U.S. Department of Health and Human Services (HHS)
The Office of the National Coordinator for Health Information Technology (ONC)

eConsent Trial Project

Architectural Analysis & Technical Standards

Produced for the U.S. Department of Health and Human Services by:
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Version: March 2013

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Acronym Index

Acronym	Definition
EA	Enterprise Architecture
ebXML	e-business eXtensible Markup Language
GUI	Graphical User Interface
HHS	U.S. Department of Health and Human Services
HIE	Health Information Exchange
HIPAA	Health Insurance Portability and Accountability Act of 1996
HL7	Health Level Seven International
HTML	HyperText Markup Language
HTTP	HyperText Transfer Protocol
ID	Identification
IHE	Integrating the Healthcare Enterprise
MPI	Master Patient Index
NwHIN	Nationwide Health Information Network
ONC	Office of the National Coordinator for Health Information Technology
PDQ	Patient Demographics Query
PHI	Protected Health Information
PIN	Patient Identification Number
PIX	Patient Identifier Cross-Referencing
S&I	Standards and Interoperability
SOAP	Simple Object Access Protocol
SQL	Structured Query Language
WNY	Western New York
XDS.b	Cross Enterprise Document Sharing
XML	eXtensible Markup Language

1.0 Introduction

In accordance with Contract HHSP23320110023WC, this Architectural Analysis Work Product serves as a summary of the technology behind the design and implementation of the eConsent pilot program conducted in Western New York (WNY) October 22, 2012 through November 16, 2012. It summarizes the integration of computer software and hardware that provides the core content and other materials used for educating patients on making a meaningful decision as to whether to allow health care providers to share their medical information with other health care providers as part of a Health Information Exchange (HIE). This document discusses the technology behind the eConsent project as it pertains to an installation on a web server only. It is submitted by the APP Design Team for the U.S. Department of Health and Human Services (HHS) Office of the National Coordinator for Health Information Technology (ONC) eConsent project.

For the open source application software used to author program content, APP Design Team developers decided an enhancement of their existing product, named Story Engine, would fit the requirements for content generation and delivery. The APP Design Team had previously developed Story Engine to deliver personal health record information and gather patient information for topics such as smoking cessation and weight loss.

Story Engine consists of two parts: Story Builder, the authoring tool, and Story Presenter, the viewing interface. As part of this project, the developers revised Story Engine up to current technology standards and enhanced the story statistics gathering capabilities of the application. Detailed information relating to use of the application can be found in the Task 9 "Graphical User Interface (GUI) Design and Authoring Guide" and the Task 10 "Code Set and Installation Guide for eConsent Story Engine (Story Builder and Story Presenter)." The APP Design Team encourages readers to review these documents before deciding to use any products described within these pages.

To electronically capture, submit, and update patient consent, the APP Design Team also leveraged an existing tool for the project. The tool, RHIOnet, is an administrative companion to HIE clinical software. The APP Design Team knew that using the proven RHIOnet would save time and expense, as the software currently delivers more than six million health care transactions per month to more than 35,000 registered users. RHIOnet is based on health care standards such as the Health Insurance Portability and Accountability Act (HIPAA), X12 (a sequential designator assigned by the American National Standards Institute), Health Level Seven International (HL7) version 2/3, eXtensible Markup Language (XML), and Cross Enterprise Document Sharing (XDS.b). Having these standards pre-built and "baked in" simplified development for this project. RHIOnet technology is part of HEALTHeLINK, an HIE with whom APP Design partnered for this pilot program.

The authors have drafted this analysis into two distinct parts. Section 2.0 Open Source Solution discusses the technology behind the open source tool (Story Engine) that will be delivered to ONC for public availability. This section purposely discusses the tool in somewhat generic terms in order to appeal to the widest range of potential facilities looking to utilize the tool for their needs. Interested parties should review the previously mentioned task guides in order to drill down into more specific details on the tool.

Section 3.0 eConsent Technology Overview summarizes the technologies as they apply to the eConsent project itself. Discussions in Section 3.0 involve technology components used in the project which are necessary to the project but are exclusive of the open source authoring tool.

2.0 Open Source Solution

Based on project requirements, the technical design included ONC-mandated components covering script/authoring interface, GUI and design, and machine-readable text. Story Engine has been architected to allow multiple stories to re-use the same content with no need to modify the content itself to accommodate changes in story flows.

2.1 Script/Authoring Tool (Story Builder)

The APP Design Team's approach was to build a tool that allows non-technical authors to build content consisting of audio, video, HyperText Markup Language (HTML), and control logic into a presentation about patient choice. This web-based tool allows authors to upload audio, video, and image content and compose presentation pages using that content. Authors will be able to link pages together to build a "story." At each page in the story, the author has the ability to add decision points. At these decision points, the author has the ability to choose the next content page to be displayed.

2.2 Graphical User Interface (GUI) (Story Presenter)

The GUI tool is intuitive and supports interactive education regarding patients' eConsent choices. This tool, Story Presenter, reads the story script generated by Story Builder and moves along the story path created by the author, displaying the content as a complete presentation.

Story Presenter is compatible with all current major web browsers. Patients should find screen navigation easy; all on-screen instructions are given in plain English text, and graphics are designed to look familiar to the user wherever possible.

2.3 Machine-Readable Text

The developed content incorporates formatting to flow in a logical manner, making the program intuitive. By using ONC's Standards and Interoperability (S&I) framework in collaboration with design concepts, the APP Design Team developed a common way of describing patient choice that is both a machine-readable and flexible language for consent education.

The programming language and application server for Story Engine is the open source Ruby on Rails version 3.2 XML, a type of markup language which defines a set of rules for encoding documents in a format that is both human-readable and machine-readable. Ruby on Rails is used on this project to export and import stories. Stories are usually stored in files in XML format. However, because the eConsent pilot involves other technology besides Story Engine, a relational database (Structured Query Language or "SQL") was used to provide better consent repository access.

This technical design offered a number of advantages:

- Well-designed interfaces for vital application services
- Simplified implementation by encouraging the reuse of application components and by making many operational requirements configuration policies instead of programming issues
- Simplified network and application scalability by providing a distributed architecture
- Simplified planning by making development and deployment more predictable
- Simplified process of bringing mission-critical enterprise applications to the Internet by utilizing open standards and integrating them into web software

The system architecture was created with the pilot workflow in mind to maximize results while still maintaining expandability.

3.0 eConsent Technology Overview

The following diagram depicts the data flow within the eConsent Pilot.

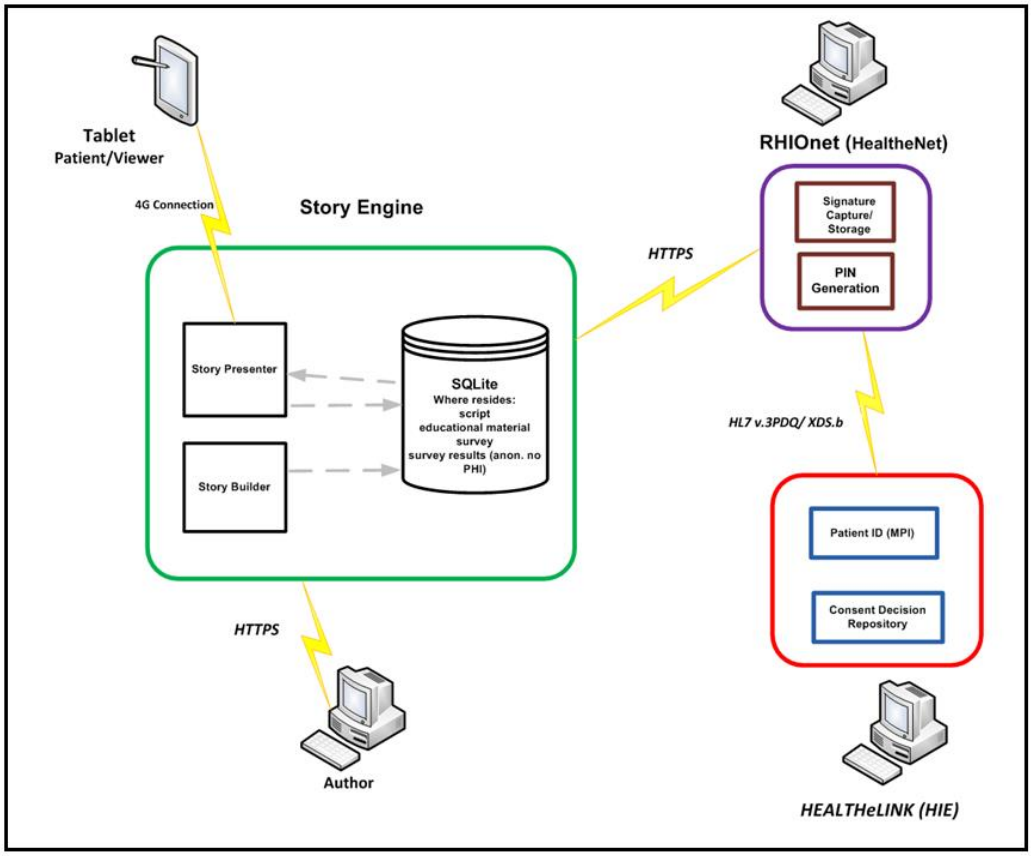

Figure 1: eConsent Architecture Showing Data Flow[1]

[1] HTTP = HyperText Transfer Protocol; PHI = Protected Health Information; ID = Identification; MPI = Master Patient Index; PDQ = Patient Demographics Query; XDS.b = Cross Enterprise Document Sharing.

3.1 eConsent Dataflow Description

The colors within the figure above denote the following:

- **Green** – represents the eConsent Story Engine, the open-source tool developed for the eConsent project. This box is representative of the product that will be available to the public from ONC.
- **Purple** – represents the RHIOnet tool used to retrieve patient demographic and consent data from the HEALTHeLINK HIE.
- **Brown** – represents the place with the actual signature is stored. Note: the signature is stored separately from the decision.
- **Blue** – symbolizes patient consent and demographic information. This information will be retrieved from the HEALTHeLINK HIE via HL7 Patient Demographics Query (PDQ) and saved in RHIOnet. This patient information will be associated with an anonymous identification (ID) used during the pilot program to further safeguard PHI.
- **Red** – represents the HEALTHeLINK, HIE. The HIE is where the master patient index (MPI) and the consent decision repository are stored. RHIOnet and HEALTHeLINK are existing HIE technology leveraged for the eConsent project and are not included as part of the open-source deliverable.
- **Yellow** – represents encrypted internet communications (HTTPS[2]). See also Section 8.3.1
- **Grey** – represents internal communications.

3.2 Workflow

Four clinical sites in the WNY region agreed to host the pilot program. All four pilot sites selected are in the HEALTHeLINK HIE of WNY. At these sites, patients used handheld tablets to view the pilot, which consisted of 1) educational material related to sharing their health information, 2) a consent decision interface (giving patients the opportunity to make or edit their decision concerning whether to share their health information electronically), and 3) a short, anonymous survey asking patients to evaluate their experiences with the presentation. Tablet connectivity operated on a regional telecommunications service so the pilot would not impact pilot site networks.

The architectural design, explained in the following sections, was flexible enough to accommodate changes in the workflow as needed.

3.3 Technical Design

The technical features of the eConsent project design are described as follows:

1. **Architecture** – The overall system comprises three separate systems. *HEALTHeLINK* contains the patient demographics and consent status. *RHIOnet* is the communications channel between HEALTHeLINK and the Story Engine, holding the patient demographics and consent status and generating the anonymous session PIN so no patient identifiable information is stored on the tablets. The *Story Engine* will be a standard

[2] HTTPS = Hypertext Transfer Protocol Secure.

client server/web server model with Story Engine running on a server computer and sending HTML presentation data over standard Hypertext Transfer Protocols (HTTP/HTTPS) similar to most other web-based systems.

2. **Development Language/Application Server** – The development language/application server for Story Engine will be Ruby on Rails. This language/application server was chosen for its ability to quickly develop easy-to-use user interfaces, which makes it ideal for the Story Builder user interface. The existing RHIOnet server is implemented in Java. RHIOnet communicates to HEALTHeLINK using Nationwide Health Information Network (NwHIN) standard transactions.
3. **Platform** – Ruby on Rails runs on most hardware/operating system platforms, including the Linus variants, Windows, and Macintosh OS X.
4. **Database** – Story Engine will use an open source SQLite database to hold content, story pages, and audit statistics.
5. **Scalability** – The architecture is highly scalable as multiple servers can be used together to manage heavy user loads. Scalability can be achieved by load-balancing multiple servers.

The eConsent Story Engine integrates the following components:

- **Story Builder** – supports authoring question script, answers, alternatives and control logic about patient choice.
- **Story Presenter** – provides the viewing interface patients will use for presentations created in Story Builder. It also provides auxiliary services such as statistics generation and auditing capability for both Story Builder and Story Presenter.
- **Internal SQLite Database Server** – serves as the home for pilot content, educational material, survey material, and survey results.

4.0 Technical Standards

The APP Design Development Team uses industry best practice standards to maintain a secure and reliable environment for submission of electronic data. Those standards consist of HL7 v3 PDQ for patient consent retrieval, Cross Enterprise Document Sharing (XDS.b) for consent decision updates, and XML for educational content. All are used extensively in health care information exchange.

4.1 HL7 v3 PDQ

HL7 v3 PDQ allows formatting messages in XML. In this new version, the scope of Patient Identifier Feed, Patient Identifier Cross-Referencing (PIX) Query, PIX Update Notification, and PDQ is identical to HL7 v2.5. HL7 provides consistency between all artifacts and enables a standardized approach to Enterprise Architecture (EA) development and implementation as well as a way to measure the consistency. Version 3 provides more details for implementers of individual health transactions. HL7 v3 PDQ provides cross-referencing capability of patient identifiers from multiple patient identifier domain sources. These identifiers are used by health care systems to correlate information about a single patient from multiple sources that recognize a patient from other identifiers. PDQ functionality enables a system to perform consent queries.

4.2 XDS.b

XDS.b includes both repository and registry services. XDS.b is considered a health industry standard profile fashioned by Integrating the Healthcare Enterprise (IHE) to make possible the sharing of documentation between all health care organizations (enterprises) or support services. XDS.b re-uses the OASIS web service standard e-business XML (ebXML) document registry technology in providing a method for indexing and storing searchable meta-data (e.g., document types, sizes, creation dates, service dates) at a central location.

4.3 XML

XML is a markup language that defines a set of rules for encoding documents in a format that is both human-readable and machine-readable. It is defined in the XML 1.0 Specification, produced by the World Wide Web Consortium standards committee, and several other related specifications, all open standards.

The design goals of XML emphasize simplicity, generality, and usability over the Internet. It is a textual data format with strong support via Unicode for the languages of the world. Although the design of XML focuses on documents, it is widely used for the representation of arbitrary data structures, for example in web services.

4.4 Description of eConsent Components

The eConsent architecture consists of the following components:

1. **Story Builder** – tool for authors to create, define, and organize the educational content. This code is written in the Ruby open source language. It will be implemented as a Ruby on Rails web application that records the story designer's decisions in a SQLite database. Stories can be exported in an XML format. This XML can be imported to another Story Engine so the story can be run anywhere the Story Engine is available.
2. **Story Presenter** – a web servlet configured to play the story designed by the Story Builder. As the patient proceeds through the interactive story, all button presses, choices, and the chosen paths are recorded in the database for statistics compilation. Together, Story Builder and Story Presenter make up the Story Engine application. Enclosed by a green border in Figure 1, the Story Builder and Story Presenter represent those technical applications being developed for ONC under the eConsent project.
3. **SQLite** – database that stores content and scripts created by the author and displayed to patients.
4. **HEALTHeLINK** – the existing HIE system, used as the source of patient demographics and eConsent status. The application has published Simple Object Access Protocol (SOAP) interfaces that will be used for querying patient information and recording their consent decisions.
5. **RHIOnet** – an existing web application that retrieves the patient's demographics and consent status from HEALTHeLINK and creates an anonymous PIN for Story Engine.

5.0 Conclusion

This document addresses the technology the APP Design Team used for designing and building the eConsent pilot. This document provided an overview of the technology requirements for this

project and the APP Design Team's conformity and use of those requirements in pursuit of project goals. Some of the information discussed in this document covers technology that is relevant only to the eConsent project and would not apply to other facilities wishing to download Story Engine for their use. An example of technology not included with the tool is a method to capture or store a consent decision. Other facilities, whether a hospital, physician's office, or other health care facility, would need to research their location's requirements to determine what they need in order to capture and store patient consent data.

This internal work product is not intended to provide answers to those issues surrounding the key question of this project: "What information do I need to make an informed decision on sharing my medical information digitally?" Nor should this work product be considered a user guide or operational manual for the pilot. What this work product provides is a schematic of technology used during the eConsent project in WNY; the project's goal is to explore and evaluate ways of 1) presenting people with educational material, 2) obtaining and recording meaningful and informed choice from these people regarding the electronic sharing of their health information, and 3) evaluating their experience with the presentation.