

## **AHRQ Grant Final Progress Report**

**Title of Project:**

### **Scalable Decision Support and Shared Decision Making for Lung Cancer Screening**

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## Structured Abstract

**Purpose:** The specific aims of this study were as follows: (1) Adapt the standalone Decision Precision low-dose computed tomography (LDCT) shared decision making (SDM) tool for lung cancer screening (LCS) into a standards-based clinical decision support (CDS) tool (Decision Precision+), develop CDS tools for optimally integrating Decision Precision+ into clinical workflows, and advance underlying standards and their adoption; (2) Integrate Decision Precision+ with multiple electronic health record (EHR) systems and widely disseminate the tool; and (3) Evaluate the impact of the CDS tool, including for adoption and impact.

**Scope:** Diagnostic LCS for patients eligible for screening according to US Preventive Services Task Force (USPSTF) guidelines.

**Methods:** We used user-centered design techniques to adapt Decision Precision to Decision Precision+. A pre-post clinical trial was performed at University of Utah Health to evaluate the adoption and impact of Decision Precision+.

**Results:** Following its design and development, Decision Precision+ has been tested in multiple healthcare systems. Decision Precision+ was implemented and evaluated at University of Utah Health. The intervention was associated with increased compliance with USPSTF guidelines. Decision Precision+ is available as a free app and is being widely disseminated, including through the Epic EHR App Market.

**Key Words:** Clinical Decision Making, Patient-Centered Care, Shared Decision Making, Clinical Decision Support System, Fast Healthcare Interoperability Resources (FHIR)

## **Acronyms Used in This Report**

AHRQ – Agency for Healthcare Research and Quality

API – application programming interface

CDS – clinical decision support

CPRS – Computerized Patient Record System

CMS – The Centers for Medicare & Medicaid Services

CQL – Clinical Quality Language

EHR – electronic health record

ELICIT – Evaluation in Life Cycle of Information Technology framework

FHIR – Fast Healthcare Interoperability Resources

HL7 – Health Level Seven International

LCS – lung cancer screening

LDCT – low-dose computed tomography

SDM – shared decision making

SMART – Substitutable Medication Applications and Reusable Technologies

SUS – System Usability Scale

USPSTF – United States Preventive Services Task Force

VA – Veterans Administration

## **Purpose**

This study took a previously developed standalone shared decision making (SDM) tool for lung cancer screening (LCS), Decision Precision, and adapted it into a shareable tool that can be integrated into any electronic health record (EHR) system leveraging standards-based interoperability. This new tool, Decision Precision+, pulls various patient data from a given EHR to provide individualized benefit and risk information for LCS and to promote SDM as recommended by the US Preventive Services Task Force (USPSTF) and as required by the Centers for Medicare & Medicaid Services (CMS). Beyond Decision Precision+, the intervention included prompts to consider LCS and to use Decision Precision+ where appropriate. The investigators' goal was for patients and their providers to make informed, patient-centered decisions regarding this potentially lifesaving test.

### **Aim 1. Adapt the stand-alone Decision Precision LDCT SDM tool into a standards-based CDS tool (Decision Precision+), develop CDS tools for optimally integrating Decision Precision+ into clinical workflows, and advance underlying standards and their adoption.**

We planned to adapt Decision Precision to use cross-vendor standard for integrating Web applications into the EHR known as the SMART on FHIR (Substitutable Medical Apps Reusable Technologies on Fast Healthcare Interoperability Resources) standard from Health Level Seven International (HL7). We planned to conduct user-centered design and in-depth workflow assessments on how best to integrate Decision Precision+ into clinical workflows according to the CDS 5 Rights. Based on these analyses, we planned to develop tools to prompt use of Decision Precision+ for eligible patients. We planned to develop standards-based CDS resources compliant with HL7 Clinical Quality Framework (CQF) standards such as the HL7 Clinical Quality Language (CQL) standard, and we also planned to support EHR platform-based CDS for prompting for the appropriate use of Decision Precision+. We planned to work with the standards community and EHR vendors to improve the availability of required data in standard FHIR data interfaces, and we planned to develop and share a reference FHIR implementation for the Epic EHR platform.

### **Aim 2. Integrate Decision Precision+ with multiple EHR systems and widely disseminate the tool.**

We planned to pursue technical integration of Decision Precision+ with multiple EHR platforms, including with two widely used commercial EHR systems (Epic and Cerner). We planned to initially deploy the CDS tool at University of Utah Health. We planned to then work closely with various stakeholders to widely disseminate the tool.

### **Aim 3. Evaluate the impact of the CDS tool, including for adoption, clinical impact, and financial impact.**

We planned to measure adoption of Decision Precision+ in terms of the number of clinics and care providers using the tool. To measure clinical impact, we planned to conduct a clinical study at University of Utah Health across primary care clinics, to assess the impact of the study intervention on compliance with USPSTF screening guidelines.

## Scope

### Background

Lung cancer is the leading cause of cancer-related deaths in the US, with over 135,000 deaths in 2020.(1) The USPSTF recommends LDCT screening to reduce mortality.(2) However, among eligible patients, there is wide individual variation in expected benefits vs. harms (e.g., biopsy complications after false-positive screens).(3) Thus, SDM using a decision aid – a form of CDS – is required before LDCT screening, including by CMS for payment.(2,4) However, standalone CDS requires manual data entry and is not directly integrated into clinical workflows, while CDS developed with native EHR tools have functional limitations and are difficult to disseminate across health systems and EHR platforms. These constraints limit the adoption of CDS to support SDM for LCS, which contributes to limited screening among eligible patients (~5%).(5) A critical need, therefore, is the wide adoption of CDS to support SDM for LCS.

Dr. Kensaku Kawamoto and a group of researchers from the University of Utah, the University of Michigan, and Intermountain Healthcare examined ways to integrate this life-saving screening into clinical workflow. Study co-investigators Tanner Caverly and Angie Fagerlin previously led the development of a standalone SDM tool for LCS called Decision Precision, which is available at <https://screenlc.com>. This CDS tool incorporates the USPSTF guidelines for LDCT screening and provides patient-specific information on the expected benefits and harms of screening. When used in eight Veterans Administration (VA) medical centers, decision-making improved about LDCT screenings among at-risk patients. While standalone, Web-based CDS tools may enable clinicians to more easily personalize screening, they are also limited by a lack of workflow integration and often require duplicate data entry, thus increasing provider burden and limiting the tool's usefulness.

### Context

Diagnostic LCS for USPSTF-eligible patients.

### Settings

The study was conducted in 30 primary care and 4 pulmonary clinics at 13 University of Utah Health locations. University of Utah Health uses the Epic EHR. Primary care specialties included family practice, internal medicine, internal medicine/pediatrics, and geriatrics. Technical integration of Decision Precision+ was also tested at Intermountain Healthcare, which uses the Cerner EHR.

### Participants

For the primary analysis of the University of Utah Health clinical trial, inclusion criteria for the evaluation used the 2013 USPSTF screening guidelines that were in force at the beginning of the trial: 55 to 80 years old, 30+ pack-year smoking history, and current smoker or quit smoking in the last 15 years.(6) Participants were included if they had at least one primary care office visit

during the study. Participants were excluded when they had a history of lung cancer before the visit date.

## Methods

### Study Design

The clinical trial included three study periods: a 12-month pre-intervention phase (August 24, 2019 – August 23, 2020), a 9-month intervention phase 1 (August 24, 2020 – May 23, 2021), and a 9-month intervention phase 2 (July 28, 2021 – April 28, 2022). The study was approved by the University of Utah IRB (ID 00125797) and registered with [clinicaltrials.gov](https://clinicaltrials.gov) (NCT04498052).

### Data Sources/Collection

This study used data retrieved from the University of Utah Health EHR database.

### Interventions

The intervention tested at the University of Utah Health clinical trial consisted of (1) an EHR-integrated SDM tool (Decision Precision+) and (2) clinician-facing EHR prompts. Decision Precision+ provided individualized information based on risk factors and demographic information in the EHR. Clinician-facing prompts were introduced into the EHR to help identify eligible patients and to remind clinicians about the need for SDM discussions and annual screening for patients who decided to go through with LDCT after the SDM. Both of these interventions were introduced in phase 1. In phase 2, in addition to these interventions, a patient-facing reminder was shown in the EHR patient portal for LCS or LCS SDM for applicable patients. Patient reminders were shown for those patients eligible for LCS based on USPSTF screening criteria. Among these patients, LCS reminders were for those who had already started a screening regimen, and LCS SDM reminders were for those who had not yet started a screening regimen and did not have structured documentation of LCS SDM in the past 3 years.

### Measures

The primary outcome was USPSTF guideline compliance among screening-eligible patients, which was defined as having had LDCT in the past year, another chest CT in the past year, or SDM documented in structured form in the past 3 years. Additionally, surveys were conducted to evaluate usability and provider satisfaction.

### Limitations

Several limitations are associated with this study. As one important limitation, the clinical trial used a pre-post study design, and it did not include a concurrent control group. In large part, this was because some intervention components, such as the EHR Health Maintenance module, did not have the capacity to be only made available to certain patients or certain clinics. Given this limitation of using a non-randomized study design, we used propensity scores to adjust for changes over time. We also visualized trends to enable review of underlying secular trends.

As a second important limitation, the clinical trial was undertaken at a single healthcare system. Because of this limitation, our findings regarding intervention adoption and effectiveness require further research to verify generalizability. At the same time, the clinical trial was conducted using the Epic EHR, which has the largest share of the US EHR market.(7) Thus, the approach used has a clear path to adoption at the large number of healthcare systems in the US that use this EHR system.

As a third important limitation, some EHR vendors have been slow to support some of the desired application programming interface (API) functionality, such as for retrieving detailed smoking history in their smoking-related FHIR APIs or for using FHIR APIs to write into the EHR the results of LCS SDM. These limitations of APIs in some EHR platforms could restrict the level of functionality that can be offered across EHR platforms, e.g., beyond the Epic EHR. For example, without detailed smoking information being available through FHIR, even if pack-year information was in the EHR, Decision Precision+ would need to ask users to manually re-enter that information in the app. While not an insurmountable challenge, this type of user experience would certainly be suboptimal. Efforts were made through various channels (e.g., HL7, EHR vendor contacts, Argonaut Project, U.S. Health IT Advisory Committee) to promote the inclusion of detailed smoking history into FHIR APIs. Of note, Epic does now include detailed smoking history in its FHIR API.



## Results

This study has resulted in six published manuscripts described below. In addition, manuscripts describing the clinical trial results are currently undergoing the manuscript submission, review, and revision process. As these clinical trials manuscripts are still not published, the information provided below regarding clinical trial results is limited to high-level results unadjusted for covariates. Please see the final published manuscripts for detailed clinical trial results, including results adjusted for covariates.

## Principal Findings

The project team successfully developed Decision Precision+ as a SMART on FHIR app that pulls data from the EHR to enable providers to have an individualized risk-benefit discussion with at-risk patients on whether LCS is right for them. The core USPSTF guideline logic on LCS was also encoded using CQL and FHIR and is available at <https://build.fhir.org/ig/cqframework/lcs-cds/lcs-recommendation.html>. The source is available at <https://github.com/cqframework/lcs-cds>.

Following its design and development, Decision Precision+ was implemented and evaluated at the primary care clinics of University of Utah Health. This evaluation found that introduction of the intervention was associated with significant increases in LDCT ordering and completion according to USPSTF guidelines.

Decision Precision+ is now offered to other healthcare organizations as a free tool that can be downloaded and used within any EHR system that supports the SMART on FHIR framework. Of note, EHR vendors are required to support SMART on FHIR as a part of federal regulations.(8) Technical integration of Decision Precision+ was completed with the Epic EHR and the Fujion Clinical EHR system. Early technical integration of Decision Precision+ was conducted with the VA Computerized Patient Record System (CPRS) EHR system and the Cerner EHR system. Multiple deployments are in process with other healthcare systems.

## Outcomes

Listed in this section are the main outcomes from this study.

### Enhanced Decision Precision Standalone SDM Tool

The stand-alone Decision Precision app was iteratively refined to be more streamlined and suitable for use in primary care settings. The latest app, available for free at <https://screenlc.com>, is now the default SDM app included in Epic's recommended Foundation workflow for LCS.

### Completed Decision Precision+ SMART on FHIR SDM app

Decision Precision was successfully converted into the Decision Precision+ SMART on FHIR app. Decision Precision+ is available for free, including through the Epic App Market. Below are screenshots from this tool within the Epic EHR.

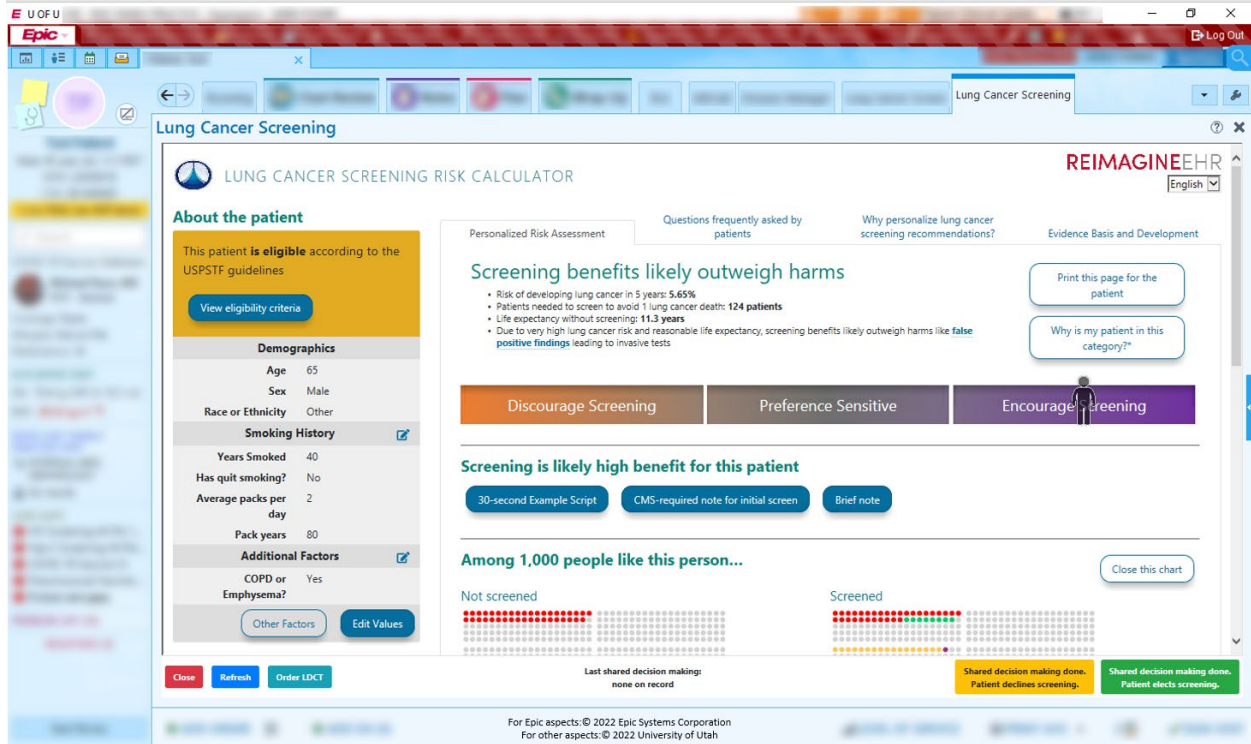


Figure 1. Decision Precision+ screenshot in Epic EHR

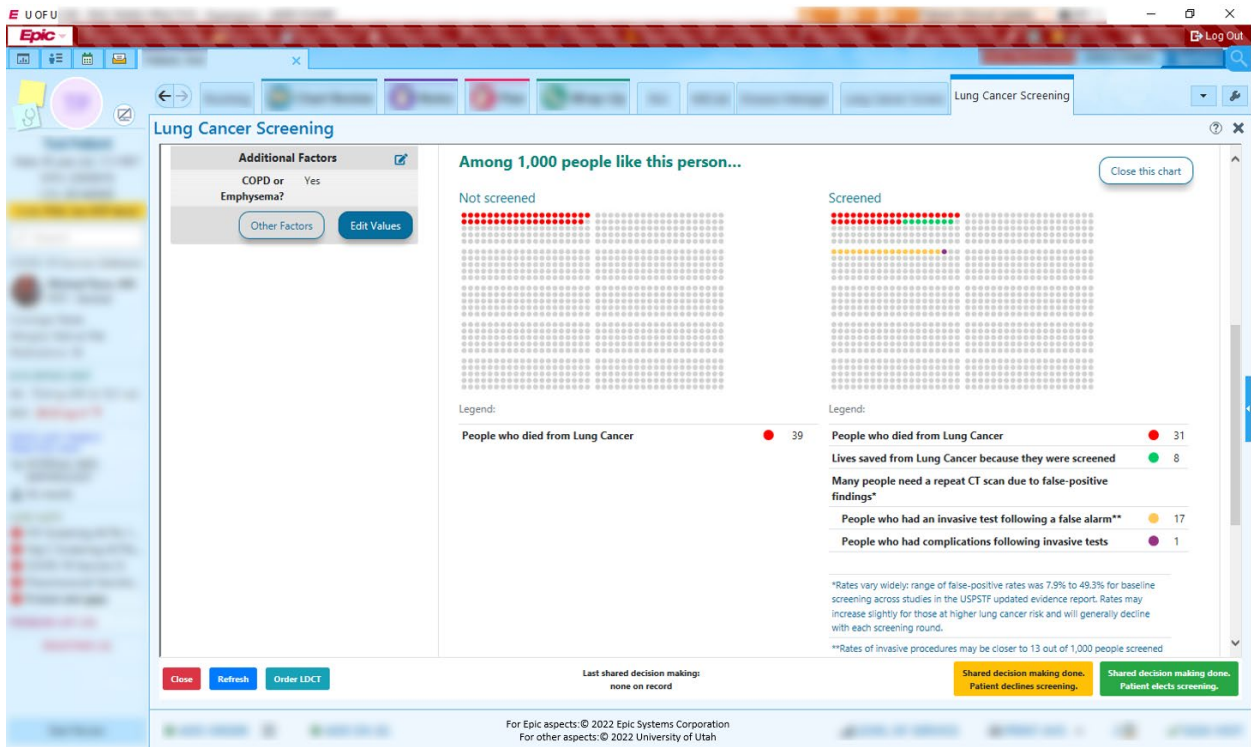


Figure 2. Decision Precision+ screenshot in Epic EHR highlighting risk pictogram

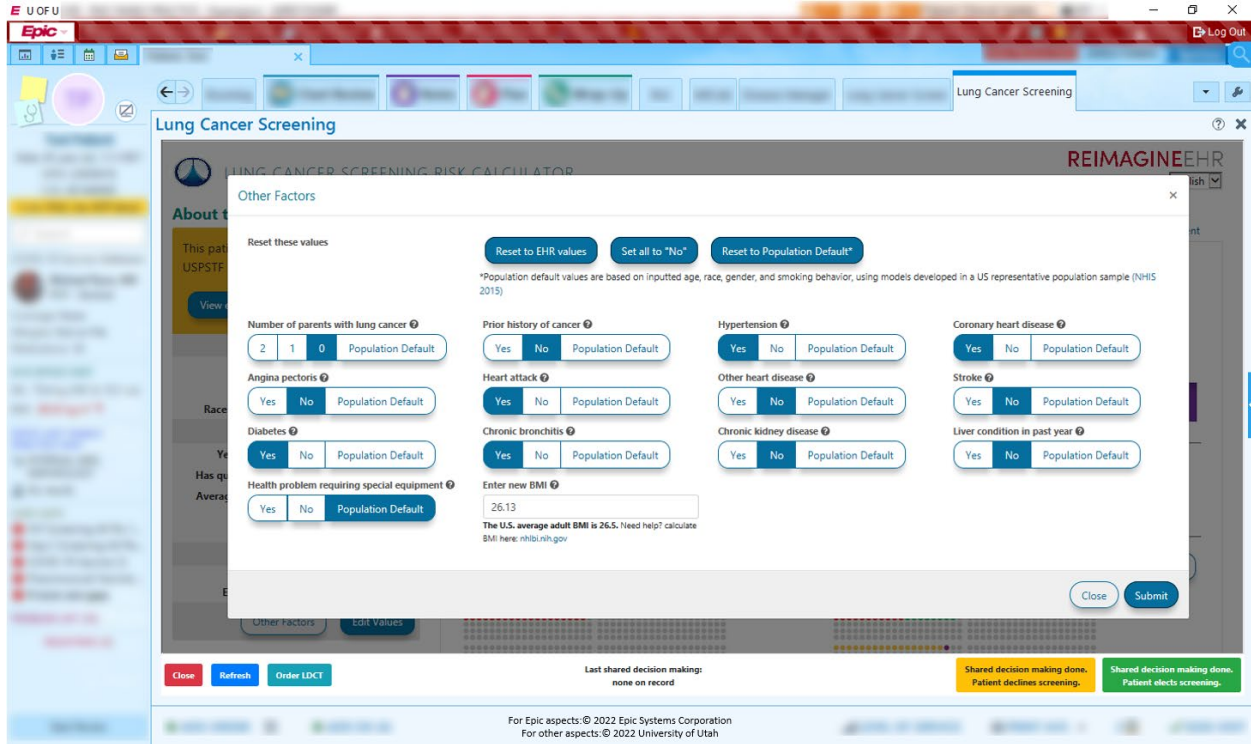
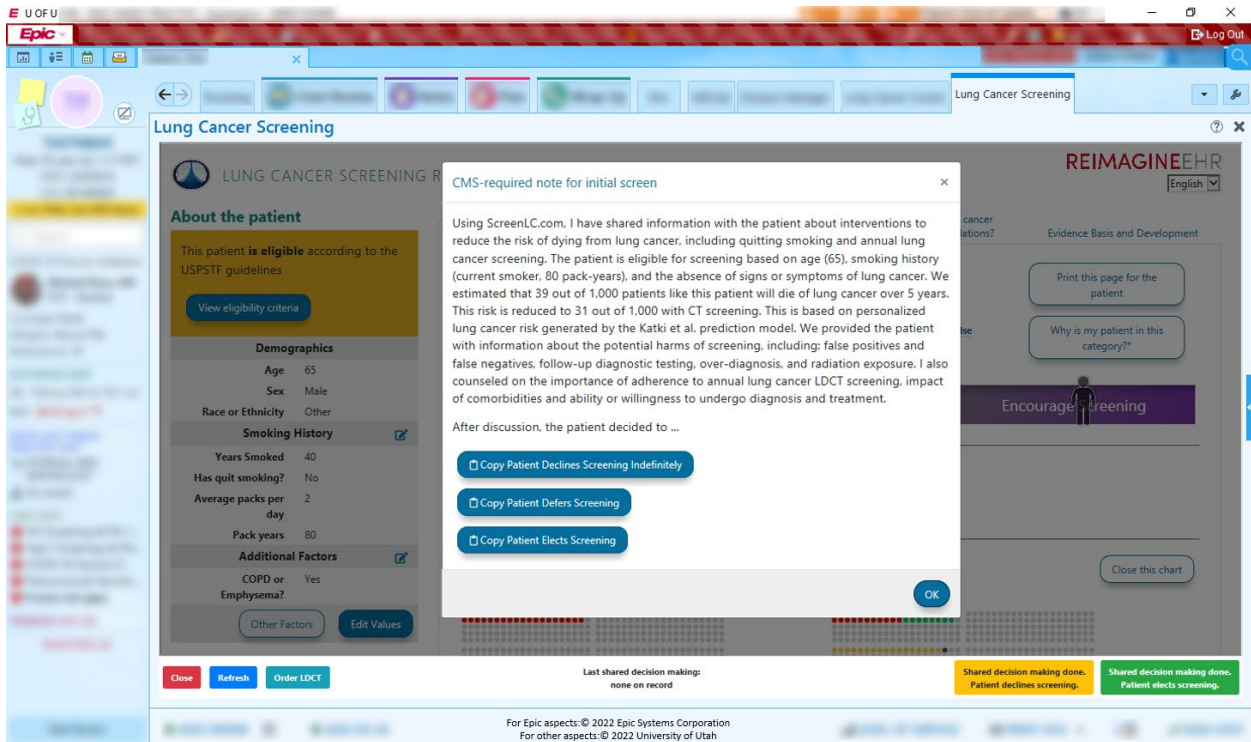


Figure 3. Decision Precision+ screenshot in Epic EHR highlighting several of the data inputs pulled in automatically from the EHR using FHIR



**Figure 4. Decision Precision+ screenshot in Epic EHR highlighting the auto-generation of a clinical note used to generate documentation compliant with CMS payment guidelines for LCS SDM**

### Ancillary CDS to Support LCS SDM Workflows

In addition to Decision Precision+, clinician-facing prompts were introduced into the EHR to help identify eligible patients and to remind clinicians about the need for SDM discussions and about annual LDCT screening for patients who decided to undergo a LDCT regimen. The project team also shared the approach used for LCS and associated SDM with the Epic Pulmonology Steering Board. The latest Epic recommended Foundation workflow for LCS now includes a model workflow that explicitly includes SDM. When this recommended workflow is used, Decision Precision+ can be used at an Epic installation site with minimal additional configuration.

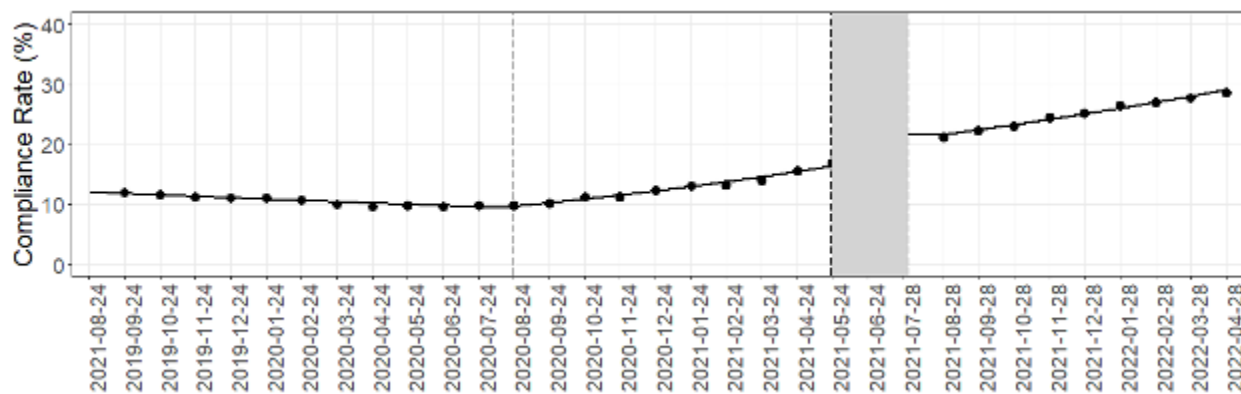
### Decision Precision+ Integration with Multiple EHR Systems

Decision Precision+ was successfully integrated with the Epic EHR and the Fujion Clinical EHR systems. Early technical integration of Decision Precision+ was conducted with the VA CPRS EHR system and the Cerner EHR system. Multiple deployments are in process with other healthcare systems. Organizations that have expressed a desire to install Decision Precision+ include academic health systems, community-based health systems, and the VA.

### High-Level Outcomes from University of Utah Health Clinical Trial

As noted above, because manuscripts are pending for the clinical trial, only high-level, unadjusted outcomes are provided here. Please see the published manuscripts for detailed results.

A two-phase clinical trial was successfully conducted, with phase 1 involving provider-facing CDS and phase 2 adding a patient-facing CDS component as described in the methods. 2,064 patients were enrolled in the trial. Among patients meeting USPSTF LCS criteria, guideline compliance rates increased from 10% at baseline to 17% in phase 1 and 29% in phase 2 ( $p < 0.001$ ) (Figure 5).



**Figure 5. USPSTF guideline compliance rates**

There were 371 individuals screened in the phase 1 and phase 2 periods, resulting in over 10,000 estimated days of life saved.

Decision Precision+ was used for 26% of orders to initiate a LDCT screening regimen. System Usability Scale (SUS) surveys showed that providers rated the app at 77 points, which corresponds to “good” usability according to Bangor *et al.*(9)

## **Discussion**

This AHRQ-funded study enabled the design, development, implementation, evaluation, and dissemination of Decision Precision+, an interoperable SDM intervention for LCS. Introduction of Decision Precision+ into clinical practice was associated with increased compliance with USPSTF guidelines. As indicated by previous studies, EHR data-driven solutions such as Decision Precision+ have potential to better integrate into clinical workflows compared to standalone solutions such as Decision Precision.(10)

Randomized clinical trials have demonstrated effectiveness of SDM, but there is a need for effective translation of SDM into clinical practice.(11,12) In particular, SDM adoption in clinical settings has historically been low,(13–16) including in busy primary care settings.(17–20) This study has demonstrated promising initial results for implementing EHR-integrated, patient-centered SDM into clinical practice.

## **Conclusions**

Implementation of a multifaceted SDM and CDS intervention was associated with a significant increase in compliance with USPSTF LCS guidelines. The EHR-integrated SDM tool was used for 26% of orders to initiate a LDCT screening regimen.

## **Significance**

If scaled nationally, optimized LDCT screening could prevent as many as 10,000 lung cancer deaths annually while minimizing adverse events associated with screening. Already, adoption of the CDS tool is in process with multiple healthcare systems.

## **Implications**

EHR-integrated, patient-centered CDS enabled by interoperability standards such as SMART on FHIR can improve LCS. Ultimately, the investigators hope that the research will enable widespread implementation of Decision Precision+ to optimize LDCT screening while providing a model for widely disseminating patient-centered, interoperable, and impactful CDS innovations.

## List of Publications and Products

The project resulted in 2 software products, 6 published manuscripts, additional manuscripts on the clinical trial results in preparation, and multiple presentations at national meetings. The software products and manuscripts are described below.

### Product 1: Updated Decision Precision (standalone) SDM app

The stand-alone Decision Precision app was iteratively refined to be more streamlined and suitable for use in primary care settings. The latest app, available for free at <https://screenlc.com>, is now the default SDM app included in Epic's recommended Foundation workflow for LCS.

### Product 2: Decision Precision+ SMART on FHIR SDM app

The SMART on FHIR app, Decision Precision+, has been validated through the University of Utah Health clinical trial and is available for free, including through the Epic App Market. Please see above for screenshots and further details.

### Manuscripts:

1. Reese TJ, Schlechter CR, Potter LN, Kawamoto K, del Fiol G, Lam CY, et al. Evaluation of Revised US Preventive Services Task Force Lung Cancer Screening Guideline Among Women and Racial/Ethnic Minority Populations. JAMA Netw Open [Internet]. 2021 Jan 12 [cited 2021 Jan 21];4(1):e2033769. Available from: <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2774854>.

This manuscript evaluated the impact of changes to AHRQ USPSTF lung cancer screening guidelines in 2021.

2. Strasberg HR, Rhodes B, del Fiol G, Jenders RA, Haug PJ, Kawamoto K. Contemporary clinical decision support standards using Health Level Seven International Fast Healthcare Interoperability Resources. J Am Med Inform Assoc [Internet]. 2021 Aug 1 [cited 2022 Oct 10];28(8):1796–806. Available from: <https://pubmed.ncbi.nlm.nih.gov/34100949/>.

This manuscript provides an overview of CDS interoperability standards such as those standards used in the Decision Precision+ SDM app.

3. Kawamoto K, Kukhareva P v., Weir C, Flynn MC, Nanjo CJ, Martin DK, et al. Establishing a multidisciplinary initiative for interoperable electronic health record innovations at an academic medical center. JAMIA Open [Internet]. 2021 Jul 31 [cited 2021 Aug 3];4(3):oab041. Available from: <https://academic.oup.com/jamiaopen/article/4/3/oab041/6333015>.

This manuscript describes ReImagine EHR, the enterprise initiative to develop interoperable digital health innovations. Decision Precision+ was developed through this initiative.

4. Reese TJ, Schlechter CR, Kramer H, Kukhareva P, Weir CR, del Fiol G, et al. Implementing lung cancer screening in primary care: needs assessment and implementation strategy design. *Transl Behav Med* [Internet]. 2022 Aug 16;12(2):187–97. Available from: <https://pubmed.ncbi.nlm.nih.gov/34424342/>.

This manuscript describes provider needs assessment and implementation strategy design for implementing lung cancer screening in primary care.

5. Kukhareva P V, Weir C, Del Fiol G, Aarons GA, Taft TY, Schlechter CR, et al. Evaluation in Life Cycle of Information Technology (ELICIT) framework: Supporting the innovation life cycle from business case assessment to summative evaluation. *J Biomed Inform*. 2022 Mar 1;127(1532–0480):104014.

This manuscript describes a holistic evaluation framework for EHR-integrated innovations such as Decision Precision+. The evaluation of Decision Precision+ played a crucial role in the development of this framework.

6. Kukhareva P, Caverly T, Li H, Katki H, Cheung L, Reese T, et al. Inaccuracies in electronic health records smoking data and a potential approach to address resulting underestimation in determining lung cancer screening eligibility. *J Am Med Inform Assoc*. 2022 Apr 13;29(5):779–88.

This manuscript describes highly prevalent inaccuracies in EHR smoking data, which resulted in an under-estimate of smoking pack-years by about 8 pack-years for current smokers.

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