

PROJECT SCOPE STATEMENT
ELECTRONIC CASE REPORTING USING THE PHCP

10/13/15



TABLE OF CONTENTS

INTRODUCTION	3
PROJECT PURPOSE AND JUSTIFICATION.....	3
SCOPE DESCRIPTION.....	3
HIGH LEVEL REQUIREMENTS	4
BOUNDARIES	5
STRATEGY	5
DELIVERABLES.....	6
ACCEPTANCE CRITERIA.....	6
CONSTRAINTS	6
ASSUMPTIONS	6
COST ESTIMATE	7
COST BENEFIT ANALYSIS	7

DRAFT

INTRODUCTION

This Project Scope Statement outlines the scope of electronic case reporting (eCR) project utilizing the Public Health Community Platform (PHCP). This project requires the close coordination of multiple stakeholders and developers, the integration of several systems, and the input of subject matter experts for consistent execution. This document will elaborate on what is required by each entity in this project and provide a baseline for project milestones.

PROJECT PURPOSE AND JUSTIFICATION

The eCR Pilot on the PHCP is designed to provide the necessary infrastructure (content, platform, and tools) to more efficiently send standards-based, secure, and confidential case reports for reportable conditions from EHR systems to state and local public health agencies (PHA). The pilot will entail implementing production end to end electronic case reporting with live data from the selected clinical provider's EHR system to the PHA environment using the PHCP. The PHCP will provide the necessary infrastructure to support a shared decision support tool (an implementation of CSTE's Reportable Conditions Knowledge Management System [RCKMS]) and the necessary integration with EHR systems and public health systems. This includes both the technological integration as well as the appropriate legal agreements.

This project is designed to align with new Meaningful Use Stage 3 public health options for electronic case reporting. Additionally, the project will modernize how clinical providers meet regulatory mandates to report persons of public health interest to PHAs. Case reporting from clinical providers is still primarily a manual, paper-based process that requires forms to be filled out and sent via mail or fax to the PHA. Providers are often unaware of reporting requirements in their practicing jurisdiction and may not know how to report cases. Some PHAs have developed systems that allow providers to complete electronic forms, but the case identification and data entry is still a manual process, burdensome for both healthcare providers and PHAs.

The complexities and inconsistencies of case reporting from clinical providers has resulted in underreporting of cases of public health interest, blinding PHAs to emerging threats, delaying investigations and interventions, and ultimately enabling the spread of serious illnesses in vulnerable populations.

This pilot will automate the triggering and sending of potential cases, centralize decisions support logic, and route patient encounter data elements to the correct PHA.

SCOPE DESCRIPTION

Generally, a national set of reportable conditions trigger codes (ICD, SNOMED-CT, LOINC, CPT, and possibly others) would be integrated into the EHR system. These trigger codes would be

used to filter patient encounters and initiate a transaction of that data¹ to the PHCP. The PHCP would use the integrated RCKMS tool to determine if that encounter is reportable to the PHA based on jurisdictionally defined rules. A notice of reportability will be returned to the EHR system with the RCKMS decision results. If reportable, the PHCP would send the CDA (representing the initial case report) to the PHA and a notice of reportability to the EHR system.

The scope of this project involves defining the requirements for system integration between the PHCP, EHR system and the PHA system. This project will utilize “pilot teams” comprised of PHA and facility representatives and the EHR vendor that supports the pilot facility. The pilot teams will help to identify the requirements, test the integration points, and validate success. Additionally, this project scope will align with the emerging standards in Meaningful Use Stage 3, allowing for vendor certification to MU stage 3 requirements.

HIGH LEVEL REQUIREMENTS

The following high level requirements have been identified for the eCR Project:

- State or Local PHA
 - Team roles include end user SME for case reporting and PH systems IT developer
 - Willingness to commit to Agile² development with the developers.
 - Present lessons learned and best practices to the wider community.
 - Participate in regular project updates.
 - Integrate with PHCP for initial case report transport
 - Be able to sign appropriate DURSA or other agreement with appropriate association dba PHCP

- Clinical Provider
 - Team roles include end user SME for provider and reporter.
 - Willingness commit to Agile development with the developers.
 - Present lessons learned and best practices to the wider community.
 - Participate in regular project updates.
 - Integrate eCR into clinical workflow
 - Work closely with PHA to ensure quality and accuracy
 - Continue other reporting mechanisms to measure efficacy
 - Provide rollout training for staff responsible for reporting
 - Be able to sign appropriate agreement with appropriate association dba PHCP

- EHR Vendor
 - Willingness commit to Agile development with the developers.
 - Present lessons learned and best practices to the wider community.

¹ Data elements are being defined as a CDA by CSTE and HL7 PHER workgroup. The PHCP can accommodate a variety of transactions.

² Agile is a development management methodology designed using sprints of activity with iterative feedback and stakeholder acceptance. Development teams will be involved in daily scrum meetings and stakeholders will have regular scrum reviews at the end of each sprint cycle (usually every two weeks).

- Participate in regular project updates.
 - Integrate trigger codes into EHR system
 - Test trigger code delivery from PHCP to EHR
 - Implement standard for electronic Initial Case Report data elements
 - Implement transport/transaction requirements to send/receive data from PHCP
 - Be able to sign appropriate agreement with appropriate association dba PHCP
- Public Health Community Platform Development Team
 - Lead Agile Development Process
 - Gather requirements and verify/validate with Pilot Teams.
 - Architect overall process and functional design of shared infrastructure
 - Develop and host shared infrastructure for electronic case reporting.
 - Complete development and host publish/subscribe capability for trigger codes
 - Demonstrate success with production level transmission/engagement of clinical partners and public health jurisdictions.

BOUNDARIES

The eCR project includes the iterative planning, designing, development, testing and production of automated electronic case reporting from clinical providers to public health agencies. This includes the technical and non-technical components (such as data use agreements). This includes requirements gathering, technical design and coding work, server configuration and user authentication, testing, troubleshooting, and deployment of the eCR application across the pilot teams.

Not included in the scope of this project are:

- Integration of Structured Data Capture for completion of full case report
- Development and implementation of “forms server” with unique case reports forms by condition.
- Delivery of full case report to PHA
- Electronic integration of “Electronic Initial Case Report” into PHA surveillance system

STRATEGY

This project will be developed by the APHL AIMS team for the PHCP. Overall project management is the responsibility of ASTHO. Pilot teams consisting of a PHA jurisdiction, EHR vendor, and clinical facility will help inform the other partners about their requirements, both programmatic and technical. Development work will be required within the facility environment and the PHA environment. Centralized EHR platforms may be utilized to streamline the connection and integration between EHRs and the PHCP.

- Standards will be aligned with Meaningful Use Stage 3 regulations.

National subject matter experts from the PHCP eCR committee will be utilized to ensure the application development meets the requirements for a national solution.

DELIVERABLES

Project deliverables will evolve as the project participants are identified and requirements are fully developed. However, the following are high level deliverable goals:

- Distribute national trigger codes from PHCP to EHR System
- Integrate national trigger codes into EHR system
- Generate initial case report from EHR system based on trigger
- EHR onboarding with PHCP
- Initial case report transaction between EHR and PHCP
- PHA onboarding with PHCP
- PHA onboarding with RCKMS application
- Routing initial case report to correct PHA based on RCKMS determination
- Routing Notice of Reportability to EHR

ACCEPTANCE CRITERIA

- Successful demonstration of trigger codes downloaded from PHCP repository
- Successful demonstration of trigger codes integrated into EHR application by March, 2016
- Successful secure connection to PHCP/AIMS and ability to send data/messages to PHCP/AIMS using nationally recognized transport protocol such as (but not limited to) Direct, Web Services, PHINMS, SFTP, etc. by March, 2016
- Demonstrated ability to send CCDAs (or similar document compliant with MU Stage 3 final rules) to the PHCP containing data stipulated in the final CSTE sponsored IG by April, 2016
- Demonstrated ability to accept a return CCDAs message from the PHCP/AIMS containing notice of reporting information with data elements to be agreed during project by April 2016
- Successful transport to, and acceptance by PHA of CCDAs message containing “electronic initial case report” as defined by CSTE and the HL7 PHER workgroup and/or Stage 3 MU regulations by May 2106

CONSTRAINTS

This project is constrained by the current scope of CDC funding and timelines.

1. Entire project must be completed by June 30, 2016.
2. Pilot development should be completed by the end of the first quarter of 2016.
3. No funding has been allocated for pilot teams.
4. All data providers and receivers must have the legal agreements in place to transport live data.

ASSUMPTIONS

During the project planning cycle every effort must be made to identify and mitigate any risk associated with the following assumptions:

1. HL7 PHER group will have successfully identified data elements and draft standard for initial case report.
2. RCKMS will be successfully integrated into AIMS and ready for production.
3. Developed solution will comply with MU Stage 3 regulation.
4. The eCR Project has full support from the PHCP interim executive committee, ASTHO leadership and members, CSTE leadership and members.

COST ESTIMATE

Development and integration of trigger codes and eCaseReport to be ready for “test” implementation by April, 2016. The following table represents our best estimates of effort required for EHR vendors. Feedback regarding accuracy of time estimates will be greatly appreciated so we can more effectively estimate EHR vendor impacts in future integration efforts.

Estimate of effort:

Requirements gathering and specification development:	100 hrs
Transport development and implementation:	45 hrs
Trigger code list development and integration (assume repurposing of trigger functionality already in use for other functions):	240 hrs
Develop “Electronic Initial Case Report” form and function (assume repurpose of CCDA in use for transitions of care and other functions):	120 hrs
Integration of “Notice of Reportability:”	160 hrs
Testing and test script development:	200 hrs
Project Management:	80 hrs

COST BENEFIT ANALYSIS

The true cost and benefit of eCR is difficult to capture without a thorough economic analysis which is beyond the resources of this project. This section elaborates on the potential value of eCR using shared infrastructure. Notably, inputs for the cost of eCR include developing, implementing, and maintaining the infrastructure to support eCR. This cost would be associated with clinical providers, EHR vendors, and PHAs. Savings could be realized in workflow efficiencies of providers, reporters, and PHA staff. Additionally, incentive payments would be included for providers through MU. More difficult to calculate is the savings realized by more complete case reporting. For example, the savings from earlier detection of a communicable disease that leads to better public health intervention, decreased transmission, fewer cases, and less reduction in productivity. The cost savings will vary greatly by disease prevalence, severity, transmission rate, and treatment.

Supporting eCR using the PHCP can provide further value in the following ways:

- The PHCP can present a more consistent interface for clinical providers, EHR vendors, and HIEs to connect to PHAs.
- The PHCP can offer value to public health agencies by providing technologies that are difficult for any individual agency to develop, procure, and implement on its own.
- The PHCP can support the brokering of clinical care Business Associate Agreement authorities and other legal agreements.
- The PHCP could provide value to health care providers by ensuring they comply with mandated public health reporting regulations and by helping to communicate information on reportable conditions from public health to clinical care.

DRAFT