The Integration of Home Collected Data into the Veterans Administration Health System

The Home Telehealth VistA Integration Project: The Validation of New Components

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***Abstract*—In 2004, the US Department of Veterans Affairs (VA) was confronted with the creation of an enterprise application based upon multiple triage systems supplied by vendors who had dramatically different levels of experience with system integration or with the Health Level 7 International Standard (HL7). One objective of the Home Telehealth application was to leverage the capabilities of the existing VA Electronic Medical Record (EMR) system and medical software wherever possible. To accomplish this objective, a strong integration approach was required. The selected approach was the development of a reference engine that could be used to validate the communication between existing VA medical applications and the newly procured triage systems. This paper describes the validation approach used to evaluate a procured system's readiness to operate in the collaborative environment of VA's enterprise medical record system of over 200 distinct independent systems. The paper represents the opinion of the authors and is not a statement of any official position of the VA.**

Keywords-telehealth; home telehealth; telemental health; HL7; CCOW; protocol validation; realtime HL7 transactions; collaborative processing; system validation.

I. Introduction

The introduction of new components into an existing mature distributed environment is a complex problem. The objective is that the new component performs its task reliably and without adverse impact on the distributed environment. To achieve this result there must be a thorough system validation prior to placing the system in production. It is generally acknowledged that key to a well-behaving system is adherence to a System Development Life Cycle (SDLC) model; that the creation of a well-formed requirements document set, a well-formed testing plan, and the development of a testing laboratory. The requirements document must be complete and accurate; however, all documentation is stale the minute it is published. The documentation can be validated by a test the existing systems; this validation is beyond the subject of this paper. The validation plan for the new components should cover all the transactions with cases that include normal expected valid messages and exceptional conditions, such as those that create retransmissions and those that indicate an error. The testing must include the building and processing of messages, the movement of message, and the building and processing of transactions; that is, the testing sequences must cover both normal sequences (error free) and exceptional sequences (error indications). With the testing of both valid processing sequences and the handling of exceptional conditions, there is a confidence that the existing environment will not be impacted by the introduction of a new or updated component. This paper addresses the validation testing of an addition of a new telehealth component to an existing mature distributed medical distributed system. The validation of the new system's compliance with security requirements is a separate subject.

Section II of this paper introduces the major systems involved in the home care and the interaction between the systems. Section III describes the process used to validate that a procured system is ready to support patient care. Section IV discusses the acceptance testing challenges for the procured system. Section V lists the major documents used to support the integration. Section VI introduces the primary validation tool set. Section VII discusses the lessons learned and future tasks.

II. Home Based Care

A. Background

The United States Department of Veterans Affairs (VA) [1] Home Telehealth program is clinically managed by the Office of Telehealth Services (OTS) [2]. The program is supported by the VA's Office of Information & Technology (OIT) [3] Home Telehealth Program Management Office. The program uses a telemedicine approach for the care of patients with a chronic illness such as diabetes, congestive heart failure or chronic obstructive pulmonary disease. Care is also provided for patients suffering from post-traumatic stress disorder. A patient's current medical condition is collected using Interactive Voice Response (IVR) scripts, a specialized home device, and/or an intelligent mobile device. The collected information is sent to a triage system in a VA data center. The triage system analyzes the submissions from each patient and creates a prioritized list for the care nurses; that is, the triage system orders the nurse's medical care. The nurse uses the clinical desktop (Graphical User Interface/GUI) to monitor the patient condition and direct patient care for a panel of over one hundred patients.

B. VA Health Care

The Veterans Health Administration (VHA) is America's largest integrated health care system, providing care at 1,243 health care facilities, including 170 medical centers and 1,063 outpatient sites of care of varying complexity serving 9 million enrolled Veterans each year. VHA has an integrated health system based upon a distributed Electronic Medical Record (EMR) system that allows clinical personnel to access all patient data that has been collected at any VHA medical facility in the US and abroad. Each of the medical centers hosts an instance of the medical record system. The core component of the health system is the Veterans Health Information Systems and Technology Architecture (VistA) [4]; the clinical desktop for a VistA system is Computerized Patient Record System (CPRS). A patient's data can be presented as an aggregation independent of the original visit location. The VHA's approach to patient care is based upon the ability to access a patient's complete medical record from any VHA location.

C. The Home Telehealth Triage System

The core component for the care of a patient in the home is a triage system supplied as a Commercial off the Shelf (COTS) system with the required modifications to meet the interface to VHA systems. The COTS portion addresses the telemedicine componentry:

1. the devices used by the patient to collect their current medical state,
2. the system that performs the triage function to rank the patient needs, and
3. the transmission components that transfer the collected data to the triage system.

The development of the interface to the existing VHA systems is a task for the supplier; it would be very uncommon for a supplier's system to support HL7.

The VA supplies the necessary documentation defining the HL7 encoding specifics and all the transactions used to allow the integration of the supplied triage system with the VistA environment. All communication with VA systems is based upon HL7 messaging as defined in the HL7 2.4 standard with the specific definition of each HL7 message field as would be required for any usage of a standard.

The distributed environment is an autonomous environment where systems perform an automatic recovery from exceptional conditions. This expectation is a normal requirement for systems have an associated urgency, such as a medical care system. The movement of each message includes confirmation of receipt within an appropriate period; if the receipt confirmation is not received, the message is retransmitted automatically. A transaction is normally moved in a single message; however, some transactions require multiple messages. The processing of a transaction generates a completion status message; that is, the transaction was, or was not, processed successfully. Once again, if the completion message is not received within an appropriate period, the transaction will be retransmitted. The consequence of these processing rules is that the overall system can operate autonomously with no manual intervention; manual intervention has a tendency to introduce undesired delay and unexpected problems. A consequence of autonomous operation is that a violation may create havoc. A misdirected message may cause indefinite retransmissions or an output queue stall; for example, a misdirected receipt confirmation would confuse the receiving system while causing the proper system to not empty its output queue causing a stall. A system that does not retransmit a message due to a missing receipt confirmation will also experience an output queue stall.

D. VistA Integration

The telehealth component of the program is based upon a strong binding between the triage system and the devices used by the patient; that is, the triage system provider supplies the devices used by the patient and the analysis engine (the triage system itself). VHA procures new triage systems periodically so that the latest technology is available. With each new award the program is confronted with the integration of multiple triage systems developed by suppliers with a varied amount of integration experience or HL7 experience. Each triage system supplier also wishes to keep abreast of technology and clinical desires by providing new capabilities. Depending upon the complexity of an upgrade, a new system validation may be required for such technology upgrades. The clinical team may require a new set of data be sent from a triage system to the VHA EMR; that is, the clinical team may require a change in the VHA EMR environment interface. The upgrade would also require a new validation of the triage system along with an update of the documentation.

The objective of the triage system integration with the VHA EMR is to leverage the capabilities of the existing VHA EMR and medical software wherever possible. The care providers (doctors and other clinicians) should not be required to access the clinical desktop of the triage system.

The objective of the Home Telehealth VistA Integration project is the integration of the Home Telehealth triage systems into the VHA distributed processing environment. This is a real time sharing of data between an individual triage system and the VHA EMR systems. This integration approach starts with the establishment of a patient record in the triage system using VHA identifiers and the synchronization of the patient identity using the VHA identity management system. With a consistent identity, the triage system can send patient data collected at the home to VHA systems in a computable form so that the data can be used in standard VHA patient care analysis packages. The triage system presents the collected information to VHA systems such that the information has the look and feel of data collected by any other VHA medical facility. The data is then available to all VHA medical personnel and all the VHA medical outcomes analysis processing engines without requiring access to the triage system itself. The end result of the integration requirement is the home care component of the patient's medical program is not an isolated data island, but is a system integrated into the VHA's approach to patient care.

III. VALIDATION STRATEGY

The fundamental elements of the SDLC approach is based upon

1. the development of a document [7] that defines all the transactions used by the Home Telehealth program,
2. a reference engine that implements all the transactions and processing rules defined by the document, and
3. a validation test plan.

The document supplements the HL7 and CCOW standards with the specific VHA encoding definitions and processing rules.

The reference engine emulates a triage system to existing VHA systems to validate the transactions and encoding definitions. The reference engine also emulates VHA systems to a triage system to validate the conformance and operation of the triage system's HL7 engine and transaction processing. This use of a single reference engine presents a reliable base for the evaluation of the triage system integration into the mature VHA distributed processing environment.

The triage system validation is performed in three phases. The first two phases are directed by a set of functional validation objectives in two different testing laboratories. The third phase is a slow start deployment of patient care to minimize risk. The focus of this document is the first phase of the validation.

The first phase is performed in an External Integration Test Laboratory (EITL). The EITL contains a full emulated environment of the VHA systems and software that would peer with a triage system. The EITL is accessible via the Internet allowing the System Under Test (SUT) to be in its own laboratory. The experience gained since the program's inception in 2005 is that successful real time processing (autonomous processing) of transactions requires reliable, predictable and consistent performance of the HL7 engine and transaction processor in the triage system. These required characteristics are achieved by the proper handling of exceptional conditions that occur during transmission and other events that occur during normal system operation. The objective of the EITL laboratory testing is to verify that an SUT is capable of the real time processing requirements required for VistA Integration in the presence of anomalous conditions.

The second phase is performed in the VHA Integration Test Laboratory (ITL). The ITL contains a full environment of the VHA systems and software that would peer with a triage system in production. In the ITL, an SUT is evaluated while supporting test patients. VHA clinicians evaluate the SUT clinical desktop; VHA IT staff evaluates system logs for proper system performance. Anomalous conditions are not generated in the ITL unless there is a defective application.

The third phase is a limited national release (controlled release) of a production version using a slow start approach. The production system is first brought into use at a single VHA facility for Home Telehealth patient care for a five-week evaluation period. A second and the third facility are added to the environment at weeks three and four as the testing progresses. The operation is evaluated at the end of each week. At the end of evaluation period, national use is authorized for all 170+ VHA major medical facilities and their subsidiary treatment centers

IV. ACCEPTANCE TESTING CHALLENGES

A. *Program Start Up Consequences*

The program started in 2004 as a set of pilot programs ended and the national program started. The program approach was based upon the procurement of a set of triage systems from suppliers experienced in providing remote home health care, but little experience with HL7; thus, the initial stand up did not include VistA Integration. Patient identity and demographics information was manually entered into the triage systems. The impact of the manual entry of the patient identity was keystroke errors and the copying of the wrong information from other system displays. Unreliable data entry creates a problem when a clinician wishes to correlate data in the triage system with data in the VHA EMR. Our research found that the error rate for manually entered patient information was 7%. The end result of the manual entry of patient identity in the triage system was the duplication of patient records and orphaned patient records in the triage system. The impact of the errors has haunted the program since its inception; the identification of orphan records is a difficult task.

B. *Acceptance Testing Approach*

It is well recognized that acceptance testing is required for a distributed processing environment. This testing is generally a duplication of the Software Quality Assurance (SQA) testing of software in the second phase of the SDLC model. VHA has a testing lab that mimics the operational (production) environment. It includes

1. multiple medical record systems instances (VistA),
2. an identity management system (Master Patient Index/MPI or Master Veteran Index/MVI),
3. a medical database system (Health Data Repository/HDR),
4. a patient census and survey repository system (Census and Survey/CNS),
5. a patient database, and
6. other various systems.

The focus of this lab (Integration Test Lab/ITL) is the SQA testing of VHA applications and the validation testing of procured systems. There is no capability to generate abnormal conditions since the ITL is a replication of the operational environment ("real world"). No system in the operational world intentionally generates exceptional conditions; no system creates conditions that require a recovery from an exceptional condition. It is this property that prevents an environment, such as the ITL the deep inspection for the validation of a new system and some system upgrades. Due to these limitations, the Home Telehealth program decided to create the EITL which is designed to generate anomalous conditions during a test.

C. VistA Integration Challenges

VistA Integration uses messages defined by Health Messaging Level 7 International Standard [5] (HL7) to communicate with VHA medical systems and HL7 Clinical Context Object Workgroup [6] (CCOW) defined application context control to integrate the triage system clinical desktop with the standard VHA desktop applications. VHA has an extremely mature HL7 environment. The first challenge of the integration is the verification that a triage system has an HL7 engine implementation that would allow the integration. The emulator was developed to perform the verification. The second challenge is the implementation of a CCOW environment for the triage system clinical desktop. The solution of these two challenges allowed the program to start the piloting of VistA Integration.

D. Data Collection Challenges

The triage system receives data from multiple sources within the home. The use of this data requires that the triage system maintains an appropriate data quality inspection identifying a questionable submission. The triage computation is based on an accurate collection from the home. The data sent by the triage system to the VA databases must be an accurate representation of the patient state. The triage systems are time synchronized with the VHA systems and all end devices are synchronized with time servers either directly or via the triage system. However, some of the devices can be used in a disconnected mode with internal power and a manual configuration. The user might have to initialize the end device. The disconnected operation of end devices allows for the device to lose time synchronization with the triage system. The device itself might fail and present an incorrect reading. The patient might make a transcription error when the reading the value for a manual entry. Entries with an error are sent to VA databases with an indication of "entered in error"; thus, the entry will be tracked, but not used.

E. Autonomous Processing Challenges

The system concept is that the triage systems operate autonomously. The guiding tenet for any system must be based upon Jon Postel's guidance "an implementation must be conservative in its sending behavior, and liberal in its receiving behavior." Every system must focus on the generation of correct and accurate messages; however, a system must be prepared for the messages received from the real world. The real world is imperfect and capable of corrupting transmissions in an unpredictable manner.

F. Validation Testing Approach

The Home Telehealth program is providing daily care to patients that are not in a medical facility. The objective of the program is to improve the medical condition of the patient or provide the necessary medical care that will address the patient's current condition. It is most important that the readings are presented in a timely manner along with the triage analysis is available promptly. The system must be able to deal with an exceptional condition, such as a communication error, a message with questionable data, or processing that is delayed. All the exceptional conditions mentioned above have led the program to adopt a more exhaustive approach to the acceptance criteria of a triage system.

V. DOCUMENTATION

The guiding document for the integration of a procured triage system with the VHA EMR is the *Home Telehealth HL7 Functions Overview* [7]. The *Home Telehealth VistA Integration Test Plan* defines the individual tests. All documentation is available upon request.

VI. REFERENCE ENGINE

The development of the reference engine started in late 2004 when research indicated that there was no publicly available software package that would validate the processing of the transactions used to integrate an external system with the VHA processing environment. The testing tool must provide for the ability to tailor each HL7 message field for a thorough inspection of the message processing.

VistA Integration forces the triage system to slave patient identity to the MPI and not allow changes from any other source including the triage system clinical desktop. There is the requirement to validate that the SUT will properly process an update of each component of an HL7 identity. The difficulty of the construction of the required tests to perform this task has the natural consequence of ignoring the test. The reference engine was developed to perform such a task.

TABLE 1. HOME TELEHEALTH TRANSACTIONS

HL7	Source	Peer	Function
ADT-A04	VistA	Triage	Create a new patient record and/or activate patient care
ADT-A03	VistA	Triage	Inactivate patient care
QBP-Q22	Triage	MPI	Register with the MPI
ADT-A24 **ADT-A31** **ADT-A43**	MPI	Triage	Patient record update
MDM-T02	Triage	VistA	Progress Note
MDM-T02	Triage	Survey	Patient Survey Response
MDM-T02	Triage	Census	Triage System Census
ORU-R01	Triage	HDR	Patient Vitals Submission

The reference engine (commonly call the emulator) includes the ability to perform as either a single triage system (triage system emulator) or a set of systems that exist the distributed medical system (VistA, MPI, HDR, Census and Survey systems emulator). This approach guarantees that the reference engine is a system using the same operational rules for the communication with every system that exists in the distributed processing environment while allowing it to perform inspections of diverse components of the environment.

The transaction set used in the Home Telehealth program are listed in Table 1. The **HL7** column lists the HL7 message used for the transaction. The **Function** column describes the purpose of the transaction. The **Source** column indicates which system of the distributed processing environment would generate the transaction. A triage system emulator would be used to validate the processing rules described in the program documentation or participate in the testing of a new application or capability; Section VI.A describes the operation and objectives of a triage system emulator. A medical system emulator would be used to validate the processing by a triage system or generation of transactions by the triage system; Section VI.B describes the processing and objectives of a medical system emulator.

A. Triage System Emulation

The triage system emulator was used to validate that the *Home Telehealth HL7 Functions Overview* did indeed reflect the operation rules for the VHA systems. The development was started in late 2004 and the initial validation of the program documentation was completed in early 2005. The capability of the reference engine to generate any transaction with all appropriate HL7 message movement proved to be extremely useful and supplied a unique tool for development teams. This capability was first used in the spring of 2005 to aid the development of the VistA component that receives patient progress notes from external systems.

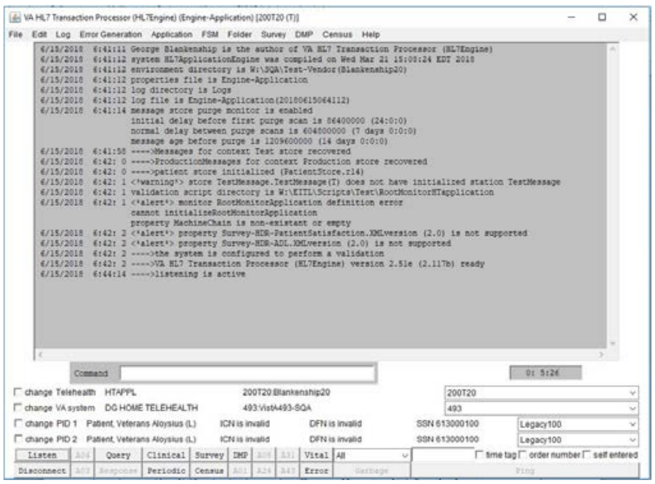

Figure 1: Reference Engine GUI (Triage System Application)

Figure 1 shows the GUI (desktop) for the triage system emulator. The figure shows the current GUI as of 2018; there have been many revisions since the emulator was used in 2005. At the bottom are six rows of widgets used to select configuration items and transactions to be generated. The triage system facility number is shown in the first row. The second row identifies the peer system to receive a transaction generated by the emulator. The third and fourth rows identify the patient or patients that are in a transaction. The bottom two rows are used to select an asynchronous transaction to be sent to the peer system (see Table 1). The GUI is common for both emulation modes and buttons that are not applicable in the current mode are disabled. A button from the bottom two lines is used to select the HL7 message to be sent. Some exception conditions can be injected by use of the **Error Generation** menu item at the top of the GUI.

The triage system emulator processes all transactions autonomously as would a real triage system. The following paragraph describes the processing of a patient activation by a triage system.

The ADT-A04 transaction establishes a new patient to be serviced or activates an existing patient for service. The transaction is sent by a VistA system to a triage system. The triage system must register with the MPI. A successful registration would allow the activation to be successfully completed by the triage system. The processing rules include the following three items.

1. The processing of the transaction must not cause a data conflict in the triage system database.
2. The MPI can identify the patient; that is, the registration is successful.
3. All components of the patient identity are consistent with the MPI.

This transaction is used as an example due to its complexity and the global impact of a violation. If the rules are not followed, multiple peer applications will not be able to process transactions from the triage system. There are three unique identifiers used in the VHA medical record: a VA national identifier, a US government national identifier, and a medical center identifier. Every medical record must contain the same set of identifiers for patient identification. The Home Telehealth program uses the VA national identifier for patient identification. It sends transactions to other applications that use one of the other two identifiers. With the successful processing of the activation message, the triage emulator will be able to process received transactions.

B. Medical Record System Emulation

The original objective that started the development of the reference engine was the necessity to validate that a procured triage system did, indeed, meet the requirements. From the beginning it was obvious that the only approach was a "black box" approach; that is, it would not be possible to instrument the SUT. The validation engine started out in 2005 with the generation of correct data in all transactions sent to the SUT and the ability to force retransmissions.

The 2005, a validation required that each test was controlled using the widgets. The validation started in May of 2005. The National Rollout of the first validated triage system started in August of 2005. During the first three years of the program rollout, conditions were encountered that led to the consideration the development of an automated test generation and scoring component; time and resources always postponed the work. Most of the conditions are discussed in the earlier sections of this paper. For a system to be reliably capable of error recovery, a test tool must exist that can create the exceptional conditions on command. Every few years new triage systems were procured. With each procurement the test coverage was expanded. With the improvements and correction were made over the years, the validation was strengthened. There was one glaring problem; the testing was a manual effort. Each test was built through the GUI. The scoring of the test generally required a manual examination of the system log file. The process was very tedious. At the same time, while the improvements did uncover latent problems, the most vexing problems remained as troublesome issues in production. The problems were of a very low occurrence in the production world and did not apparently cause patient care issues; thus, the problems remained a discussion items in weekly conferences and buried by larger issues. The problems seemed to indicate that the autonomous processing was flawed in selected systems. A possible explanation over the years was improper recovery or improper processing sequences.

For a system to be reliably autonomous, a test tool must exist that can generate the conditions that force a system to choose a transaction sequence order; the sequence should comply with the Atomicity, Consistency, Isolation, and Durability (ACID) database principles. The use of more extensive testing required a major enhancement to the emulator. In 2014, a major enhancement to the validation component of engine was finely started. The enhancement was the addition of scripting component that would allow more complex tests to be generated with a minimal effort and the automatic scoring of tests results. Before the development of the scripting component, the validation was performed using 140 distinct tests. Each test had distinct sequence of manual operations performed by the test conductor on the emulator GUI. Due to time constraints, a successful validation required two to three months; if any issues were uncovered, the validation period increased. In late summer of 2014, the first usable component of the scripting was completed and used for an ongoing validation. The addition was based upon the use of a publish and subscribe component in the core of the emulator. This component was always intended to instrument a system based upon the core software but had not been used in the emulator. The addition of a component that subscribed to change in the processing state of the engine allowed for the monitoring of messaging flow; the scripts supply the expected state using a finite state machine approach and expected conditions. The result was the ability to generate a transaction sequence with scoring.

The enhanced emulator immediately detected that the current SUT had ACID violations. The SUT had been in service since 2005 and had just undergone a major revision requiring a re-validation. Over the years, it experienced some strange problems that defied resolution or reproduction. The system was finally identified a fatally flawed. The development of the scripting was completed in early 2015. The impact of using scripting was dramatic. The scripts for the almost 1,000 distinct tests were developed in a month. The tests are bundled into test sets. The test conductor starts a test set. The test set identifies the preconditions for the testing. After the preconditions are established, the tests run autonomously. As each test completes, an error conditions generates an email to the triage system administrator. Four new triage systems were validated in 2017 in a 6-month period.

VII. CONCLUSION

System validation in a distributed environment is a difficult and tedious task. System components are developed in isolation. The tools to build software components do not have the capability to reproduce the distributed environment; the testing focus is generally on the user interface (GUI) with a limited capability to simulate the communication with a remote system. Many test cases just cannot be covered; many test cases cannot be defined.

The development of the Home Telehealth emulator enabled the validation phase of the program SDLC to approach a realistic evaluation of the readiness of a system's capability to support patient care in the VA medical network. The major enhancement of the testing scripting in 2014/15 allowed the actual validation of proper processing in the presence of exceptional conditions. Unfortunately, the avoidance of the developing the necessary software is realistic; the Home Telehealth emulator is over 1,000,000 lines of Java code (over 450 Java classes).

The most dramatic impact on the validation was the release of the validation tool to the triage suppliers. Until the suppliers installed an instance of the testing tool in their lab, their testing was impacted by scheduling. Each supplier had to have a dedicated testing slot with publicly available validation engine in the EITL.

The observations derived from each validation of updated or new components are not unique to the medical world. All distributed processing environments would benefit from a concerted effort to develop or acquire the necessary tools to perform a comprehensive evaluation of additions before the addition is joined to the environment.

A new validation round is currently scheduled for the 2019/20 period with the acquisition of a new set of triage systems providing the latest technology. During the intervening period the validation test set will be enhanced to cover more problems that have vexed the program over the years. VHA is also planning to add the use of the HL7 standard Fast Healthcare Interoperability Resources (FHIR) to the EMR. This effort will start a new major update to the Home Telehealth emulator. The initial research for the emulator's support for FHIR should start in the summer of 2018.

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