Multiple Chronic Condition (MCC) eCare Plan Project

Pre-read material in preparation for the
Federal Partner Meeting on June 29, 2023

National Institute of Diabetes and Digestive and Kidney Diseases

About This Pre-Read

To optimize our time during the Multiple Chronic Condition eCare Plan Federal Partners Meeting on June 29, 2023, we are presenting in this pre-read deck some background information and additional project updates that we may not have the time to go into fully during the meeting.

We plan to reserve some time during the meeting to answer questions regarding this material so we invite you to review this deck if time permits and bring your questions to our meeting on June 29.

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History of Federal Investment in Care Planning/Coordination

Over a decade of federal investment in advancing the development and use of standards for care planning and related care coordination activities:

- **ONC**: 2015 Edition Care Planning Criterion
- **ONC/CMS**: electronic Long-Term Services and Supports (eLTSS)
- **SAMHSA:** Omnibus Care Plan
- **CMS**: PACIO Project
- **NIDDK/AHRQ**: MCC eCare Plan
- **ONC/AHRQ/ACL/CMS**: Gravity Project
- **ACL**: Social Referral Challenge Program
- **ONC**: LEAP Grant Program
- **CDC**: MedMorph
- **CDC**: Clinical Practice Guidelines (CPG) on FHIR
- **ACF**: Human Services Interoperability Innovations Grant
- **CDC**: SDOH Use Case for Chronic Disease Prevention

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Comprehensive Shared Care Plan Definition

1. Gives the person **direct access to health data**.
2. Puts the **person's goals at the center** of decision-making.
3. Is holistic, including **clinical and nonclinical data** (e.g., home- and community-based and social determinants needs and services).
4. **Follows the person** through both high-need episodes (i.e., acute illness) and periods of health improvement and maintenance.
5. Allows **care team coordination**. The Care Team is able to 1) view information relevant to their role, 2) identify which clinician is doing what, and 3) update other members of an interdisciplinary team.

U.S. Department of Health and Human Services 2015 Stakeholder Panel | Baker, et al. Making the Comprehensive Shared Care Plan a Reality. *NEJM Catalyst*. 2016: https://catalyst.nejm.org/making-the-comprehensive-shared-care-plan-a-reality/

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NIDDK/AHRQ e-Care Plan for Multiple Chronic Conditions (MCC) Project

Build capacity for pragmatic, patient-centered outcomes research (PCOR) by developing an **interoperable electronic care plan** to facilitate aggregation and **sharing of critical patient-centered data** across **home-**, **community-**, **clinic-**, and **research-**based settings for people with **multiple chronic conditions** (MCC).

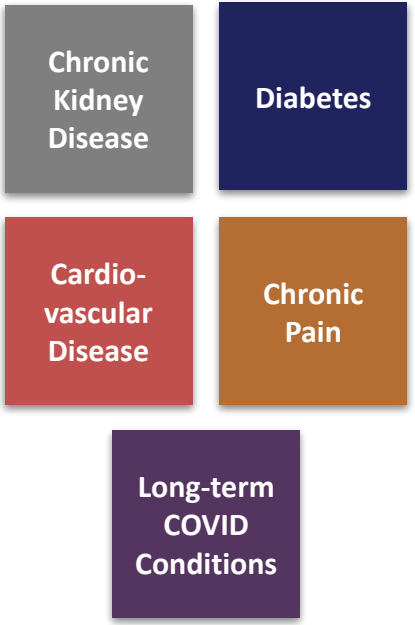
https://ecareplan.ahrq.gov/collaborate/

MCC eCare Project Deliverables*

1. **Data elements, value sets, and FHIR mappings** to enable standardized transfer of data across health and research settings for kidney disease, diabetes, cardiovascular disease, chronic pain, and long-term COVID.

2. **HL7® Fast Health Interoperability Resource (FHIR®) Implementation Guide** based on defined use cases and standardized MCC data elements, balloted for trial use.

3. **Pilot tested provider-facing and patient/caregiver-facing e-care plan applications** that integrate with the EHR to pull, share, and display key patient data.



*All deliverables will be open-source and freely available.

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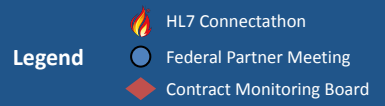
Overview of Work Year Over Year

	Year 1 (Fall 2019-Fall 2020)	Year 2 (Fall 2020-Fall 2021)	Year 3 (Fall 2021-Fall 2022)	Year 4 (Fall 2022-Fall 2023)
Data elements, value sets, and FHIR mappings	• HL7 project approval. • MCC use case development. • Built CKD and other prioritized value sets in NLM VSAC and mapped to FHIR constructs. • Began identification of data elements for CVD, chronic pain, and T2D. • Facilitated TEP.	• Completed identification of 1,100+ data elements for CVD, chronic pain, and T2D. • Facilitated TEP. • Developed data standards approaches for person/plan details, health concerns, and social concerns.	• Conducted quality assurance and review of existing value sets. • Identified long COVID data elements and facilitate TEP. • Built additional, new value sets in VSAC. • Mapped new/revised data elements to FHIR.	• Revise and finalize new value set libraries and tables. • Update use cases. • Build and update new profiles.
HL7 FHIR IG	• Conceptualization and design of the MCC eCare Plan FHIR IG.	• Developed draft MCC eCare Plan FHIR IG.	• Developed high-level mapping and design approach for the MCC eCare Plan FHIR IG. • Restructured the IG to include new guidance and library of value sets. • Expanded to incorporate value sets for all five clinical domains (CKD, CVD, chronic pain, T2D, and long COVID).	• Revise, update, and submit IG for comment HL7 ballot in Jan 2023 cycle. • Integrate ballot comments and perform reconciliation. • Prepare and submit FHIR IG for STU ballot in Sep 2023 cycle.
Patient/ Caregiver and Provider eCare applications		• Developed v1.0 application for patients. • Developed v1.0 application for providers. • Facilitated configuration of apps at OHSU site for pilot testing.	• Built patient/caregiver app v2.0. • Developed features to support goal-oriented shared care planning. • Set up sandbox environment on Azure cloud for demonstration and testing. • Formed an agile team with RTI/OHSU to support development and pilot design. • Conducted iterative user feedback sessions.	• Develop and revise a common data services library. • Allow for multiple, simultaneous logins in the patient/caregiver app. • Patient/caregiver UI redesign. • Modify backend of both apps to use common data services library. • Support pilot testing at OHSU.

Three Year Roadmap



		2021	2022			2023				2024			
	Activity	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3
		EMI Base Year (9/30/21 - 9/29/22)				EMI Option Year 1 (9/30/22 - 9/29/23)				EMI Option Year 2 (9/30/23 - 9/29/24)			
Stakeholder Engagement	Events												
	PCWG and TEP meetings												
Data elements/ Value Sets	Review and QA of existing MCC value sets												
	PASC data element identification with TEP												
	Build PASC value sets in VSAC												
MCC IG	FHIR profile domain mapping												
	Restructure and expand MCC eCare IG												
	Prepare MCC IG for Comment Ballot												
	Review MCC IG Comment Ballots												
	Prepare MCC IG for STU Ballot												
	Reconcile STU Ballots												
	Prepare and publish MCC IG as STU												
eCare Apps	Evaluate/design interoperability architecture												
	Provider app v1.1 revisions												
	Patient/Caregiver app v2.0 development												
	Build and iterate common data services												
	Update Provider app v1.3 backend												
	Update Patient/Caregiver app v2.1 backend												
	Revise/release Provider app v2.0												
	Revise/release Patient/Caregiver app v3.0												
Pilot site testing	Conduct v1.0 app pilot												
	Build research store												
	Conduct v2.0 app pilot												

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A Primer on FHIR Implementation Guides

What is a FHIR implementation guide?

A FHIR implementation guide (IG) is a set of rules about ***how FHIR resources are used (or should be used) to solve a particular problem***. It contains associated documentation to support and clarify the usage.

Who uses them and for what purpose?

- **Architects and developers of healthcare information technology (HIT) systems** - Follow guidance for developing implementations.
- **Business analysts** - Assist developers in understanding system implementation requirements.
- **Project managers** - Gain understanding of how to manage or prioritize implementation.
- **Clinical informaticists** - Interpret clinical implications and provide feedback.
- **Policymakers** - Understand the IG and encourage implementation once deemed valuable for the industry.

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MCC eCare Plan FHIR Implementation Guide (IG)

The HL7® MCC eCare Plan FHIR Implementation Guide (IG) defines FHIR R4 profiles, structures, extensions, transactions, and value sets needed to represent, query for, and exchange Care Plan information to support care planning for people with multiple chronic conditions (MCC).

The IG supports the following use cases:

1. Generate and update comprehensive e-care plan in clinical setting.
2. Expose (Share) e-care plan to clinical care team, patient, or caregiver.
3. Identify care team members.

HL7 FHIR

Improve care coordination without increasing clinician burden

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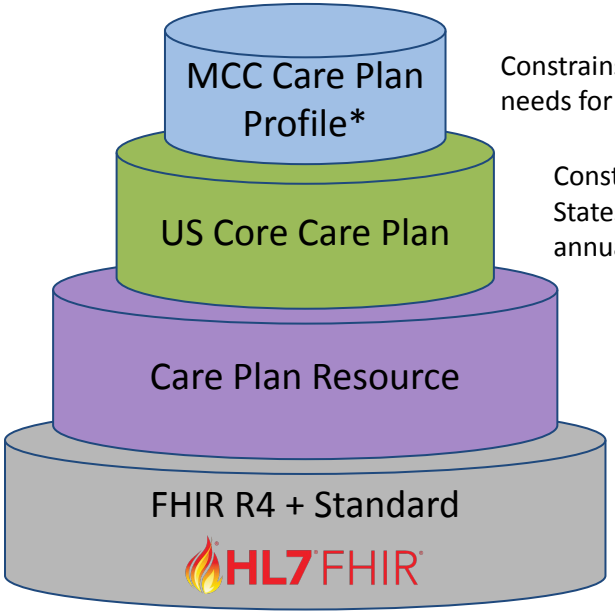
Reusing and Constraining the FHIR Care Plan Resource

The MCC eCare Plan FHIR Implementation Guide is built on the FHIR Care Plan Resource framework.

Each layer in the cake diagram demonstrates how the FHIR Care Plan Resource is reused and constrained for the MCC Care Plan use cases.

**The MCC IG adds additional items or guidance beyond what is available in US Core or FHIR resources but it cannot loosen existing rules from what is constrained.*



Constrains the US Core FHIR Care Plan Resource to meet the needs for multiple chronic conditions (MCC) care planning.

Constrains the Care Plan Resource for use in the United States. US Core incorporates USCDI data elements annually and according to HL7 ballot cycles.

Describes the intention of how one or more practitioners intend to deliver care for a particular patient, group, or community for a period of time.

FHIR is a standard for health care data exchange, published by HL7®.

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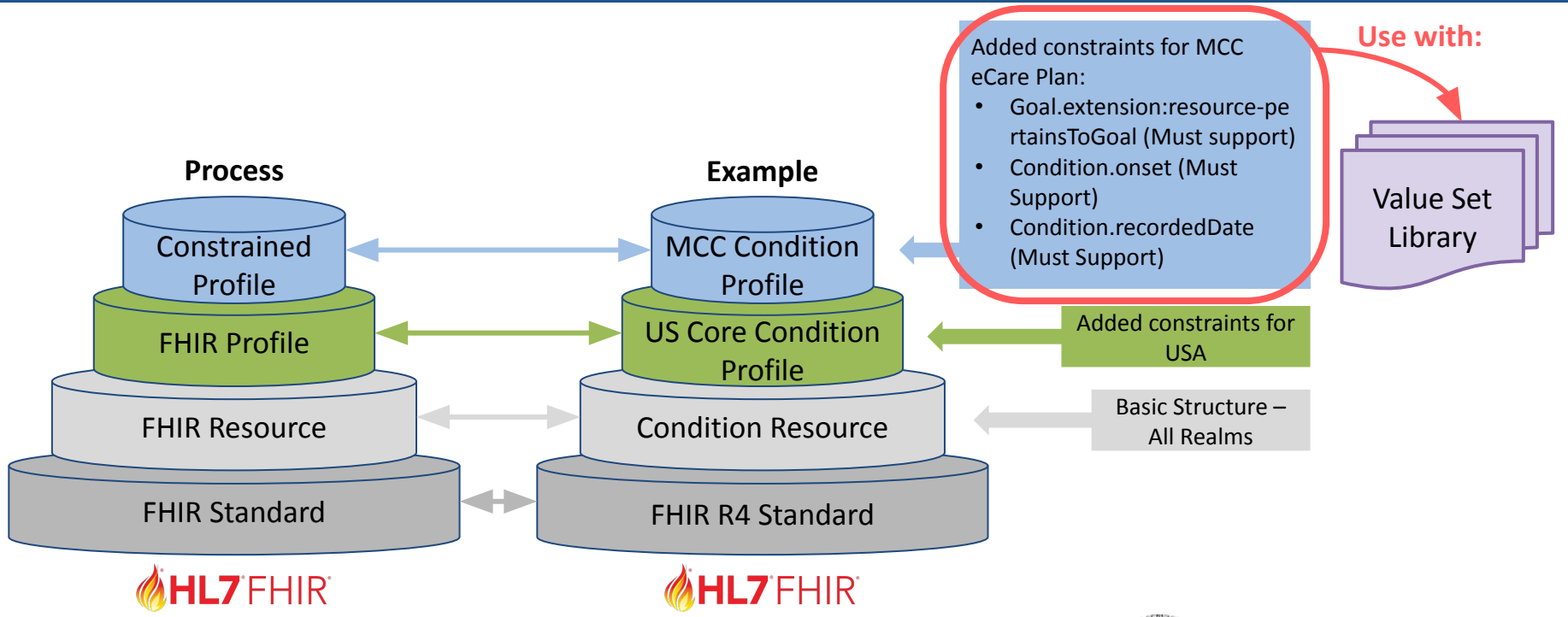
Reusing and Constraining: Value Set Library



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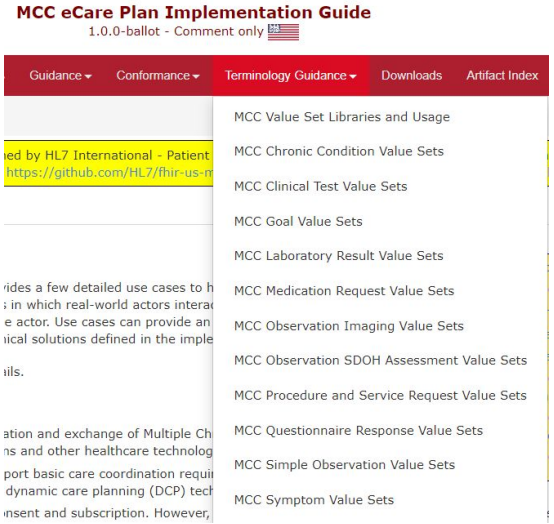
What is “The eCare Plan MCC Value Set Library”?

Similar to the Dewey Decimal System of old, the MCC Value Set Library:

- Organizes the value sets based on their subject.
- Identifies the profiles that the value sets can be used in and where within the profile they can be used.
- Provides links to the Profile from each library (and vice versa).



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MCC eCare Plan FHIR IG Timeline

Balloting is a formal process used by HL7 to get feedback and comments on specifications prior to publication. There are different ballot levels: For Comment, Informative, Standard for Trial Use (STU), and Normative. Over the course of this project, the MCC eCare Plan IG will be matured through the For Comment ballot and the STU ballot. Below is a timeline for the development of the IG:

New additions include finalized value sets, updated Use Cases, capability statements.

Triage comments received during the For Comment ballot and begin comment reconciliation.

Update FHIR IG based on latest version of US Core IG and comments from the January 2023 For Comment ballot.

Triage comments received during the STU ballot and perform comment reconciliation to update the FHIR IG.

Prepare the IG for publication as an STU meaning that the IG is substantially complete and ready for implementation.

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IG Requested Changes

The for comment balloting responded yielded 4 main themes of comments:

1. Tech Edit Changes (grammar, broken links, typos) (12)
2. Value Set Related - Additions or updates (3)
3. Update to US Core 6.0.0 (1)
4. Profile Design Change Requests (12)

IG Requested Changes -Status

Comments category:

1. Tech Edit Changes (grammar, broken links, typos) (12)
    a. Easy fixes being addressed as we touch the profiles
2. Value Set Related - Additions or updates (3)
    a. Review completed, necessary changes 50% done

IG Requested Changes -Status

Comments Category:

1. Changed depency to US Core 6.0.0 (1) required:
    a. Several Observation Profile changes:
        i. US core both added and simplified its Observation profiles resulting in corresponding changes made to the US Core profiles MCC derives derives from
        ii. US Core added a Simple Observation that previously was not present. MCC Simple Observation now derives from that
    b. A significant amount of Narrative Guidance in US Core was improved with some page restructuring referenced to from MCC requiring linking changes and some text adjustments
    c. US Core now allows for either QuestionnaireResponse or Observation with nested observations to represent Questionnaires and SDOH Guidance was incorporated into how to handle Questionnaires guidance. While we expect MCC stakeholder will continue to prefer QuesionnaireResponse, this required pointing to the new guidance page and some text adjustments

IG Requested Changes -Status

Comments category:

1. Profile Design Change Requests
    a. Simplify Caregiver on Care Team (too complicated for today's EHR implementations)
        i. Will be removing Multiple Chronic Condition Care Plan Caregiver on Care Team Profile and will be making the following related changes:
        ii. Retain Multiple Chronic Condition Care Plan Caregiver Considerations Observation (may need to modify name).
        iii. Edit Profile text as appropriate
        iv. Remove Care Team from observation.focus and change to RelatedPerson
        v. Observation.value will hold the "issue"

IG Requested Changes -Status

Comments category:

1. Provide Guidance and/or profile on FHIR Bundle for sending an MCC Care Plan to another system
   a. Discussions occurring as to appropriate level of guidance

   vs

   b. MCC Bundle Profile

   vs

   c. FHIR Operation

IG Ballot Comments Next Steps

To prepare the MCC IG for STU ballot in September 2023, the team plans to:

- Update to US Core 6.0.0 dependency.
- Update value sets or add sets as needed per the comments.
- Provide a patient facing summary of the IG to provide guidance on use.

Schedule

- June 25 - Submit the Notice of Intent to Ballot
- July 12 - Patient Care Work Group meeting to discuss preballot preview
- July 26 - Request ballot readiness sign off
- August 4 - STU ballot opens for voting
- September 4 - STU ballot closes for voting

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- Project background and high-level update
- HL7® FHIR® Implementation Guide development and balloting
- **HL7® Connectathon 33**
- eCare Plan SMART on FHIR applications
- Pilot updates

HL7 FHIR Connectathon Testing

An HL7 FHIR Connectathon is a testing event used to develop HL7 FHIR Specifications including resources, profiles, and implementation guides. The purpose of a Connectathon is to prove that the specification is complete and facilitates FHIR implementation guide maturity. The MCC eCare Plan Project has led a track at or participated in Connectathons regularly for the last three years. The most recent ones are captured below:

Connectathon 29	Connectathon 30	Connectathon 31	Connectathon 32	Connectathon 33
January 2022	**May 2022**	**September 2022**	**January 2023**	**May 2023**
Hosted the Care Planning Track.	Hosted the Care Planning Track.	Attended as the MCC eCare Plan team.	Attended as the MCC eCare Plan team.	Hosted the Coordinating Care for Patients with Chronic Conditions Track.
• Examined the clinical feasibility and interoperability of goals.	• Explored clinical workflow surrounding goal documentation using observation.	• Tested the MCC eCare Plan FHIR IG and SMART on FHIR applications through related tracks.	• Defined testing plans for the MCC eCare Plan FHIR IG to prepare for track testing in May 2023.	• Demonstrated ability to write and display a goal to a shared FHIR repository between two apps. Hosted an Educational Tooling Session.

Connectathon 33 Notable Achievements

- Facilitated an educational tooling session on open-source FHIR-based tools, presenting an overview of the project and application architecture. Discussed potential use cases for integrating with several EHR system vendors, and challenges with saving patient/caregiver-authored content to cloud-hosted FHIR repositories that provider organizations trust with ONC FHIR at Scale Task Force (FAST).
- Discussed CBO authorization to access data and the need for a centralized "hub" to assist with referrals and care coordination in the future, as well as temporary alternatives during a breakout room session with BSeR and Gravity
- Demonstrated the ability of The MyCarePlanner app to write a health concern to a shared FHIR repository during testing with NACHC. The Health Flow app was able to successfully read and display the information.
- Developed a plan for value set updates and maintenance.
- Gained insights on and confirmed compliance testing plans with ONC certification.

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Overview: SMART on FHIR Applications

Deliverable **3**

Pilot tested provider-facing and patient/caregiver-facing e-care plan applications that integrate with the EHR to pull, share, and display key patient data.

Year 4

Develop **Common Data Services Library.**

Modify **Provider and Patient/Caregiver Application to use Common Data Services Library**.

Support for **data aggregation and pilot implementation.**

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eCare Apps Support Comprehensive Shared Care Planning

	Comprehensive Shared Care Plan Definition*		MCC eCare Plan Applications
1	Gives the person **direct access to health data**.	→	Apps query EHR and other FHIR endpoints.
2	Puts the **person's goals at the center** of decision-making.	→	Apps designed around the process of goal-oriented shared decision-making.
3	Is holistic, including **clinical and nonclinical data**.	→	Apps supports SDOH data and patient/caregiver-reported data.
4	**Follows the person** through both acute and chronic care.	→	Apps can be used anytime and support transfer of data between acute and primary care contexts.
5	Allows **care team coordination**.	→	Apps allow caregiver (proxy), patient, and all providers to coordinate and plan care.

*U.S. Department of Health and Human Services 2015 Stakeholder Panel | Baker, et al. Making the Comprehensive Shared Care Plan a Reality. *NEJM Catalyst*. 2016: https://catalyst.nejm.org/making-the-comprehensive-shared-care-plan-a-reality/

Context Setting

Project Objective: Build data capacity for pragmatic PCOR by developing an interoperable electronic care plan to facilitate aggregation and sharing of critical patient-centered data across home-, community-, clinic-, and research- based settings for people with MCC.

eCare App Focus

Proof of concept for an interoperable platform that enables standardized data exchange for data elements critical to care planning.

Limitations/Challenges

- Limited EHR support for capturing data relevant to goal-oriented care planning
- Very limited write access to EHR systems via FHIR.
- Challenge of where/how to store supplemental data that health systems would be comfortable with for contributions by patients/caregivers or not supported by EHRs.

Future Scopes/Out of Scope Now

- Features that enable greater accessibility (i.e., multiple languages).
- Robust user features that provide a more full care planning experience (i.e., med reconciliation, corrections, scheduling, alerts, secure messaging).
- Clinical decision support.
- Aggregated data for data analytics research.
- Full integration with social care and care providers who don't use EHR systems.
- End-to-end shared decision-making workflow support.

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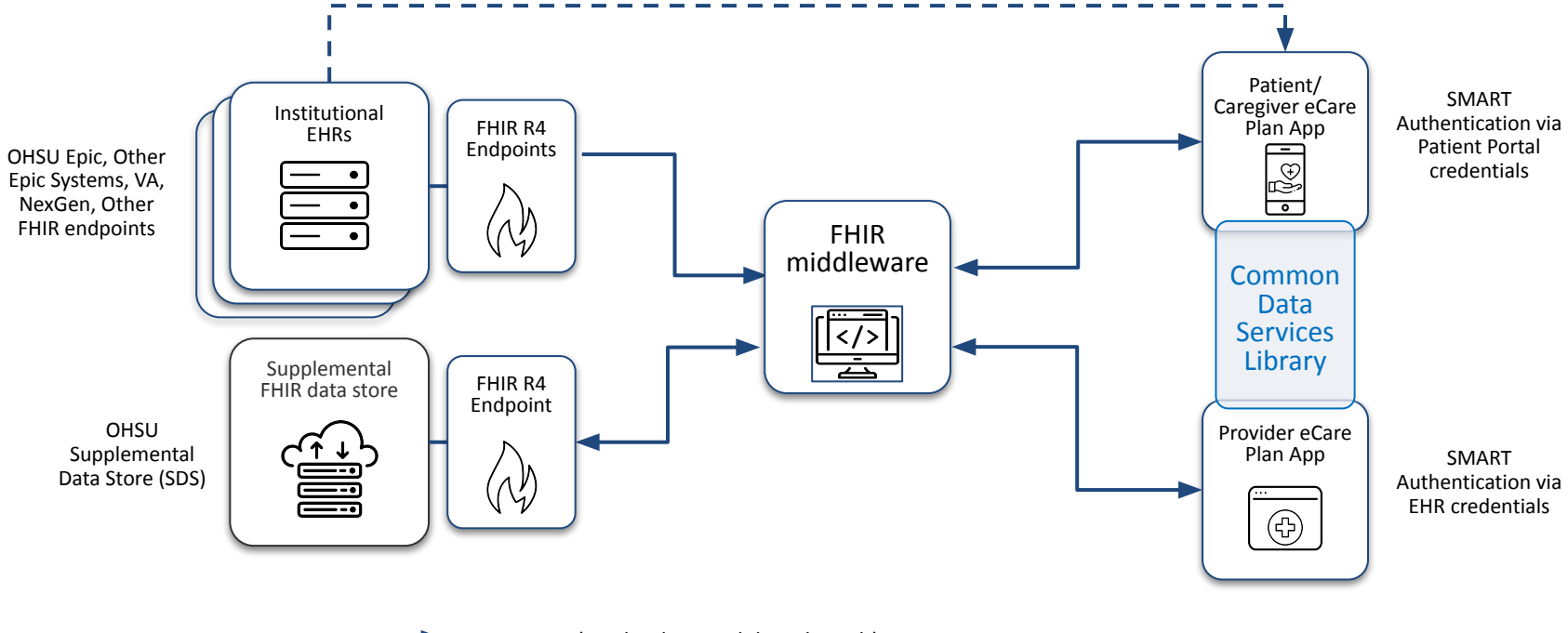
eCare Plan Applications Architecture



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Provider App Vision

- A **standards-based application** platform for providers that supports them in patient-centered care planning and **care coordination** by surfacing key factors and data to improve outcomes for people with multiple chronic condition.
- Serves as a complementary app to an EHR system to:
  - **Improve provider productivity** and **reduce provider burden**, and
  - Bring together in a **single view** care planning data from multiple EHRs and patient-/caregiver-authored data not supported in EHRs.
- Serves as a companion app to the patient/caregiver app enabling **shared care planning** between all members of the care team.

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Patient/Caregiver App Vision

- A **standards-based application** platform for patients and caregivers to engage them in **participating in their care planning** for MCC.
- Allows patients and caregivers to **write information** into the app that can be shared with their providers.
- Allows patients and caregivers to see their health data from all of their providers in one place to fully enable **goal-oriented care planning**.
- Supports better care coordination through **interoperable data exchange**.
- Serves as a companion app to the provider-facing app enabling **shared care planning** between all members of the care team.

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Summary of Key Updates in the Last 12 Months

Provider eCare Plan App

- Removal of Java dependency (non-standard middleware).
- Default to Goals tab upon launch.
- Ability to filter out labs without results.
- Created an “add goal” functionality that works with a supplemental FHIR store/sandbox.
- Sandbox functionality to connect to a second endpoint for Supplemental Data Store.

Patient/ Caregiver eCare Plan App

- Questionnaire administration (PROMIS-29, PRAPARE, Caregiver Strain Index).
- Categorization of conditions using CQL logic.
- Updated UI for entire app.
- Added provenance to queries and display.
- Connected MyCarePlanner to the Epic, Cerner, VA Sandbox, NextGen, and AthenaPractice.
- Display FHIR data query progress and errors on the home tab.
- Improved response time between switching tabs.

Common Data Services Library

- Designed architecture and specifications for the Common Data Services Library.
- Built MVP.

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What's Next

- Collaborating on the development of a **supplemental data store** at OHSU as a repository to save data authored or collected by the patient/caregiver app and enable sharing those data with others on the care team.
- Display aggregated data from multiple login functionality in the patient/caregiver app.
- Exploring other efforts that support patients in **getting access to their data**, including personal health devices and wearables, in a consistent FHIR standard so it can be shared and used for care planning.
  - HL7 FHIR IG for Standard Personal Health Record (SPHR)

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- HL7® Connectathon 33
- eCare Plan SMART on FHIR applications
- **Pilot updates**

Key Questions to Explore

- What **factors affect implementing** the eCP apps from an organizational and technical perspective?
- What **factors affect using** the eCP apps within and across organizations?
- How does use of the eCP apps **influence data collection and sharing** across settings?
- What are the **intra- and interorganizational sociotechnical factors to consider when implementing and using** the eCP apps?

Implementation & Usability Testing

- Round 1: Clinician and patient apps implemented at OHSU
  - Focus groups with clinicians using implemented version of apps
  - Controlled testing in clinician-patient dyads
- Round 2: recruiting primary and specialty ambulatory care practices
  - Multiple EHR systems: Epic, VA Vista, NextGen
  - Multiple Epic system environments: OHSU, Providence, Legacy and OCHIN
  - >100 patients and >10 providers across sites
  - Sharing of data across various EHR implementations
- "Sandbox" testing at MedStar using Cerner to establish a read-only connection for both applications

Real World Evaluation Components

- Round 1: Single Site Implementation & Usability Testing (2020-2021)
  - Formative user testing
  - Implementation feasibility
  - Single site aggregation of data from the EHR
- Round 2: Multi-site testing; interoperability of data (2022-present)
  - Implementation enhancements – expanded to multiple sites
  - Multi-site, multi-EHR aggregation of data

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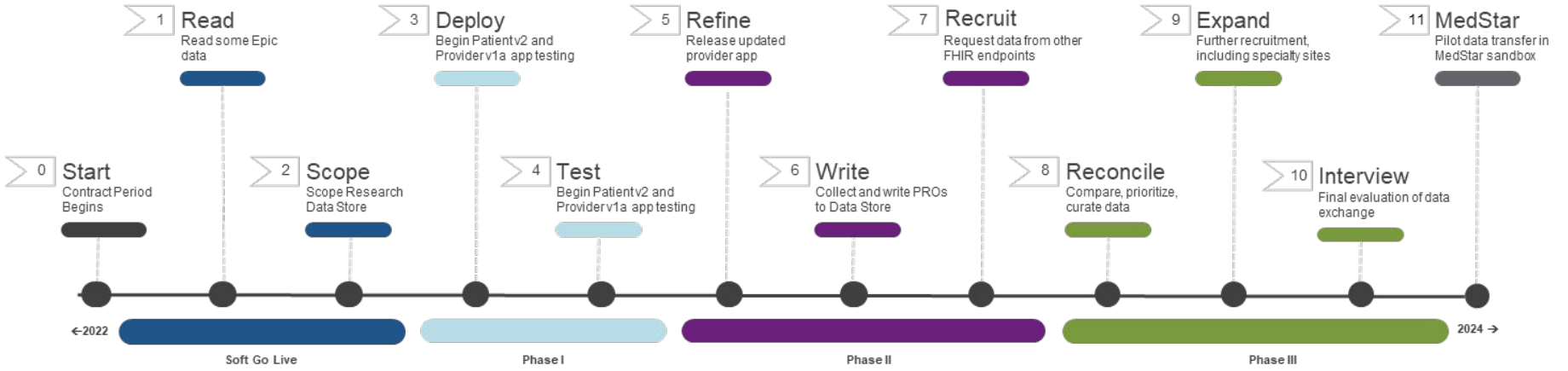
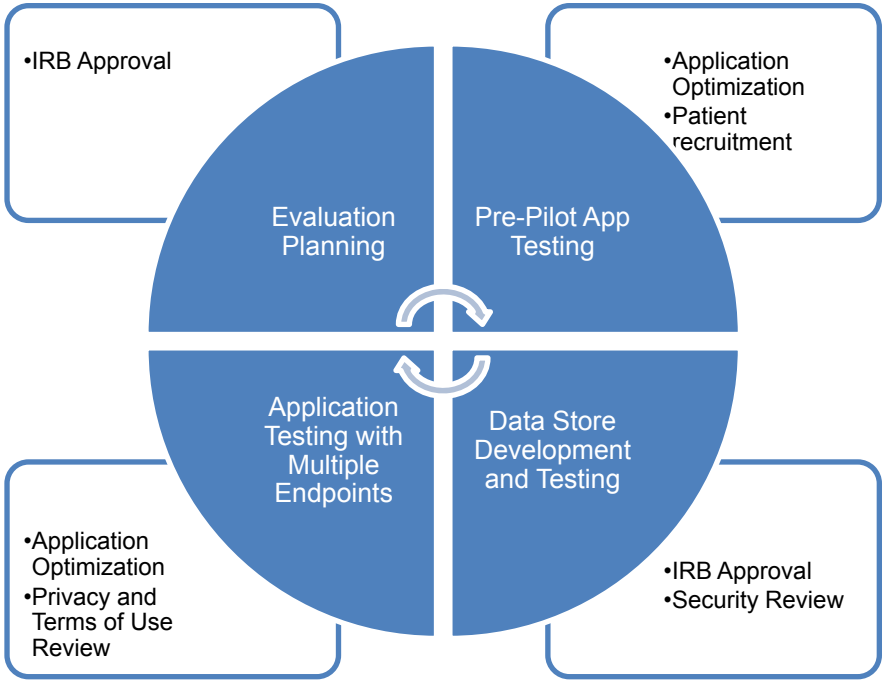
eCare Plan V2 Testing Timeline Projection



Real-World Challenges

- **FHIR Adoption and Use:** most FHIR implementations use US Core for Data Interoperability (USCDI) version 1, which lacks essential care plan components (e.g., limited goals, Questionnaire and QuestionnaireResponse used for patient reported data)
- **Writeback**: Most EHR vendors allow very limited ability to write data into the EHR from any external source (governance issue, not technical issue)
  - Requires use of a supplemental data store
- **Bulk FHIR data requests:**
  - Limited in terms of the specificity of the data that can be requested challenges in load times.
  - Alternative approach: batch transactions with the Bundle resource - not required by USCDI v1
  - Apps may require a large number of API calls to retrieve or store all of a patient's data
- **Volume of data:**
  - Delays in loading in app loading times introduction of status bar
  - Use of value sets and Clinical Quality Language to group conditions, lab results, goals, etc to make data more meaningful and digestible

Concurrent Activities and Barriers



Pre-Pilot Activities

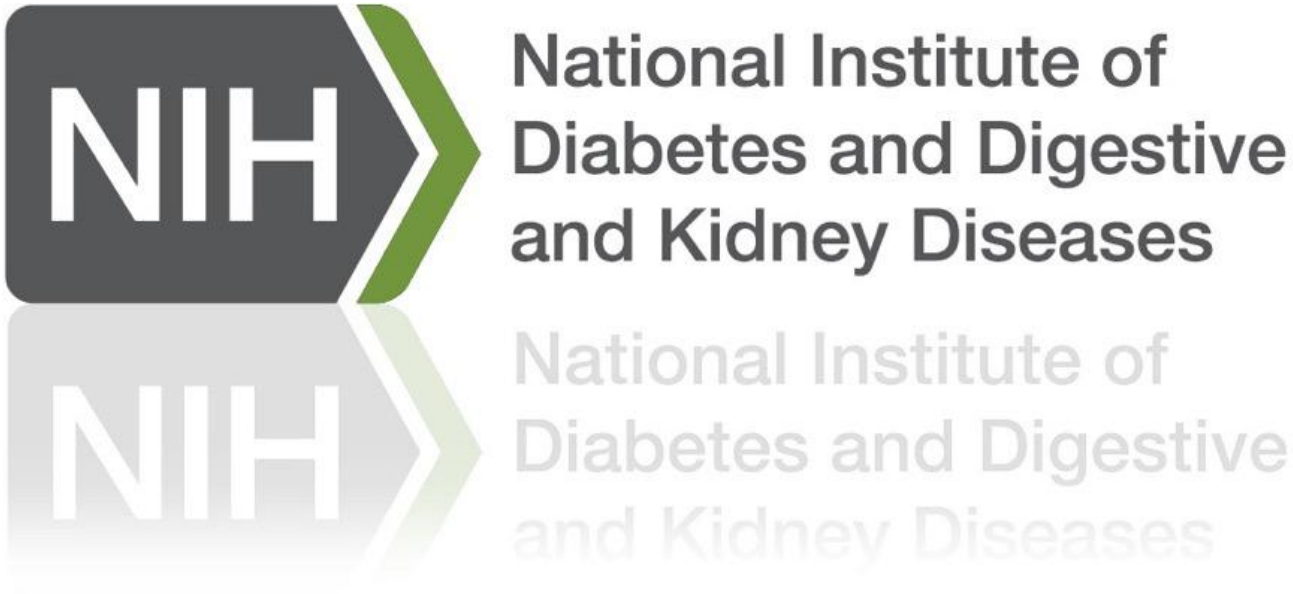
- Activities and Barriers
  - Application testing beyond Soft Go Live (SGL) requires complex patient data to test all aspects of functionality
  - Initial testing with a complex patient in SGL failed because of long load times, performance issues are being addressed
  - Test data either not available or hard to develop to represent complex patients
  - Patient participation not guaranteed through course of project (consent withdrawal, death, etc.)

Technical Development

- Supplemental Data Store (SDS)
  - Consent process required
  - Need to work out the details of partitioning
  - Security review required when system is complete
- Application Testing
  - Performance optimization required to move toward pilot
  - Multiple endpoint functionality development requires close coordination with SDS build

Sociotechnical Factors

- IRB approval needed to establish consent to access other FHIR endpoints – **approved on June 12, 2023**
- Application registration needed to access other FHIR endpoints
  - Stewardship by OHSU necessitated development of relevant Privacy Policy and Terms of Use
  - No clear precedent for drafting these or for legal review
  - Registration process still to follow final approval
- Security review happening concurrently with development but must be complete prior to pilot launch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