.1.3 Challenges in Interoperability

Presently, most FHIR-based apps are not listed in EHR galleries, app libraries, or other inventories, which makes it difficult to find and implement these apps for patient care.[12] Furthermore, while FHIR standards and APIs are increasingly being adopted by EHR vendors and app developers, they are far from ubiquitous. Fewer than a quarter of healthcare organizations report adopting FHIR APIs at scale.[32] As of 2020, only about one-fifth of healthcare apps available in the app galleries managed by EHR developers supported FHIR, and nearly half of these were used primarily for research purposes.[2] Many organizations and health IT products continue to use legacy, non-standards-based, proprietary APIs for data exchange.[33] Patient apps also vary in their use of standards.[33]

Even where APIs are available, not all the capabilities of FHIR APIs are being realized in practice. API-enabled bidirectional flow of data between apps and EHRs is rare,[34] in part due to reticence from EHR developers to allow external apps to “write” data into the EHR (i.e., directly import data from the app into the EHR).[33] Most patient apps remain “read only” in their integration with the EHR, meaning data generally flow unidirectionally from the EHR to the app.[33] While Federal rules require free public access to APIs to read data from EHRs—allowing patients to download their personal health data and supporting integration of third-party apps—developers are not required to allow apps to write data into the EHR.[2,12]

Several additional challenges hinder integration of patient apps and clinician EHRs in practice.[7,8] These include issues related to data provenance, concerns regarding impacts on clinicians, privacy and security, legal concerns, costs, organizational governance and IT effort, and limitations of current standards.[33] For example, concerns regarding how and what data will be transmitted from the patient app to the EHR are front-of-mind for many EHR developers and health systems. EHR products tend to have carefully designed, proprietary structures and validations to control the information stored in the EHR. Issues such as the quality of app data, where to store it in the EHR, and how to record data provenance need to be resolved before EHR developers and health systems open their systems up to app data at scale.[33] Relatedly, some stakeholders have expressed concerns regarding the volume of app data that may enter the EHR, which may overwhelm clinicians.[35]

The data privacy and security implications of allowing apps to access EHR data and write into the EHR are another concern.[35,36,37] Additionally, there may be legal and/or liability issues related to what, how, and when data are shared with clinicians and patients[36]—for example, if an app provides an alert or writes in a critical value in the EHR and clinicians do not act on it in a timely manner, resulting in patient harm.

Cost considerations are another major factor. Many apps are developed without broad interoperability features built in, leading to one-off integrations with IT systems and workflows that are costly and time-consuming to implement and maintain.[38,39]

Finally, app integration is impeded by technical barriers like insufficient data standards and disparate semantics used across tools and systems.[10,35,36] While FHIR is an important approach to promote interoperability, FHIR standards do not currently exist for all types of data elements and activities. In the absence of standards-based approaches, proprietary workarounds may be required, apps may limit their functionality, or health systems may limit the apps they can support. Furthermore, the use of FHIR does not guarantee interoperability, as coding of data elements can differ even within FHIR resources.[40]

These challenges have real-world implications for the utility of patient apps. Without integration, healthcare teams often cannot efficiently access data from patient apps within their workflow. As a result, they are less likely to utilize patient-provided data for clinical decision making, since accessing and analyzing the data requires additional steps and cognitive work, which may be impractical for a busy clinician.[38,41] Also, clinicians may not receive timely notifications or alerts of significant or critical events that patients log in the app, such as a sustained increase in body weight in a patient who has been diagnosed with heart failure. Moreover, if the app cannot access EHR data, then the app’s guidance to the patient may be based on incomplete or outdated information (e.g., missing medications, comorbidities). Finally, PC CDS systems that fail to incorporate both app and EHR data may generate inappropriate guidance.

1.2 Roadmap of Report

Given current barriers to interoperability between patient apps and the health IT ecosystem, this product identifies technical requirements for integrating patient apps into EHRs—a necessary first step in improving the integration of patient apps and data with the broader health IT ecosystem. Given the report's focus on interoperability between apps and the EHR, the content of the report applies to apps that are prescribed by clinicians or recommended by health systems, rather than apps selected by patients and used without clinician engagement or health system authorization. In addition to describing key integration scenarios and requirements, the report highlights interoperability issues and areas where additional standards, implementation, or guidance are needed to support interoperability between patient apps and EHRs, culminating in a list of recommendations for the field.

Chapter 2, *Methods*, describes the process used to create this report, including a targeted literature review, discussions with the CDSiC Standards and Regulatory Frameworks Workgroup, and interviews with key informants. Chapter 3, *The Integrated PC CDS Ecosystem,* provides an overview of how data flows across different health IT technologies and stakeholders in an interoperable ecosystem. Chapter 4, *Interoperability Roadmap,* outlines specific interoperability scenarios, requirements for integration, available standards, and current challenges. Finally, Chapter 5, *Discussion: An Action Plan for an Integrated PC CDS Ecosystem*, discusses opportunities for CDS stakeholders to achieve interoperability among patient apps and the EHR.

2 Methods

To develop this report, the CDSiC team relied on the real-world app implementation experience of CDS experts, as well as a targeted literature review, input from the CDSiC Standards and Regulatory Frameworks Workgroup, and key informant interviews (KIIs). These methods were used to develop and validate: 1) a diagram of the Integrated PC CDS Ecosystem; 2) an index of key interoperability scenarios, requirements for integration, and available standards; 3) a summary of current interoperability gaps; and 4) opportunities for the field to further develop and implement standards to improve interoperability. These methods are briefly expanded upon below.

2.1 Literature Review and Initial Development of Ecosystem Diagram and Scenarios

The team conducted a targeted literature scan in PubMed to identify recent articles relevant to mobile patient apps and mobile app integration with health IT systems. Articles published in the last 5 years in the United States were prioritized for review. The team also conducted supplemental grey literature searches to identify relevant standards and implementation guides applicable to patient app interoperability. Additional resources were recommended by CDS stakeholders or found via backward reference searching.

The Integrated PC CDS Ecosystem Diagram and Scenarios were developed based on the literature review and in conjunction with CDS experts, informaticians, clinicians, health system representatives, and EHR developer representatives. They are based on real-world experiences and knowledge gained from implementing apps for patient use and improving app interoperability with the EHR. The diagram, scenarios, interoperability issues, and recommendations were initially developed and validated with the CDSiC Standards and Regulatory Frameworks Workgroup, which consists of a range of experts representing diverse perspectives within the CDS community.

2.2 Key Informant Interviews

KIIs were conducted to understand current needs and challenges related to EHR and patient app interoperability; validate the Integrated PC CDS Ecosystem Diagram, scenarios, and requirements; and identify any additional interoperability issues and recommendations to improve interoperability between patient apps and the EHR.

Between February and March 2023, the team interviewed five key informants who were experts in diverse disciplines related to PC CDS, including one standards developer, one patient representative/software engineer, one informatician, one EHR developer, and one app developer. Semistructured interview guides were created to facilitate the interviews, with questions tailored to informant type. Informants were provided with the Ecosystem Diagram, scenarios, and requirements in advance of the interviews.

Each interview was conducted via Zoom, lasted approximately 60 minutes, and was recorded with the informant's consent. Transcript-style notes were created for each interview to support analysis. The team analyzed the interview transcripts to identify modifications to the Ecosystem Diagram and scenarios, as well as salient themes within and across interviews. The team further revised the Ecosystem Diagram and scenarios by synthesizing the expertise and experiences of KIIs with findings from the literature and Workgroup member experiences.

3 The Integrated PC CDS Ecosystem

Interoperability between patient-facing digital health technologies and clinician health IT systems is fundamental to realizing the potential of apps to provide opportunities for PC CDS. With interoperability, apps that include PC CDS can move closer to adhering to the "Five Rights" principles of CDS interventions: "delivering the right information…to the right people… through the right channels…in the right intervention formats…at the right points in the workflow (for decision making or action)."[42] Achieving interoperability requires intentionally designing systems and technologies that permit the exchange of different types of data relevant to managing, interpreting, and acting on app data.

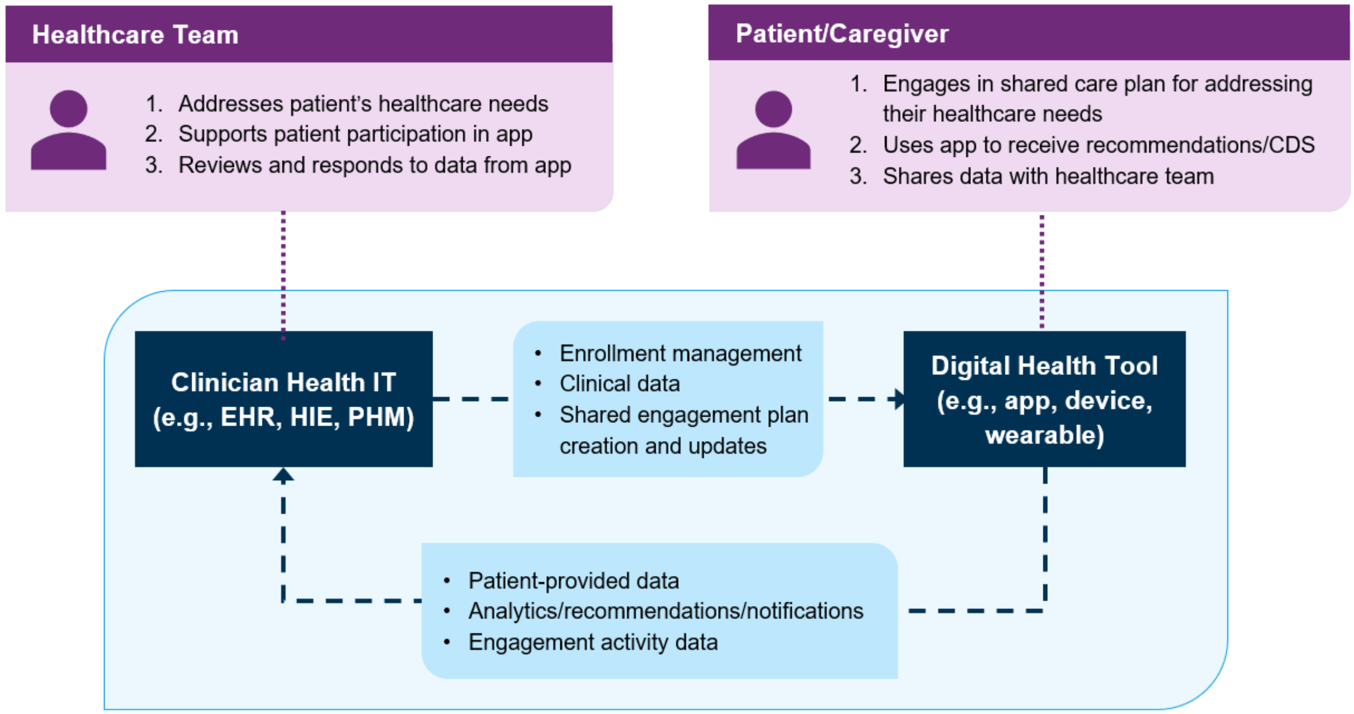
3.1 Overview of the Integrated PC CDS Ecosystem

The Integrated PC CDS Ecosystem ("Ecosystem;" Exhibit 1) illustrates the flow of data across technologies in an interoperable ecosystem. The Ecosystem represents the optimal exchange of information—and the activities this enables—when systems and technologies are integrated. The focus of the Ecosystem is specifically on patient-facing technologies that are prescribed, recommended, or monitored by a clinician to manage a patient's healthcare, rather than a technology the patient decides to engage with independently outside of the healthcare setting (e.g., a sleep tracker used by a patient without clinical supervision or intervention). As such, there is an expectation that the patient engages with the technology, the healthcare system has authorized patient data sharing, the patient's participation is actively monitored by the healthcare team and/or a contracted third-party, and the management of care is adjusted as needed.

Within the Ecosystem, patients, caregivers, and healthcare teams can monitor patient health and make healthcare decisions, facilitated by the regular exchange of data between patient-facing digital health technologies and clinician-facing health IT systems. Although not depicted in the Ecosystem, health care professionals outside of the healthcare system may also monitor patients' app usage and data and support patient engagement in apps (e.g., health coaches associated with the app or a remote patient monitoring company). These individuals would access patient data via a standalone app portal and are thus outside the focus of this report.

Furthermore, the Ecosystem may apply to a single episode of care (e.g., preparation for a surgery) or it may be established to address a chronic condition (e.g., diabetes) over time.[8] Eventually, fully interoperable systems may also facilitate managing multiple chronic conditions.[43] In all cases, clinician- and patient-facing technologies are integrated such that users and systems have access to the combined data from either system to fulfill their responsibilities. Underpinning the system are common standards that facilitate data exchange across the different technologies involved. Examples of the types of data exchanged between the health IT system and patient app include data related to enrolling the patient in the app, clinical data, the app engagement plan, patient-provided data (including data related to patient preferences, values, and treatment decisions stemming from shared decision making), analytics, recommendations, alerts, and data on patient engagement with the app.

Exhibit 1. Integrated PC CDS Ecosystem



Note: Dashed lines indicate data flows; dotted lines indicate user interaction with the Ecosystem.
EHR = Electronic Health Record; HIE = Health Information Exchange; PHM = Population Health Management

The patient app landscape is evolving quickly, and some data flows are more mature than others. This report focuses on a specific Ecosystem use case: integration between the clinician EHR and patient-facing digital health technology, such as mobile or web-based apps, which may be associated with Bluetooth-enabled digital health devices (e.g., "wearables") and/or other digital engagement technologies, like text messaging, interactive voice response, and chatbots. Given the focus on data interoperability between apps and clinician health IT systems, the content of the report applies to apps that are prescribed, recommended, or monitored by clinicians and vetted by health systems to allow for integration with healthcare IT systems. For the rest of the report, the term "app" is used to refer to mobile and web-based apps, including those associated with digital health devices. Box 1 provides a recent real-world example of an app that was integrated with the clinician EHR to help monitor women with hypertension disorders of pregnancy post partum.

Box 1. PC CDS Integrated Ecosystem Example: Hypertension Disorders of Pregnancy Monitoring App[44]

The Hypertension Disorders of Pregnancy Monitoring (HDPM) app, developed and implemented in two hospitals, provides a use case to illustrate how the Ecosystem operates in practice. The purpose of the HDPM app was to monitor the health of women at risk of post partum hypertension in the weeks following labor and delivery. The general workflow, described below, illustrates the key aspects of the Ecosystem: how patients were enrolled, the types of data collected and exchanged, and how patients and clinical teams used that data to inform clinical decisions.

Prior to discharge, labor and delivery patients with a history of preeclampsia or hypertension were invited to participate in a phone-based remote monitoring program. For the week following discharge, enrolled patients were instructed to report two types of data daily: blood pressure readings collected through either a Bluetooth-enabled or analog blood pressure monitor, and responses to a questionnaire—sent via either text message or a web link to their phone—that asked a series of questions related to symptoms associated with hypertension and preeclampsia, such as headaches, abdominal pain, and vision change. After the first 7 days, patients provided blood pressure readings only for several more weeks.

To keep patients engaged, the app sent patients daily reminders to complete the questionnaire. The app also provided an element of PC CDS directly to patients. If patients entered significantly elevated blood pressure readings (systolic blood pressure over 160 mmHg) or symptoms, they received a prompt to call their clinical team, with the associated phone number.

The HDPM app supported the exchange of blood pressure and questionnaire data, including yes/no, free text, and “select all that apply” responses. Once patients entered their questionnaire and blood pressure data, the data were automatically sent by the app to the hospitals’ EHR and stored in an existing EHR flowsheet. The flowsheet allowed the clinical team to view the patient responses and blood pressure data over time in a single place, integrated with their EHR. Additionally, the EHR provided decision support to providers by sending notifications for high blood pressure and flagging values in the EHR that were abnormal for followup with the patient, as needed.

3.2 Assumptions and Limitations

Regardless of the specifics of the technologies, data, and stakeholders involved, the Ecosystem rests on several assumptions. First, data should be available to the systems and users with minimal impedance for performing their given tasks. In other words, patient- and clinician-facing technologies are assumed to be interoperable, with the data presented to users in a usable format. Second, the volume of data exchanged may vary, both in terms of the size of the data, as well as over time. For example, the Ecosystem can accommodate data such as a single clinical data point (e.g., blood glucose reading) or as complex as a genomic sequence. Additionally, the volume of data may change longitudinally based on the frequency of data collection and reporting, notifications, and changes to the care plan. Finally, the Ecosystem makes no assumptions about whether data needs to be written from the EHR to the app, or vice versa. Emphasis is first given to meeting the information needs of the different actors over a specific architectural solution.

While not the focus of this product, additional data flows may need to be further developed to support interoperability with other clinician-facing health IT systems, such as Health Information Exchange Organizations (HIOs) and public health information systems. Data flows may also need to consider additional stakeholders beyond health systems and clinicians to include other organizations that provide app management and data support. This may include third-party remote monitoring companies that provide and help manage patients utilizing digital healthcare technologies in their homes, or technology brokers that can support integration across multiple apps or devices. These variations are beyond the scope of this product but may be topics for future research. Moreover, while regulatory issues will impact how these apps are integrated and used in real-world settings, regulations are beyond the scope of this report. For example, digital therapeutics that include apps are regulated as medical devices and require unique regulation and parameters for monitoring and use.

4 Interoperability Roadmap

The Ecosystem described above provides an inclusive overview of the means through which different actors, technologies, and data can be integrated in an interoperable ecosystem. In this section, we specifically examine interoperability needs for data exchange between the patient-facing app and the EHR, as the EHR forms a critical first “waypoint” for integrating patient app data within the rest of the health IT ecosystem. We recognize that the range of health issues (i.e., use cases), the requirements for patient engagement, the functional capabilities of apps, and the clinical workflows at different sites is enormous. It is difficult to identify a single set of requirements or standards that may be applicable to this variety of requirements. Instead, we have identified a set of scenarios listed below in which interoperability is required (e.g., enrolling a patient in an app).

Within each scenario, we further describe alternative approaches to how the health IT ecosystem may integrate with the app, with a focus on the EHR. We then identify standards that can be used for integration, as well as current challenges. Although we focus on the use of data exchange standards within these scenarios, the concurrent use of terminology standards, such as LOINC and SNOMED CT, will also be essential to support interoperability across all scenarios.

There are five key interoperability scenarios: 1) managing patient enrollment in the app, 2) healthcare team review of data from the app, 3) integrated PC CDS and population-level analytics based on app and EHR data, 4) notifying the healthcare team, and 5) notifying the patient. These are described further in Exhibit 2.

Exhibit 2. Five Key Patient App-EHR Interoperability Scenarios

Managing Enrollment

The EHR should be able to communicate with the app about patient enrollment and unenrollment.

Healthcare Team Review of Data

The healthcare team must be able to monitor patient-provided data entered in the app—ideally combined with EHR data in an integrated view—to make informed decisions.

Integrated PC CDS and Population-Level Analytics

Incorporating data from both the patient app and EHR into CDS logic will yield more relevant PC CDS and support population health and quality reporting.

Notifying Healthcare Team

Apps may need to notify the healthcare team regarding clinically significant events, patient questions, and lack of patient engagement with the app.

Notifying Patients

Interoperability is required for the app to communicate with the patient about their care plan or upcoming appointments outside of the app, such as through the EHR’s patient portal.

4.1. Managing Enrollment

Apps are typically used to help patients manage chronic illnesses for an episode of care or over a longer period of time.[8] Patient app enrollment is analogous to the patient being enrolled in a care program, albeit one mediated by an app. Managing enrollment requires the ability to both enroll and unenroll the patient. Box 2 describes a real-world example of patient enrollment in a COVID-19 remote monitoring app.[10]

4.1.1 Considerations for Patient Enrollment

The first requirement for an integrated ecosystem involves managing patient enrollment in the app. Enrollment may be triggered by a user (e.g., clinician or other clinical support staff), through programs or scripts running in the EHR, and/or through automated population health management (PHM) tools. The enrollment request must be communicated to the app for enrollment to occur. Furthermore, linkage between the patient app and EHR must be established for future interoperability scenarios.

Box 2. Technical Example of Patient Enrollment

Purpose. Developed in consultation with the clinical team at Yale New Haven Health (YNHH) in 2021, the COVID-19 tracker was designed to allow care coordinators to remotely monitor outpatients with COVID-19, while enabling patients to conveniently provide care coordinators with their data.[10]

Workflow. Using YNHH's Epic EHR, care coordinators contacted eligible patients—those who tested positive for SARS-CoV-2 but did not need hospitalization—referred for text-based remote patient monitoring by their clinicians. If the patient agreed to the program, the care coordinator created an "Episode of Care" in the EHR, which triggered a request from the EHR to a COVID-19 Tracker API that enrolled the patient. Once the coordinator entered the patients' consent and enrollment information into the EHR, a CDS Hooks request was automatically triggered to request that the app enroll the patient. Upon enrollment, patients were sent welcome text messages. Patients had the option to unenroll from the program at any time by texting "STOP."

Challenges. Although the team had planned to use the FHIR Subscription resource to identify patients for enrollment, this resource was not implemented by the EHR. Similarly, the team had planned to use the FHIR CommunicationRequest resource to inform the patient about their enrollment in the app; however, this resource was not implemented by the EHR and therefore could not be used.

4.1.2 Standards for Patient Enrollment

An interoperable patient enrollment process may be broken into five discrete activities. These activities are described in further detail below, along with relevant standards, where available, and their applicability to each activity. The steps and activities are summarized in Exhibit 3.

1. Identify patient to enroll

The first activity in patient enrollment involves identifying an appropriate patient to enroll in the app. This can occur in a variety of ways: 1) the healthcare team may manually identify the patient during an encounter (i.e., office visit or telehealth visit), 2) the patient may be identified as part of a larger "batch" in a PHM tool, or 3) a patient-specific event (e.g., new discharge, new lab result) can trigger automated identification through CDS rules.

Several standards available for automated identification through PHM or CDS rules. For example, Clinical Quality Language (CQL) is a standard for representing clinical knowledge (e.g., guidelines and recommendations) in human and computable formats.[45] In this context, CQL can be used to select groups of eligible patients (i.e., batch selection) based on certain clinical or demographic inclusion criteria or paired with FHIR PlanDefinition for CDS logic. PlanDefinition is a FHIR resource that can be used to specify CDS rules in a shareable and executable manner to support CDS.[46] PlanDefinition, with

CQL libraries, can be used to share standard knowledge artifacts that recommend enrollment to healthcare team members or to patients.

The emerging FHIR Subscription resource provides an alternative approach to identifying patients who may be candidates for enrolling in an app.[47] Similar to HL7 v2 trigger events,[48] subscriptions can be used to trigger CDS in response to changes in data in a FHIR server. Subscriptions allow CDS developers to specify events that should trigger CDS rules that can be used to identify patients for program enrollment (e.g., when a lab result is returned in a particular range or when a patient reports a new vital sign).

CDS Hooks can also be used to trigger CDS in response to designated user actions in the EHR (e.g., opening a patient chart).[49] In this case, CDS Hooks can match a user's clinical role, their current workflow, and patient context to patient enrollment criteria that would then deliver a message to the clinician suggesting the patient's enrollment.

2. Request patient enrollment and customize engagement plan

Next, the healthcare team must request that the patient be enrolled in the app. The healthcare team may provide specific enrollment parameters for the app, such as through the customization of an engagement plan (e.g., how often a specific exercise is recommended). This can be achieved using FHIR resources.

The FHIR Questionnaire resource is a set of questions that can obtain information from end users (often patients) according to a pre-specified, structured format.[50] The responses to the questions can be captured via the FHIR QuestionnaireResponse resource.[51] In this context, the resource can be used to obtain responses from the clinician on how to customize the engagement plan. The resulting responses can be used by the app to customize the engagement plan. FHIR Parameters can also be used to pass information to, and back from, an operation.[52] This resource provides an alternative mechanism to create customized parameters for the engagement plan.

3. Send enrollment request to app

After the healthcare team enters enrollment parameters for the app, the enrollment request must be successfully sent from the EHR to the app. At present, no standards are designed to guide this step in a way that would achieve interoperability between the app and EHR.

However, it is currently possible to leverage the SMART on FHIR standard to launch a web-based app from the EHR to enroll the patient. SMART on FHIR is an open, standards-based API used to create interoperable, user-facing apps that can launch inside different EHRs across the healthcare system.[53] A SMART on FHIR app associated with the patient health app can be used by the healthcare team to customize the engagement plan and create the patient enrollment. This would allow the app to subsequently manage the enrollment process. This interoperability solution creates a portal into the patient app for the healthcare team to enroll a patient. Since the EHR does not transmit an enrollment request or receive a status, it remains unaware of the patient's enrollment.

4. Enroll and inform the patient via the app

After receiving the enrollment request, the app typically will generate a message inviting the patient to use the app. The invitation may be sent via the healthcare organization's patient portal, or via email or a text message. For the invitation to be sent via the portal, the FHIR CommunicationRequest resource can be sent from the app to the patient portal. This resource type allows a request for a communication to be performed or for certain information to be conveyed to a specified recipient.[54] The invitation also should include instructions for the patient to complete their enrollment and access the app (e.g., download the app, provide their consent, set notification preferences, etc.). Although portal integration has higher interoperability demands than email or text message, organizations could potentially use patient portals to coordinate or streamline communications with patients if they are enrolled in multiple apps.

5. Update enrollment status

Once the patient has responded to the enrollment request (i.e., by consenting or declining), the app should share an enrollment status update with the EHR to inform the healthcare team of the patient's enrollment status. At present, no standards are available to guide this step.

Exhibit 3. Activities and Standards for Patient Enrollment

Activity	Mechanism	Existing Standards
Identify patient to enroll	Clinician manually identifies during encounter	Not applicable
Identify patient to enroll	Batch selection in PHM tool	• CQL
Identify patient to enroll	CDS rules triggered by event	• FHIR PlanDefinition + CQL • FHIR Subscription • CDS Hooks
Request patient enrollment and customize engagement plan	Clinician or system enters enrollment parameters for app	• FHIR Questionnaire • FHIR QuestionnaireResponse • FHIR Parameters • SMART on FHIR
Send enrollment request to app	EHR transmits request to app	No standard available to exchange enrollment request; SMART on FHIR could potentially be used to enroll patient
Enroll and inform patient via app	Invitation message with instructions sent to patient	• FHIR CommunicationRequest
Update enrollment status	App exchanges an enrollment status update with EHR	None available

4.1.3 Standards for Patient Unenrollment

Patient unenrollment can take place through different scenarios, described in more detail below. A few standards are available to facilitate patient unenrollment at present. The scenarios and available standards are summarized in Exhibit 4.

1. Patient unenrolls from app

A patient can decide to unenroll via the app, which should then notify the EHR of the unenrollment. No standards exist at present to facilitate the latter exchange.

2. Healthcare team unenrolls the patient

The healthcare team can unenroll the patient from the EHR. In this case, the EHR would need to notify the app to unenroll the patient. The app can notify the patient about their enrollment status change (see Notifying Patients for more information) and then confirm unenrollment to the EHR. At present, no standard mechanisms exist for the EHR to communicate the unenrollment request to the app or for the app to confirm unenrollment with the EHR. An alternative, similar to the enrollment activity, is for the healthcare team to use a SMART on FHIR app to unenroll the patient.

3. App unenrolls the patient

The app can unenroll the patient based upon the patient matching certain criteria, such as completing the engagement plan or no longer meeting the app's requirements for enrollment. In these cases, the app should notify the patient about their enrollment status change (see Notifying Patients for more information) and exchange an enrollment status update with the EHR.

Exhibit 4. Activities, Mechanisms, and Standards for Patient Unenrollment

Activity	Mechanism	Existing Standards
EHR informed of patient unenrollment	App sends notification to EHR	None available
Healthcare team requests app to unenroll	EHR sends request to unenroll the patient	No standard available to exchange unenrollment request; SMART on FHIR could potentially be used to unenroll patient
App confirms unenrollment to EHR	App sends notification to EHR	None available
App unenrolls patient	App notifies patient portal	• CommunicationRequest
App unenrolls patient	App exchanges an enrollment status update with EHR	None available

4.1.4 Managing Enrollment: Challenges

Although some standards currently are available to assist with identifying patients for enrollment, barriers to widespread implementation exist. For example, CQL can be used to share criteria for batch selection in population health tools and to inform the healthcare team of individual patients using CDS rules, but CQL implementation by EHR developers has been limited to date, and CQL may be immature for large-scale adoption.[55] Similarly, although FHIR Subscription and CDS Hooks can also be used to facilitate patient identification and enrollment, their implementation by EHR developers has also been limited to date.[47,56]

In addition, although FHIR resources like Questionnaire, QuestionnaireResponse, and Parameters can be used to allow a clinician to customize a patient engagement plan, no implementation guides describe how to use them for the enrollment activity. In addition, while CommunicationRequest can be used to correspond with the patient about their enrollment status, there has been limited to no implementation of this FHIR resource to date by EHR developers.[54]

Finally, no standards are available for exchanging enrollment requests and enrollment status updates between the app and EHR. Of note, although patient apps can currently manage enrollment through a SMART on FHIR integration, this solution is not fully scalable. Each patient app would need its own SMART on FHIR app for enrollment purposes, and the clinician would need to navigate to each of those apps separately. With this strategy, clinicians would not be able to place an order or a prescription to prescribe an app using their customary EHR tools.

4.2 Healthcare Team Reviews Data

For monitoring purposes, the healthcare team needs to be able to easily review the patient-provided data collected by the app. To help clinicians make better decisions, optimize their time, and reduce burden, the view should integrate data from both the EHR and the app. If the app and EHR are not integrated, clinicians must continually switch back and forth between the EHR and app view (often, a clinician-facing portal provided by the app) and mentally integrate the data. Box 3 illustrates a real-world example of data review using data integrated from the EHR and app.

4.2.1 Considerations for Reviewing Data

Data may be viewed in three different ways: in an app portal, in the EHR, or in a standards-based “EHR-extender” such as a SMART on FHIR app. The integrated view may encompass patient-level data or population-level data that incorporate different types of data from the EHR and the app. Common data types from the app include observations (e.g., vitals, symptoms), PROs, or tasks performed, while data types from the EHR include a wide range of clinical data.

Ideally, the view also incorporates relevant data from other apps that share data with the healthcare team. In an integrated view, clinicians should also be able to distinguish between patient-provided data and clinically sourced data (i.e., data provenance) to guide their decision making.[55]

Key informants suggested that clinicians will likely prefer to view data from patient apps directly in the EHR, as long as the source of the data is clear. They also noted that viewing app data in the EHR is likely to be more feasible than viewing EHR data inside an app portal. In addition, key informants noted that depending on the type of data (e.g., data from

Box 3. Technical Example of Data Review

The Asthma Health App, built on Apple's ResearchKit platform using HL7 standards, allows patients to share data on inhaler usage and peak expiratory flow rate (PEFR) with a physician who ordered this data through Epic's EHR. ResearchKit was integrated with HealthKit so that the data can also be shared with other Apple Research Kit or HealthKit apps given user permission.

To transfer HealthKit data to an EHR (1) a provider must “order” their patient’s data, (2) a patient must use an eligible iPhone with Epic’s MyChart patient portal platform installed and activated, and (3) the Asthma Health app collecting data on PEFR and inhaler usage must give permission for the data to be shared with HealthKit and MyChart data integration between the patient’s app and the EHR.[5]

a blood pressure device used at home), a clinician may need to review patient-provided data before it is recorded as part of the patient's health record and used in clinical decision making or within other applications.

4.2.2 Standards for Reviewing Data

Several standards can be used to facilitate the viewing of app data in the clinical workflow (Exhibit 5).

1. Viewing data in app portals

Data may be viewed in the app, often through the clinician-facing portal, using app-native features. This requires that EHR data be written to the app. United States Core Data for Interoperability (USCDI)[57] FHIR APIs can be used by apps to obtain data elements from the EHR. FHIR APIs support exchange of all the core data elements required by the USCDI.[58]

2. Viewing data in the EHR

Patient data may be viewed in the EHR, using EHR-native features, which requires that data from the app be written to the EHR. Several standards are available for the EHR to receive data from the app. FHIR Observation resources can capture a large array of patient-centered data.[59] The FHIR QuestionnaireResponse can represent patient responses to surveys or questionnaires represented as FHIR Questionnaire resources.[51] In addition, the FHIR Task resource describes and tracks the state of a task through to completion.[60] Tasks may provide "outputs," such as a task for a patient (e.g., "walk 30 minutes" or "lower back exercises"). FHIR-based APIs use standard procedures to enable data exchange between different systems, including sharing and integrating patient-provided data from devices and apps into the EHR.[61] FHIR Create APIs allow information to be written into the EHR as Observation, QuestionnaireResponse, and Task resources.[28]

3. Viewing data in a SMART on FHIR app

Patient data may be viewed in SMART on FHIR, a standards-based "EHR-extender." SMART on FHIR apps can read data via APIs from multiple sources, including the app, EHR, or other clinical data repositories, and present the data in an integrated view. For example, the patient app may write data to a clinical data repository at the healthcare system, instead of the EHR itself. Storing all app data in an internal clinical data repository may assist with integrating data from various apps into a SMART on FHIR app to facilitate viewing related data from different apps within the EHR.

In addition to providing an integrated view, using a SMART on FHIR app can also allow for using risk algorithms and CDS recommendations. To view population data, combining large volumes of data in real time from the app and EHR may not be practical. A clinical data repository that contains data from the EHR and the app could be used to support population-level views in a SMART on FHIR app.

Exhibit 5. Activities, Mechanisms, and Standards for Viewing Data

Activity	Mechanism	Existing Standards
Healthcare team views patient or population data in EHR	App writes data to EHR	• FHIR Create APIs for Observation • FHIR QuestionnaireResponse • FHIR Task
Healthcare team views patient or population data in app (i.e., the app's clinician-facing portal)	App pulls data from EHR	• USCDI FHIR APIs
Healthcare team views patient data in SMART on FHIR app	SMART on FHIR app obtains data in real time from EHR, app, clinical data repository	• SMART on FHIR
Healthcare team views population data in SMART on FHIR app	Using a clinical data repository	• SMART on FHIR. Real-time harmonization and joining of two different data sources may not be practical or efficient.

4.2.3 Viewing Data: Challenges

Several challenges exist for integrated viewing of app data. First, FHIR Create APIs allow for data to be written to the EHR by the app; however, they have not been widely implemented by EHRs to date, thus requiring proprietary solutions.[7, 39, 55] When data are not integrated into the EHR, this contributes to burden for clinicians, who must view and cognitively integrate data from two places, which affects decision making. It also contributes to duplication of data, which itself raises the risk of inaccuracies and outdated information. Second, although FHIR-based APIs support data exchange, including among apps, EHRs, and SMART on FHIR apps, adoption of FHIR standards by EHR developers varies.[2,55] Finally, key informants noted that even when data from patient apps can be integrated into the EHR, challenges result related to data storage. They highlighted that the current EHR solutions for storing data from patient apps (e.g., flowsheets) were not designed for the technologies in use today, and that greater standardization around where to put patient-provided data—and associated meta-data—is essential to promote the scalability of patient apps.

4.3 Integrated PC CDS and Population-Level Analytics

Apps and EHRs can provide more relevant CDS and monitoring by incorporating data from the EHR and the app in CDS logic. CDS that incorporates patient-provided data can facilitate conversations that draw upon patient data to support and improve patient and clinician shared decision making.[62] Meanwhile, analytics for population health and quality reporting can be more precise with integrated data. For example, SDOH data shared by the patient via the app can be extracted and used to inform population health efforts relevant to healthcare.[24] Box 4 describes a real-world example of CDS that integrates clinical data and patient-generated health data to provide recommendations for hypertension management.

4.3.1 Considerations for Integrated PC CDS and Population-Level Analytics

Data requirements for PC CDS and population-level analytics are very similar to integrated data viewing requirements. The CDS engine needs access to relevant data from EHR and the app, including data gathered or generated directly from patients (i.e., PROs and other patient-generated health data, patient preferences, and/or nonclinical patient-centric data, such as SDOH).[64]

Healthcare data from multiple apps can be integrated, with the following considerations. Often, the same data are collected by multiple apps (e.g., blood pressure or Patient Health Questionnaire-9 [PHQ-9] data), or data collected by one app may be relevant to other apps. PC CDS or population health analytics ideally should incorporate relevant data from all apps. Practically, this may be done by bringing all data into the EHR or a clinical data repository. As noted previously, a review process may be necessary for certain types of patient-provided data before it can be used in CDS tools.

Key informants noted that many health systems would prefer to receive raw data from apps (e.g., using LOINC codes) and apply their own CDS logic, rather than relying on analytics from the app, as their data interpretation may differ from that used by the app developer (e.g., ranges used for critical values). Furthermore, this allows for the development of PC CDS that integrates data from the EHR and multiple apps. Informants also noted that clinicians themselves may not want to view raw data due to concerns about data volume (both from individual patients and the patient population at large) and corresponding burden. Clinicians may prefer that the system first review the data via integrated CDS to determine what the clinician needs to personally review.

Box 4. Technical example of integrated PC CDS

The Collaboration Oriented Approach for Controlling High Blood Pressure (COACH)[63] is an interoperable CDS app that incorporates clinical guidelines for hypertension management into recommendations aligned with care team expectations. The COACH app collects data from users, including home blood pressure readings, and uses FHIR to retrieve patient EHR data (e.g., medications and conditions) from a FHIR server, after which it curates and displays the data to assist with hypertension management. COACH can be launched using SMART on FHIR from either the clinician-facing EHR (e.g., Epic) or a patient-facing system (e.g., Epic MyChart). Patient data are retrieved from the FHIR server and displayed to the user within the COACH user interface.

4.3.2 Standards for Integrated PC CDS and Population-Level Analytics

Several standards currently are available to facilitate data access for integrated PC CDS and population-level health analytics, as seen in Exhibit 6.

1. Patient-centered CDS

Integrated PC CDS can be delivered in the EHR, in a patient- or clinician-facing app, or in the patient portal. For example, the app may use current clinical data from the EHR to provide integrated PC CDS to the patient. USCDI FHIR APIs can allow the CDS engine to obtain data from the EHR.[30] Alternatively, the EHR may use patient-provided data from the app to provide integrated PC CDS to the healthcare team. FHIR Questionnaire and Observation APIs can be used to obtain data from the app.[59, 65]

2. Population-level analytics

Population-level health analytics can use bulk data access to EHRs, whereby a bulk FHIR server allows "authorized software clients to interrogate the server and return population datasets."[66] Population-level analytics using data pulled in bulk from repositories can deliver integrated CDS with the Bulk FHIR standard.[67] The HL7 Bulk Data Access (Flat FHIR) API supports export of data for patient populations. Bulk FHIR APIs exchange large analytical data sets into a platform for analytics and can enable data requesters to access data from multiple EHRs in a standardized and secure way, without manual processing. Bulk FHIR capabilities are emerging in various FHIR servers, including HAPI-FHIR, Google Cloud Healthcare API, and Epic's EHR.[68,69]

Recently, researchers tested an approach using CDS Hooks to process populations of patients asynchronously and found that a time-triggered hook extension to the CDS Hooks specification could support population-level processing.[70] The time-triggered event can invoke asynchronous population-based evaluations at pre-specified times. While time-triggered hooks are not part of the current CDS Hooks standard, a SMART on FHIR backend service could provide similar capabilities with current standards.[71]

Exhibit 6. Activities, Mechanisms, and Standards for Integrated PC CDS and Population-Level Analytics

Activity	Mechanism	Existing Standards
Patient-centered CDS	In app (requires data from EHR)	• USCDI FHIR APIs
Patient-centered CDS	In EHR (requires data from app)	• FHIR Questionnaire and Observation APIs
Population-level analytics	Data pulled in bulk from repositories	• Bulk FHIR • CDS Hooks • SMART on FHIR backend service

4.3.3 Integrated PC CDS and Population-Level Analytics: Challenges

Many of the noted challenges with viewing integrated data also apply to accessing data to create integrated PC CDS recommendations and population-level analytics, as CDS that integrates both app and EHR data relies on the same mechanisms required to view app data in an integrated workflow. For example, while data from apps using the FHIR API can be integrated into an EHR and feed information directly into the provider's workflow,[30] most third-party apps do not currently provide FHIR APIs to allow data access.

Furthermore, most EHRs are limited in their capability to support apps to write QuestionnaireResponse or Observation data,[33] although some EHRs provide proprietary APIs for this purpose.[10] In addition, although the Bulk FHIR API standard can be used to pull data for population-level analytics using an extension (asynchronous hook),[70] few organizations have implemented the specification to date.[72] Furthermore, this approach to bulk data export provides more data than may be relevant for a specific PHM need, which has implications for efficiency, performance, and privacy.[55]

4.4 Notifying Healthcare Team

Next, we discuss notifying the healthcare team based on patient activity or new patient-provided data. For example, the care team may wish to be notified when the patient enters a relevant symptom (e.g., headache in a patient with post partum hypertension) or a critical reading (e.g., blood pressure reading indicative of hypertensive crisis, or PHQ-9 response indicating suicide risk). Apps may also notify the healthcare team if the patient has a question or request or if the patient has not performed a recommended task within an app for a specified amount of time. Box 5 illustrates a real-life example of a CDS tool that integrates data from the EHR and an external data repository to inform a clinician of a concern.

4.4.1 Considerations for Notifying Healthcare Team

Standards should allow the app to indicate urgency and the topic of the message to enable sites flexibility in routing the message. How the notification is delivered may vary by the criticality of the clinical situation, workflow variations, and the content of the notification. Critical values from the patient may require urgent notification to the care team. Other concerns might trigger notification during normal clinic/work hours or during an encounter with the patient. Workflows may vary across healthcare organizations, which may prefer different modalities of notification and different rules for doing so. Health systems are likely to have different triage and alerting mechanisms, and these processes should be reviewed to make sure they can accommodate workflows when patient data come into the EHR.

Modalities for notification may include pagers or similar devices, messages in an EHR "inbox," alerts when a healthcare team member logs into the EHR or opens a patient chart, or displaying notifications or highlighting clinically significant data values in a flowsheet or dashboard in the EHR. Alerts must be accurate, timely, clear, delivered securely, and reduce clinician alert fatigue. An unintended consequence of a growing number of alerts to a clinician is the potential for alert desensitization,[74] which can have serious consequences for patient care (including medical errors).[75] Some hospital systems are reducing the number of nonspecific alerts to clinicians with a tiered approach (i.e., alerts tiered based on severity such that only severe events trigger alerts).[76]

It is out of the scope of this document to suggest what approach to use to notify or who to notify. Health systems will have their own preferences for designing care team alerts based on their clinical context and staffing model (e.g., whether they have a dedicated team for remote monitoring).

Box 5. Technical example of notifying clinician

Researchers developed a decision support tool that notifies the clinician of drug-gene interaction as a functional prototype.[73] A medication order in the EHR triggers the decision support to review patient genetic data for potential interactions. The CDS returns recommendations to the ordering clinician.

The tool is triggered by medication order in the EHR, which triggers a "medication-prescribe" CDS Hook. To obtain a patient's genotype, the CDS tool uses a FHIR API to interact with the Genomic Archiving and Communication System, which stores sequencing data outside of the EHR. CDS recommendations are displayed within the EHR via CDS Hooks cards.

4.4.2 Standards for Notifying Healthcare Team

Several standards currently are available to assist in notifying the care team (Exhibit 7). Three types of activities may prompt clinician notification.

1. Send a message to the healthcare team

For this activity, the app sends a message to EHR with indication of content and urgency. The EHR determines how to route the message. The EHR can send messages to the healthcare team using CommunicationRequest, which includes the ability to specify a reason for the request as well as priority.[54] An example use of CommunicationRequest may be to notify a healthcare team member of a very high diastolic blood pressure reported by a patient with pre-eclampsia.

2. Display a dialog/alert when the healthcare team member logs in

For this activity, an alert is created based on data in the EHR or app. The EHR displays an alert when a healthcare team member logs in. CDS Hooks can be used to trigger CDS in response to user actions in the EHR.[49] The alert can be created from data in the EHR, app, or both. Once a user triggers a hook, it invokes a remote service that executes its own rules, leveraging FHIR data as needed. A CDS card is returned (rendered and displayed by the client).

3. Display a message in a population or patient view

For this activity, the display can be created from data stored in a FHIR resource in EHR, app, or clinical data repository. This can be done using the FHIR Observation resource, intended for capturing measurements and subjective point-in-time assessments.[59] Observations can also record derived and computed values, such as a patient state or risk score.

The Flag FHIR resource is another option for notifying the healthcare team of a significant event or finding. A Flag is often presented as a label within the EHR but can also be presented in other ways.[77] A Flag appears to whoever opens a patient's chart; it cannot be targeted to an individual clinician or healthcare team. The FHIR resource DetectedIssue may be able to be used for this purpose, although its current specification may be too narrow. It indicates an actual or potential clinical issue with or between one or more active or proposed clinical actions for a patient (e.g., drug-drug interaction, ineffective treatment frequency, procedure-condition conflict, etc.).[78]

Exhibit 7. Activities, Mechanisms, and Standards for Notifying the Care Team

Activity	Mechanism	Existing Standards
Send a message to the healthcare team	App sends message to EHR with indication of content and urgency. EHR determines how to route the message	• FHIR CommunicationRequest
Display a dialog/alert when the healthcare team member logs in	Alert created from data in EHR or app	• CDS Hooks
Display a message in a population or patient view	Display could be created from data stored in a FHIR resource in EHR, app, or clinical data repository	• FHIR Observation • FHIR Flag • FHIR DetectedIssue*

*Standard may require modification prior to use for this purpose

4.4.3 Notifying the Healthcare Team: Challenges

Challenges related to this scenario largely relate to the implementation and current capabilities of available standards. As previously noted, FHIR CommunicationRequest is available as a standard but has not been widely implemented in EHRs or adopted by healthcare organizations. Similarly, while CDS Hooks have been developed to trigger CDS in the workflow,[79] implementation of this standard and its various hooks (i.e., workflow triggering points) has been only partial. Furthermore, most EHR developers limit these integration points, only enabling a hook in response to the opening of a patient's chart.[80] This limits the ability of PC CDS developers to integrate CDS in response to other care team actions (e.g., ordering labs).

Although the FHIR Flag resource is available as a standard for notifying the healthcare team, FHIR APIs for Flag have not been widely implemented in EHRs. Additionally, Flag does not allow for targeting notifications to specific clinicians or healthcare teams. DetectedIssue may be able to serve this function, but it is not yet mature. For this use case, how the resource defines "issue" ("an actual or potential clinical issue with or between one or more active or proposed clinical actions for a patient") may be a challenge,[78] as apps may not notify about an action. Use of this standard for this scenario would likely require modification.

Key informants noted several potential legal/regulatory considerations regarding provider notifications, particularly for urgent events (e.g., critical lab values or blood pressure readings). Although healthcare organizations will need to determine how best to implement clinician alerts in these situations given the clinical context and staff bandwidth, it is unlikely that the care team will be able to monitor and follow up on alerts or flags at all times (e.g., after hours). Rather, apps may need to provide guidance to patients to address the urgent scenario (e.g., call their medical team or go to an emergency room). Alternatively, third-party remote patient monitoring services can be contracted to assist with implementing the app and providing 24/7 monitoring of patients.[81,82]

4.5 Notifying Patients

The final scenario in the integrated PC CDS ecosystem concerns the app notifying the patient. This is an emerging area in the PC CDS ecosystem. The app may notify the patient for various reasons, including: 1) new enrollment, revoked enrollment, or completed engagement; 2) change in engagement plan; 3) preparation for an upcoming appointment (e.g., CDS or appointment reminder); 4) new lab result; or 5) healthcare team sends a message. Notifications can also be developed that remind patients to complete PRO questionnaires, submit other data, or perform an action based on data received.[83]

4.5.1 Considerations for Notifying Patients

Modalities for notification may include the app itself, the EHR patient portal, text message, automated phone call, or email. Apps can notify patients within the app without requiring interoperability with the EHR; however, if the notification is to be sent via the healthcare organization's preferred channel (e.g., patient portal), then interoperability is required.

Messages and notifications to the patient may vary in urgency. If the healthcare team or CDS finds a critical value in any data (e.g., a high blood pressure reading that requires an urgent care or clinic visit), the app or healthcare team may need an immediate response from the patient. Notifications should facilitate patient adherence and response; modes for notification should be integrated into patients' routines and implemented in a way that minimizes patient "notification fatigue."[64] In addition, regulations are in place to ensure patient privacy when sharing protected health information via apps.[55]

It is beyond the scope of this report to recommend the types of notifications or PC CDS content delivered to patients. Ideally, patients should be consulted during the app development process to ensure notifications are meaningful and enhance their engagement with the app and/or their care.[84] For example, the AHRQ/NIDDK Multiple Chronic Conditions e-Care Plan Initiative[85] has engaged patients, researchers, informaticians, and standards developers to create a standards-based, patient-facing app that can facilitate the activities described in this scenario to develop and maintain an interoperable care plan that integrates clinical and patient-provided data.

4.5.2 Standards for Notifying Patients

As this is an emerging area in the PC CDS ecosystem, relevant standards for notifying a patient are still evolving (Exhibit 8). At present, a notification to the patient can be initiated in an interoperable manner in two ways. An app could initiate sending a notification to the patient via the EHR's patient portal. When the app sends the message to the EHR with an indication of content and urgency, the EHR determines how to route the message. Alternatively, an EHR could initiate sending a notification to the patient via the app. When the EHR sends the message to the app with an indication of content and urgency, the app determines how to route the message. In both instances, the FHIR CommunicationRequest standard can be utilized to specify content and priority.[54]

Exhibit 8. Activities, Mechanisms, and Standards for Notifying Patients

Activity	Mechanism	Existing Standards
Send a message to the patient from app via EHR	App sends message to EHR with indication of content and urgency. The EHR determines how to route the message.	• FHIR CommunicationRequest
Send a message to the patient from EHR via app	EHR sends message to app with indication of content and urgency. The app determines how to route the message.	• FHIR CommunicationRequest

4.5.3 Notifying Patients: Challenges

Challenges for this scenario predominantly relate to the use of the FHIR CommunicationRequest resource, as indicated in the Managing Enrollment section. The CommunicationRequest capability is often either not present in the EHR product, or the capability is present, but a healthcare organization has not implemented it.[86] Furthermore, for the CommunicationRequest standard to be used, app developers will also need to implement FHIR CommunicationRequest APIs in their apps. A potential area for future development is a step for determining if the message was read by the patient (perhaps as an additional CommunicationRequest step).

Furthermore, although CDS Hooks can be used to trigger user notifications and deliver PC CDS, CDS Hooks is currently clinician-facing only and cannot be used in a patient-facing context (e.g., the EHR's patient portal).[55] One key informant highlighted that to date, there are no standardized hooks related to patient-triggered events that allow patient portals to integrate with CDS Hooks services.

5. Discussion: An Action Plan for an Integrated PC CDS Ecosystem

The ecosystem for PC CDS is rapidly evolving. As access to mobile technologies and broadband internet has grown, so has the availability of patient-facing apps that can be used to monitor and manage health conditions, facilitate patient engagement, and support shared decision making. The availability of standard APIs in EHRs enable opportunities to integrate these apps with EHRs and clinical workflows.

5.1 Summary and Recommendations

Although clinicians are increasingly recommending and prescribing apps to patients to help manage clinical conditions, challenges remain that limit the clinical utility of these apps. Greater interoperability is needed between apps and EHRs to allow for patient data collected by apps to be integrated into clinician workflows and the broader health IT system. This integration will allow for the use of patient-provided data that can generate greater patient involvement in their own care and better-informed clinical recommendations.

This report identifies several opportunities for further advancement of PC CDS standards to support the interoperability of patient apps with the EHR and other health IT systems. For many of the requirements identified, standards are available but are inadequately implemented or used by EHRs and apps. Further, some standards may need additional refinement or specificity added for the PC CDS use cases described here. Finally, implementation guides are needed in some scenarios to support the consistent use of standards. Exhibit 9 summarizes these opportunities in the form of an action plan, with the opportunities discussed in further detail below. Each opportunity is prioritized as low-, medium-, or high-priority based on the CDSiC Standards and Regulatory Frameworks Workgroup's perception of the opportunity's potential impact on advancing patient app interoperability. High-priority opportunities reflect both critical need and readiness in the field to address the need. Medium-priority opportunities are important, but not immediately critical, and may require significant work prior to implementation. Low-priority opportunities are those with relatively lower importance and/or readiness for implementation.

Realizing the opportunities identified in this section will require joint efforts by multiple stakeholders. Standards development organizations, app developers, and EHR developers are all crucial to this work; however, these organizations must routinely engage patients, caregivers, and clinicians to ensure that the perspectives and needs of end users are addressed. In addition, Federal funding agencies can tailor their research priorities and funding announcements to promote innovation and transform the landscape for interoperable patient apps.

Exhibit 9. Opportunities to Advance Patient App Interoperability

Scenario 1: Managing Patient Enrollment	Priority
Standards exist, but require further implementation	
• Promote greater implementation of PlanDefinition and CQL to assist with identifying eligible patients for enrollment.	**Medium**
• Encourage implementation of FHIR Subscription to trigger identification of eligible patients for enrollment.	**High**
• Advance implementation and use of CDS Hooks to assist care team with identifying eligible patients for enrollment.	**High**
• Facilitate dissemination and adoption of standard terminologies and value sets that can be used to standardize patient identification and enrollment procedures and provide guidance for the consistent use of these standards.	**High**
• Encourage implementation of FHIR CommunicationRequest by EHR developers and healthcare organizations to facilitate the use of CommunicationRequest to correspond with patients about their enrollment.	**High**
Standards exist, but modification is needed	
• Modify the Bulk FHIR specification to allow standard, EHR-agnostic queries to allow this standard to be used to identify cohorts of patients eligible for enrollment in a scalable manner.	**Low**
Standards are needed	
• Develop an implementation guide on communicating enrollment requests and exchanging enrollment status updates between the app and EHR, using existing resources or developing new resource types as needed.	**High**
Scenario 2: Viewing App Data	
Standards exist, but require further implementation	
• Health apps should implement FHIR APIs to provide access to the data they obtain from users, which can be used to create integrated views of app and EHR data using standards-based EHR extenders such as SMART on FHIR.	**High**
Standards exist, but implementation guides are needed	
• Develop an implementation guide for patient app data interoperability describing the minimal data elements that should be interoperable between apps and EHRs and identifying how they should be shared.	**High**
Standards exist, but modification is needed	
• Promote development and implementation of FHIR APIs that allow write access to EHRs, especially for FHIR Observations and QuestionnaireResponses. These APIs should accept data coded with standard terminologies and provenance metadata.	**High**
Scenario 3: Integrated PC CDS and Population-Level Analytics	
Standards exist, but require further implementation	
• Promote additional implementation of the Bulk FHIR API standard.	**Medium**
Standards exist, but modification is needed	
• Bulk FHIR can be used to pull data into repositories for population-level analytics, but the specification needs to support granular queries that are more efficient and that limit receipt of unneeded/unnecessary data.	**Medium**

Scenario 4: Notifying Healthcare Team	
Standards exist, but require further implementation	
• Expand the implementation of FHIR CommunicationRequest to allow for standards-based messaging with healthcare team members.	**High**
• Broaden the implementation and adoption of CDS Hooks to enable display of CDS cards when a healthcare team member opens a chart or performs other action that may require a PC CDS intervention.	**High**
Standards exist, but implementation guides are needed	
• Develop an implementation guide on using available standards to notify healthcare teams based on app data or activity.	**Medium**
Standards exist, but modification is needed	
• Explore and test the use of FHIR DetectedIssue for displaying a message in a population or patient view, modifying the resource as needed.	**Low**
Scenario 5: Notifying Patients	
Standards exist, but require further implementation	
• Expand the implementation of FHIR CommunicationRequest to enable messages to be sent to patients by either the app or the EHR.	**Low**
Standards exist, but modification is needed	
• Develop new hooks that enable delivery of PC CDS to patients using the CDS Hooks standards (e.g., when patient logs into the portal).	**High**

5.1.1 Standards for Managing Patient Enrollment

The first scenario in an integrated PC CDS ecosystem for patient apps involves managing patient enrollment into the app. This involves multiple activities, including identifying eligible patients, requesting patient enrollment and customizing the engagement plan, sending the enrollment request to the app, enrolling the patient, and exchanging enrollment updates.

Although proprietary mechanisms currently are available for identifying eligible patients for app enrollment, the use of proprietary mechanisms prohibits the scaling of apps across different EHRs and organizations. Thus, greater adoption/implementation of standard methods is crucial, including both exchange/query and content standards. Further implementation of CQL and PlanDefinition, FHIR Subscription, and CDS Hooks can standardize the patient selection process, allowing for the development of interoperable, standards-based patient-facing apps. Further implementation of CDS Hooks, in particular, would simultaneously advance the capability of apps to notify healthcare team members and provide PC CDS in the clinical workflow (see *Section 5.1.3. Standards for Notifying the Healthcare Team*). In addition, while Bulk FHIR can be used to obtain data for a set of patients to execute CDS logic, the query to define the initial cohort is currently EHR-specific and thus not scalable. In the future, if Bulk FHIR allows requests to be created using standard queries, it could be used to identify cohorts of patients eligible for enrollment in a scalable manner. This work should be coordinated with stakeholder groups within FHIR that are working to advance cohort definition and eligibility (e.g., the Cohort Definition Track[87]).

Furthermore, the exchange and query standards that facilitate standardization of patient identification rely on the use of standard terminologies (e.g., LOINC, SNOMED CT codes defined by USCDI)[88,89,90] and value sets (e.g., HL7 FHIR and electronic clinical quality measure [eCQM] value sets)[90,91]; however, additional guidance is needed to support the consistent use of these content standards, particularly when different coding systems conflict. In addition, an implementation guide is needed to identify how standards can be used consistently to communicate enrollment parameters, customize and communicate patient engagement plans, and exchange enrollment status updates. This work may require further development of new resources or profiles of existing FHIR resources (e.g., ServiceRequest or Task). A new type of resource, with accompanying implementation guide, could be created for the specific purpose of transmitting enrollment and unenrollment requests. This resource could be modeled on the CDS Hooks request, such that it can include the engagement customizations in the context and clinical data in the prefetch elements of the request.

Finally, few standards are available to communicate with patients regarding their enrollment status at present. The FHIR CommunicationRequest resource could be used; however, it has had limited implementation to date. Implementation and adoption of CommunicationRequest by EHR developers and health systems is thus needed to enable standards-based communication with patients about their enrollment status. Further implementation of CommunicationRequest can also facilitate notifications to patients and the healthcare team more broadly, as described below.

5.1.2 Standards for Viewing App Data

Allowing healthcare teams to review patient-provided data in an integrated view that combines both EHR and app data can facilitate clinical decision making and alleviate cognitive burden. One option for reviewing app data and EHR data in a single view is to pull data into a SMART on FHIR app. However, few digital health apps provide FHIR APIs for data retrieval.[2] To support this option, app developers need to implement FHIR APIs that allow access to data collected from patients. This will reduce clinician burden and improve clinician decision making. This could also allow for data collected from multiple apps (e.g., mental health or blood pressure assessments over time from different apps or devices) to be integrated into a single view in a SMART on FHIR app.

To date, enabling the healthcare team to view app data in the EHR has been challenging because of limited availability of APIs to write patient-provided data to EHRs. Promoting the development and implementation of FHIR APIs that allow patient apps to write to EHRs, particularly data coded with standard terminologies (e.g., LOINC, SNOMED CT) in FHIR Observations and QuestionnaireResponses, will allow for standards-based solutions to allow app data to be shared with the EHR. Appropriate provenance metadata should also be incorporated in these APIs and recorded within the EHRs to allow clinicians to differentiate between patient-provided data and data from clinical sources. The FHIR Provenance resource may play a critical role in this.[92]

Furthermore, although the USCDI details data elements that FHIR APIs must provide read access to, no guides are currently available to promote standard data elements that apps should write to EHRs. Specified data elements prioritized for FHIR write-APIs may include those in the USCDI, as well as other data elements commonly collected across multiple apps or particularly important for care planning (e.g., mental health assessments). Development of an implementation guide for patient app data interoperability would be an essential step toward standardizing data elements that should be interoperable between apps and EHRs. EHR developers and app developers would need to be involved with this effort in tandem to ensure that the recommended implementation is feasible for both apps and EHRs.

5.1.3 Standards for Integrated PC CDS and Population-Level Analytics

CDS logic that incorporates EHR and app data can provide more relevant and accurate PC CDS and population health monitoring. Many of the issues that apply to integrated viewing of data also apply to creating PC CDS recommendations and PHM from data integrated across EHRs and apps. For example, integrated PC CDS requires the use of FHIR APIs that provide read access to app data, write access to EHRs, and guidelines specifying how data should be shared in an interoperable manner. As such, the opportunities identified in *Section 5.1.2. Standards for Viewing App Data* will also advance Standards for Integrated PC CDS and population-level analytics.

For population-level analytics, Bulk FHIR can be used to obtain data from EHRs and apps. However, this is a relatively new standard with early and partial implementations just starting to appear. Further implementation of Bulk FHIR is needed to support this use case. Of note, Bulk FHIR is currently being used for two major Centers for Medicare & Medicaid Services initiatives.[93,94] Furthermore, Bulk FHIR has limited granularity and may provide more data than needed for the specific operation.[55] The Bulk FHIR specification will need to evolve and provide greater granularity for this to be an efficient option.

5.1.4 Standards for Notifying the Healthcare Team

Health systems may decide to implement healthcare team notifications based on data entered in the app, with specific workflows varying by context, message content, and message urgency. The FHIR CommunicationRequest can be used to send an urgent notification message to the healthcare team, but as noted previously, this resource will need to be implemented more broadly in EHRs to facilitate interoperability. Similarly, apps will need to implement the CommunicationRequest API.

In some situations, it may be preferable to display a dialog box or alert to a healthcare team member when they log into the EHR based on patient activity or app data. Although CDS Hooks can be used for this purpose, it will need to be more broadly adopted and implemented in EHRs to facilitate this notification option. In other situations, it may be beneficial to display a message while a care team member is viewing data in the population or patient view. Although no mature standards currently are available for this need, FHIR DetectedIssue is a possible strategy.[78] Originally designed to detect drug-drug interactions, DetectedIssue indicates a potential or actual clinical issue between one or more actions for a patient. Although DetectedIssue is not currently mature, further exploration of this resource can identify if and how it can be modified to support care team notifications based on data collected by patient apps. For example, the definition/scope of DetectedIssue may be expanded to include concerns arising due to new data (e.g., high diastolic blood pressure reported by patient).

Finally, given the potential complexity in designing standards-based healthcare notifications that can be tailored to meet health system needs (i.e., based on urgency, message content, clinical workflows, and desired mechanism for display), it would be advantageous for CDS stakeholders—including standards developers, app developers, EHR developers, and health systems—to develop an implementation guide on using available standards (e.g., CommunicationRequest and CDS Hooks) to deliver care team notifications based on activity or data entered into apps. This effort could leverage the work of existing HL7 Workgroups (e.g., HL7 FHIR Patient Care Workgroup, Mobile Health Workgroup, and/or Clinical Decision Support Workgroup) to advance an implementation guide.

5.1.5 Standards for Notifying the Patient

Finally, patients may wish to be notified by the app based on changes to their enrollment or engagement plan, upcoming appointments, care team messages, and/or new lab results. Patient notifications may also be used to request patient-provided data and/or deliver PC CDS interventions. This is an emerging area, and we were unable to find a real-world example of an app that used standards for communication with patients. To advance interoperability between the app and EHR in this scenario, FHIR CommunicationRequest is available. However, it must be more broadly implemented by both EHR and app developers to facilitate patient notifications, such as from the app to the patient portal, or the EHR to the app. In addition, the creation of new CDS Hooks that are relevant to patients' use of digital health technologies will enable CDS services to be implemented with patients and their caregivers as the recipients (e.g., via the patient portal).

5.2 Conclusion

As the landscape for health apps matures, clinicians are increasingly recommending and prescribing apps to patients to help manage clinical conditions. Patient apps can collect a variety of patient-provided data that can be used to foster patient engagement, advance the relevance and value of PC CDS, and improve clinical decision making. However, to fully realize the potential of apps, they must be interoperable with the health IT systems that care teams use, particularly EHRs. Further advancement of patient app interoperability will require a coordinated effort between app developers and EHR developers, alongside standards developers, Federal funders, health systems, clinicians, and patients. For example, EHR developers and health systems will need to further implement existing FHIR resources, app developers will need to implement FHIR APIs, and both EHR and app developers will need to jointly engage in the development of new FHIR implementation guides. Standards developers can work to advance existing standards and their use cases, and to create new standards where needed. All of this work should engage the end users of these technologies, including patients, their caregivers, and clinicians. Finally, it is important to note that apps and EHRs are situated in a broader health IT ecosystem (e.g., HIOs, personal health data platforms, PHM tools). Interoperability between apps and EHRs is a necessary first step to allow for interoperability between apps and these additional actors. However, this field is evolving rapidly, and further work will be needed to identify interoperability requirements and solutions in this broader ecosystem.

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