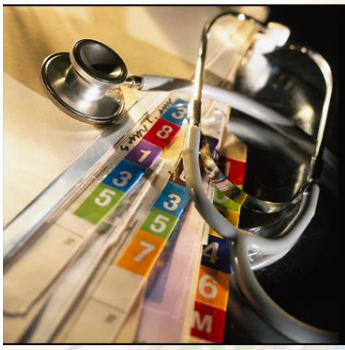

A Study of Electronic Health Record Data Interoperability in the U.S. based on the HL7 CDA and SOA Methods

Joshua Prowant

Purdue University Fort Wayne Campus
M.S. Technology, ITAC Track
Directed Project
May 2009

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Overview of Topics

- Introduction
- Project Overview
- Interoperability
- Technologies
- Project Development
- Discussion
- Future Work
- Conclusions
- Acknowledgements
- References

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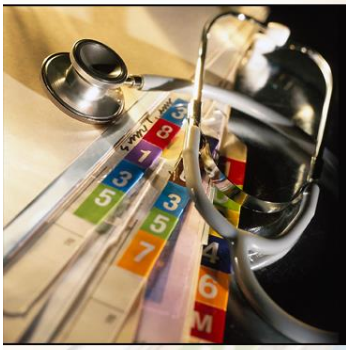

Introduction

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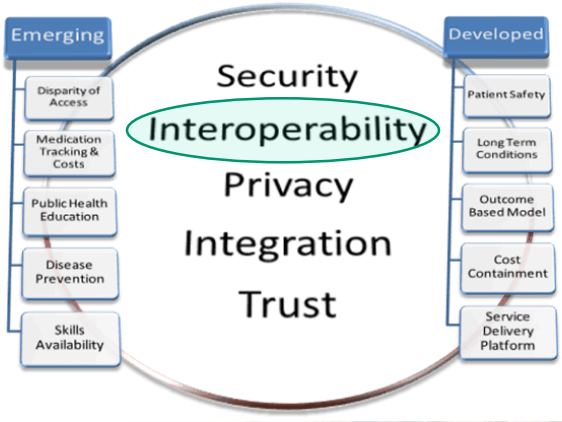
Healthcare Industry

Global Health Challenges



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Healthcare Industry

- Delivery of health-related services by doctors, nurses, hospitals, clinics, laboratories, pharmacies, and many other players
- Complex systems operating in mixed environment of public and private services
- Evolution around independent entities and business functions with no coordination
  - Clinical data stored in proprietary formats in a multitude of medical information systems on the market
  - Relational databases, structured-document-based storage in various formats, unstructured document storage, etc.
- **Design, implementation and operation of interoperable healthcare systems difficult and expensive**

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EHR Data Interoperability

- U.S. political and economic focus on nationwide Electronic Medical Records
  - EMRs owned by care delivery organization
  - EHRs subset of EMRs owned by patient
  - **Interoperable EHR → interoperable EMR**
- Significance (2007)
  - 44,000 to 98,000 deaths due to preventable medical errors each year
  - Medication errors cause 7,000 deaths each year
  - Medical errors cost $37.6 billion each year
- Implementation (2008)
  - 2758 physicians surveyed
  - 4% using fully functional EHR systems
  - 13% using basic systems

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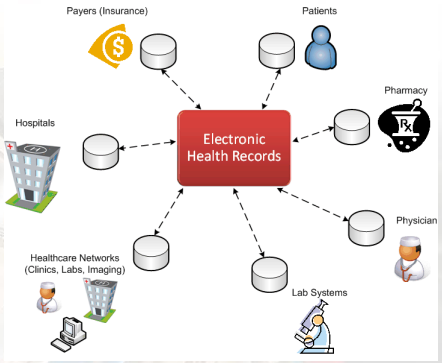
EHR Data Interoperability (cont.)

- EHR systems supporting interoperable data significant to needs of healthcare IT
  - Automated transfer between care sites
  - Built in support to reduce data entry errors
  - Enhanced productivity and quality of patient care
  - Reduced spending and preventable deaths
  - Significant stakeholder satisfaction



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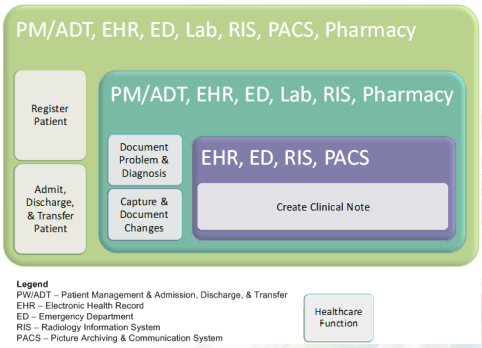
Service Oriented Architecture (SOA)

- Partial solution to EHR interoperability problem
- Platform independent architectural style of packaging business processes as functions loosely coupled within a middle layer based on Web Services, linking applications and data stores
- Eliminate redundancy and increase efficiency of data dissemination



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SOA in Healthcare

- Improved delivery and sharing of information across a community of care with manageable cost and deployment risk
- Possible healthcare services
  - Controlled medical vocabulary translation for data interoperability
  - Master-person index services, patient record locator services, insurance verification, referral management, etc.
- Problems
  - Lower adoption rates due to lack of coherent healthcare enterprise model and fragmented, uncoordinated system for providing and paying for healthcare
  - SOA and Web Services may efficiently deliver medical record summaries from multiple sources to a requesting provider's EHR system, but the EHR system may still be unable to parse the data or transform it into a format it can use
    - All source systems must use the same syntax
    - Common terminology mapping services complex, proprietary, not widely available for academic or public use, and beyond scope of this project

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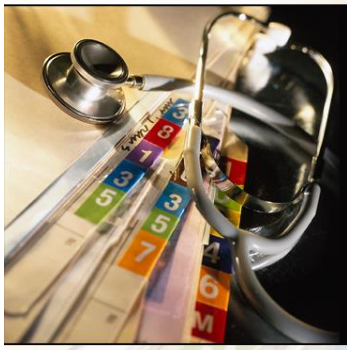

Project Overview

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Overview

- Problem
  - Data interoperability challenges of EHR systems in the U.S. healthcare industry
- Justification
  - Interoperable EHR systems offer stakeholders timely access to patient data, thereby improving patient care, safety, and quality, while simultaneously reducing preventable medical errors and costs
  - Alignment with previous academic focus and career goals
  - Help realize the goal of nationwide a EMR system
- Recommendation
  - HL7 (Health Level Seven) standard and CDA (Clinical Document Architecture) for standardizing EHR in terms of sharing and communicating clinical data and medical information
  - SOA development

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Deliverables

- Evaluation of interoperability healthcare concepts and widely accepted standards relevant to the EHR and recommendation of an appropriate standard to meet future data interoperability needs in the U.S.
- Evaluation of Microsoft technologies and reference implementations for SOA-based healthcare system approaches to providing interoperability
- Development of a patient-provider scenario using SOA methodologies
- Demonstration of a Microsoft-based example showcasing how functional and data interoperability can be provided utilizing the XML-based HL7 CDA standard for sharing and communicating clinical data and medical information
- A proof of concept describing how the provided Microsoft-based example can be expanded to utilize Web Services technology as a middle-tier between the application and data layers
- A discussion of system features and concerns such as security and return on investment (ROI)
- Opportunities for future work and expansions to the provided example based on Microsoft CHF reference implementations, namely the Health Connection Engine, IHE XDS.b, and the Health Common User Interface
- A discussion of learning outcomes, problems encountered, and conclusions relevant to the project

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Project Scope

- Assumptions
  - Applying concepts of SOA to EHRs is beneficial to healthcare providers and offers significant improvements over current systems
  - U.S. healthcare providers are willing to share health record data across institutions in realization of interoperable EHRs
- Delimitations
  - This project will focus on EHR implementation concerns in the United States only.
  - This project will rely on Microsoft platforms only, although the methods discussed may still apply to various software environments.
  - The project will focus on how to transmit EHR data via Web Services within and between the caregivers. The aspect of how caregivers gather and present healthcare information is beyond the scope of the project.
  - This project will focus on technological aspects of EHR system and not how its data is interpreted medically.
  - This project will focus on a subset of technologies and recommendations from the Microsoft CHF and not the CHF in its entirety.
  - This project will focus on a simple POC discussion and not on using complex enterprise solutions such as HCE, XDS.b or HCUI.

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Project Scope (cont.)

- Limitations
  - This project is limited by lack of prior experience in both the healthcare environment and in using related Microsoft technologies.
  - This project is not supported or financed by any healthcare provider.
  - Barriers to successful EHR adoption in the United States such as demographics, politics, and cultural perceptions may work against the goals of this project.
  - Because the actual EHR system is not in place, the project relies only on perceptions of technology acceptance, rather than actual usage behavior.
  - Any recommendations or results from this project are not indicative of behaviors or attitudes of doctors, nurses, hospitals, clinics, laboratories, pharmacies, and other players working in health systems with different types of EHR systems.

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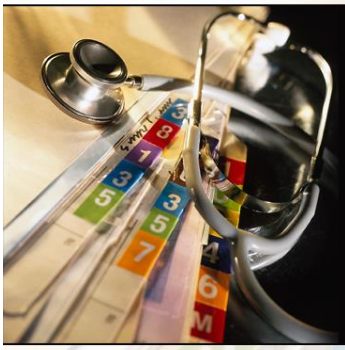

Interoperability

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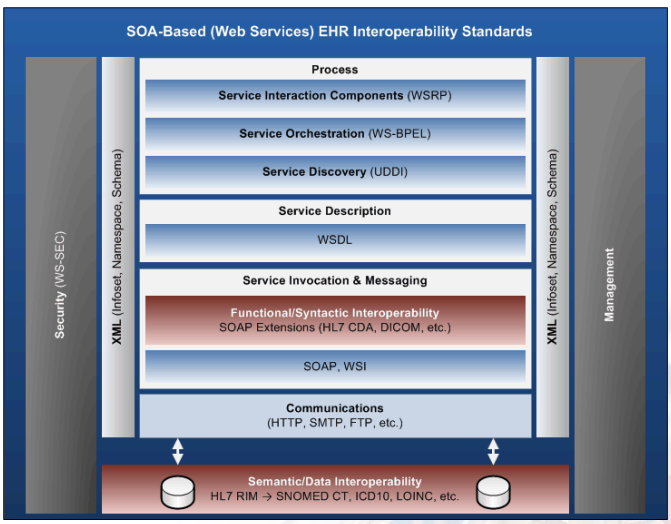
SOA Standards and Healthcare



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Interoperability Standards

- HL7 messages more prevalent today
  - Requires middleware application coupled with complex terminology and message mapping services
- IHE XDS reference implementation requires additional interfacing for data interoperability
- CDA documents for exchanging clinical information using modified commercial-off-the-shelf examples

Data Exchange Standards / Approaches	Data Content Standards
Exchange Between Lab and Provider (EHR)	
As Messages • Health Level Seven (HL7) v2.x and v3 As Documents • Health Level Seven (HL7) v3 Clinical Document Architecture (CDA/CDA R2)	• LOINC • SNOMED
Exchange via Health Information Exchange (HIE)	
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) As Messages • TBA As Documents • XDS.b and XDS-MS	• LOINC • SNOMED

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HL7 CDA

- Familiarity with current solution
  - HITSP recommendation and support by IHE
- Sophistication of IT infrastructure
  - Web browser is main requirement
  - Three levels of conformance (HL7 messages target specific use case)
- Impact on workflow
  - Easy paper-based document to electronic document transition
  - Messages require new workflow requirements
- Legacy systems
  - Not based on existing standards
  - Replacing HL7 v2.x messaging with HL7 v3 is costly and time consuming
- Learning curve
  - CDA based on single RIM
  - HL7 v3 messaging based on multitude of RIM models
- Flexibility and Interoperability
  - Flexibility in data sent with compliance through schema based validation (functional interoperability)
  - RIM and terminology support for semantic interoperability

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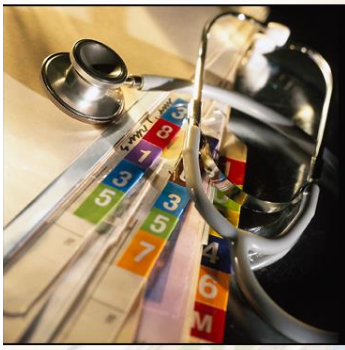

Technologies

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Microsoft CHF

- Generic platform- and vendor-agnostic guidance for healthcare enterprises
  - Based on open standards and protocols to help achieve faster ROI
- Business and technical frameworks
  - SOA with detailed business collaboration specifications
  - Web Services as the core messaging and connectivity method
  - HTTPs and WS-Security
  - Agnostic message payload could include HL7 v2.x, HL7 v2, HL7 CDA, ASTM CCR, etc.
  - Based on Microsoft products and technologies but could be adapted to other technological realms like IBM or Open Source
- Development
  - 2006 v1
  - April 2009 v2

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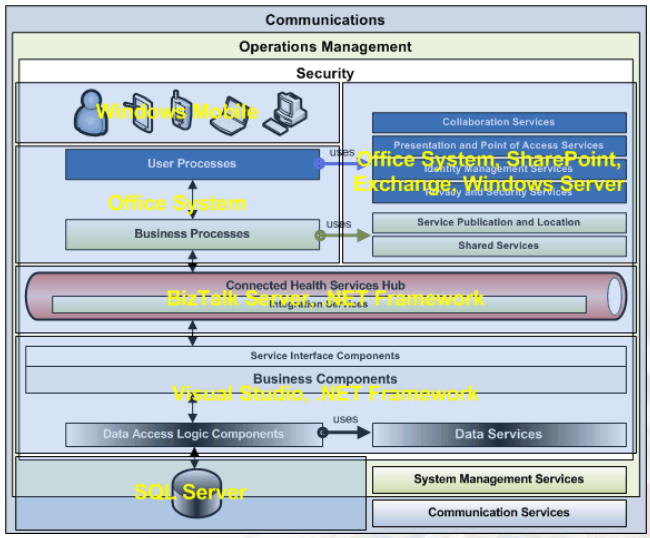
CHF and Technologies



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CHF Reference Implementations

- Enterprise solutions to healthcare interoperability and system integration problems
- Extensive configurations and complexities
- Problems with BizTalk Server 2006 and HCE (Appendix A)
- Subset of Microsoft CHF utilized

	HCE	XDS.b	HCUI
Version	2.1.1 (May 2007)	Connect-a-thon NA2009 Beta (Feb 2009)	6.5.128.000 (Feb 2009)
Healthcare Focus	Integration and messaging for various scenarios	Integration and messaging for document sharing	User interface for various scenarios
Features	✓ Message Management Services ✓ HCE and Health Domain Registers ✓ HCE and Health Domain Administration Services ✓ HCE and Health Domain Administration Portal ✓ Infrastructure Services	✓ Provide and Register Document Set-b ITI-41 ✓ Register Document Set-b ITI-42 ✓ Registry Stored Query ITI-18 ✓ Retrieve Document Set ITI-43 ✓ Patient Identity Feed ITI-44/ITI-8 ✓ ATNA	✓ Address and Contact Label ✓ Date Input Box and Label ✓ Gender Label ✓ Graphing ✓ Identifier and Name Label ✓ Medications List View ✓ Month Calendar ✓ Patient Banner and Search Input Box ✓ Time Input Box and Label
CHF Alignment	▪ Service Publication and Location ▪ Shared Services ▪ Connected Health Services Hub ▪ Integration Services ▪ Service Interface Components	NA	User interface

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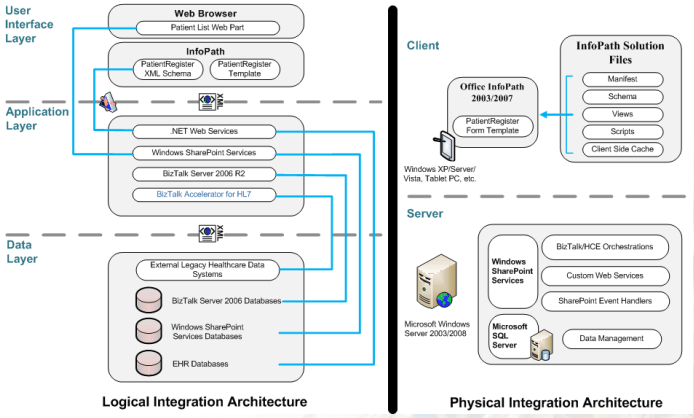
MS InfoPath 2003 HL7 CDA Demo

- Microsoft Office System functionality provided by InfoPath
- SQL Server data access components
- .NET Web Services
- eHealth Services Hub represented by middleware applications such as BizTalk Server not utilized



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CDA Demo

- Two electronic clinical form samples, **physicians progress note** and pharmacy order, based on HL7 CDA standard
- InfoPath native XML support and user-defined schemas serve as potential solution to data collection and exchange problems that have plagued healthcare
  - HL7 CDA standard use is transparent to user
  - Behind the scenes schema validation
  - Progress note form is subset of entire CDA schema but instances generated by InfoPath are validated against entire schema
  - Through business process layers, raw XML-formatted data can be transformed to any proprietary format necessary to accommodate existing interfaces and databases

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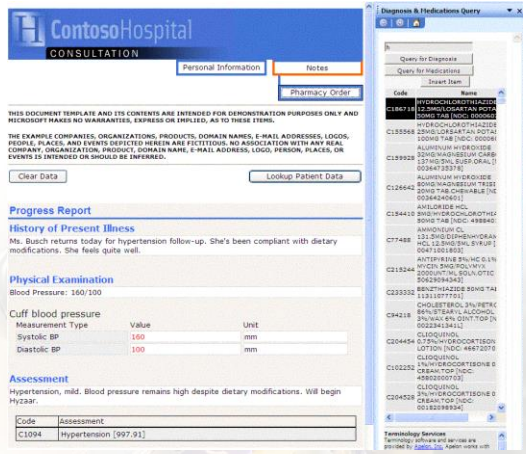
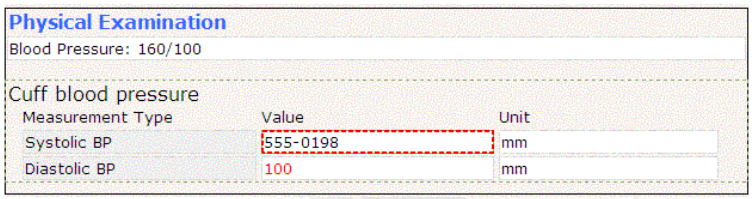
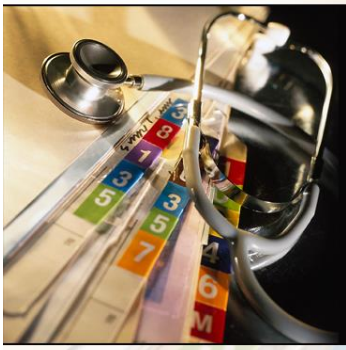
CDA Demo (cont.)



CDA Demo (cont.)





Project Development

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Methods

- Approach for SOA implementations should depend on organizational culture, willingness to embrace change, planning and budgetary cycles, and existing investments
- Hybrid top-down, bottom-up method most recommended in literature
  - Top-down modeling of primary care process and service processes based on SOA
  - Bottom-up approach to wrap applications to a data tier through Web Services
  - Recommendations of the Microsoft CHF, Healthcare Services Specification Project (HSSP), HL7, the Object Management Group (OMG), and professionals

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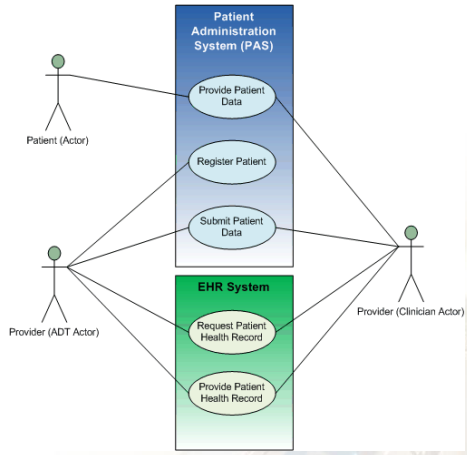
Patient-Provider Interaction



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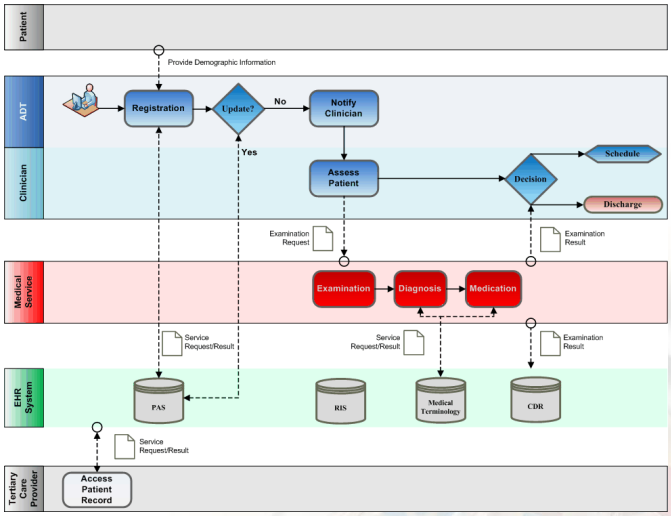
Primary Care Patient-Provider Care Process



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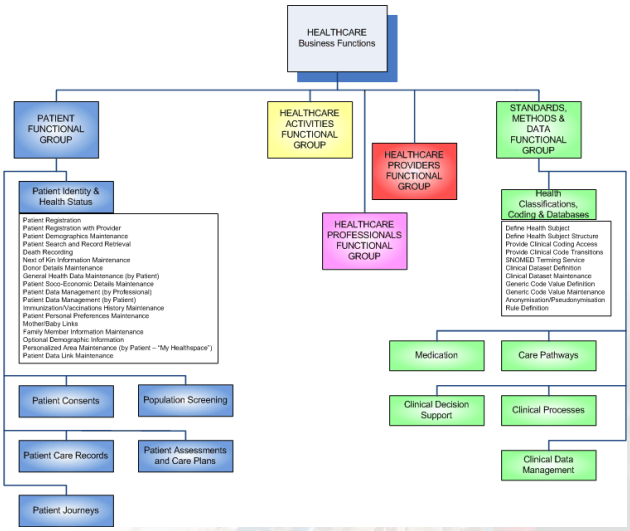
Service Candidates

- **EHR Access Services**
- **EHR Update Services**
- EHR Process Orchestration Services
- EHR Business Rules Services



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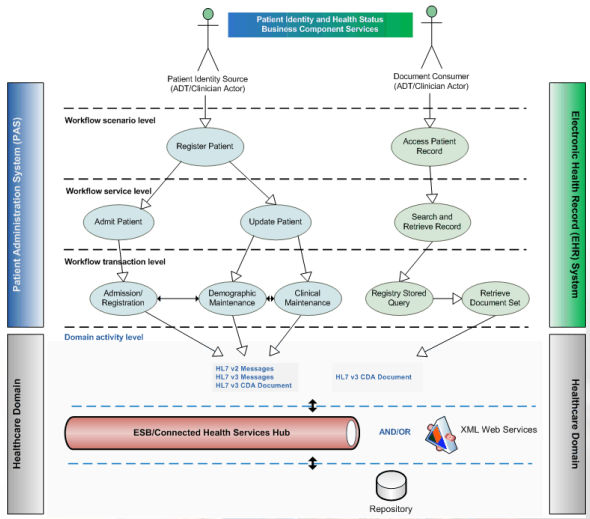
Service Identification

- InsertPatientWS
- GetPatientWS
- UpdatePatientWS



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Data Modeling

- Managed Service Model versus Central Repository Model
- CDA schema modeling deemed too complex and problematic with given experience and background
- SQL Relational Databases chosen

	SQL Relational Databases	XML Blobs	XML Fields
Description	Standard SQL relational tables and commands such as SELECT, INSERT, UPDATE	Storing XML as a typed or untyped single column with a primary key index	Storing XML as relational rowsets in alignment with traditional SQL relational tables
Learning Curve	Medium	Medium-High	High
Comments	Most familiar to work with but involves complex hierarchical-to-relational mapping to base on schemas	Retrieval and submission of full XML document instances only, but still requires some XML-specific commands	Can return subsets of XML data, but necessary to understand FORXML, OPENXML, XQuery, XPath, etc. commands and functions

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Data Modeling (cont.)

```
-- ====================================
-- Author:              Josh Prowant
-- Create date:         3/16/09
-- Description:         Simple Patient Table Example
-- ====================================

CREATE TABLE [dbo].[Patient](
        [id] [int] PRIMARY KEY,
        [firstName] [nvarchar] (50),
        [lastName] [nvarchar] (50))
```

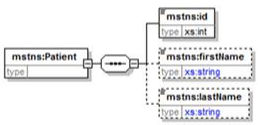

Figure 24: XML Schema for POC example (*XML Schema documentation generated by* ***XMLSpy*** *Schema Editor* http://www.altova.com/xmlspy)

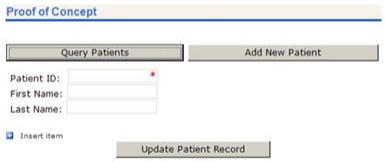

Figure 25: Proof of Concept InfoPath Patient Form

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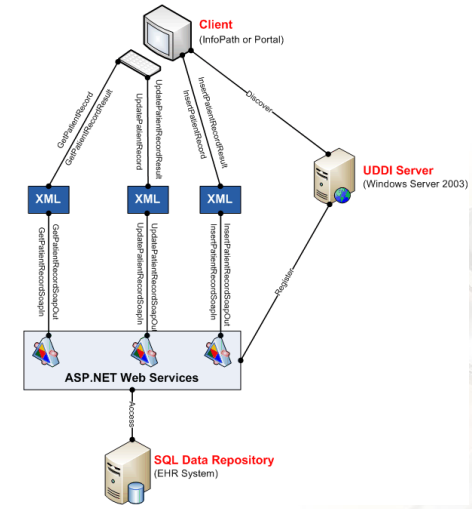
Service Modeling and Design



1. Microsoft Web Service Architecture and Windows Communication Foundation (WCF)
2. **ADO/ASP.NET Web Services developed using Visual Studio**
3. SQL Server 2005 Native XML Web Services (SOAP/HTTP endpoints)

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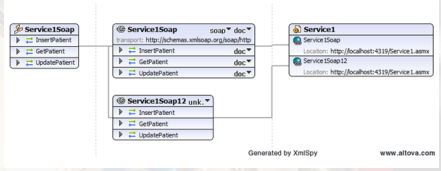
Service Modeling and Design (cont.)

- pocWebService

```
//
// Insert the Patient Record into SQL Database
//
[WebMethod]
public int InsertPatient(
    int id,
    string firstName,
    string lastName)
{
    const string INSERT_COMMAND =
        "INSERT INTO patient(" +
        "id,firstName,lastName)" +
        "VALUES (@id,@firstName,@lastName)";
    try
    {
        using (SqlConnection cnn = new SqlConnection("Integrated Security=True;Data
                                                      Source=CHEF;Initial Catalog=EHR"))
        {
            cnn.Open();
            using (SqlCommand cmd = new SqlCommand())
            {
                cmd.Connection = cnn;
                cmd.CommandText = INSERT_COMMAND;
                SqlParameterCollection ps = cmd.Parameters;
                ps.AddWithValue("@id", id);
                ps.AddWithValue("@firstName", firstName);
                ps.AddWithValue("@lastName", lastName);
                return cmd.ExecuteNonQuery();
            }
        }
    }
    catch (Exception ex)
    {
        ex.ToString();
        throw;
    }
}
//
// Get Patient Records stored in the SQL Database
//
[WebMethod]
public DataSet GetPatient()
{
    DataSet myDS = new daPatients1();
    sqlConnection1.Open();
    sqlDataAdapter1.Fill(myDS);
    sqlConnection1.Close();
    return myDS;
}
//
// Update a Patient Record stored in the SQL Database
//
[WebMethod]
public int UpdatePatient(
    int id,
    string firstName,
    string lastName)
{
    const string UPDATE_COMMAND =
        "UPDATE patient SET firstName=@firstName, lastName=@lastname WHERE id=@id";
    try
    {
        using (SqlConnection cnn = new SqlConnection("Integrated Security=True;Data
                                                      Source=CHEF;Initial Catalog=EHR"))
        {
            cnn.Open();
            using (SqlCommand cmd = new SqlCommand())
            {
                cmd.Connection = cnn;
                cmd.CommandText = UPDATE_COMMAND;
                SqlParameterCollection ps = cmd.Parameters;
                ps.AddWithValue("@id", id);
                ps.AddWithValue("@firstName", firstName);
                ps.AddWithValue("@lastName", lastName);
                return cmd.ExecuteNonQuery();
            }
        }
    }
    catch (Exception ex)
    {
        ex.ToString();
        throw;
    }
}
```



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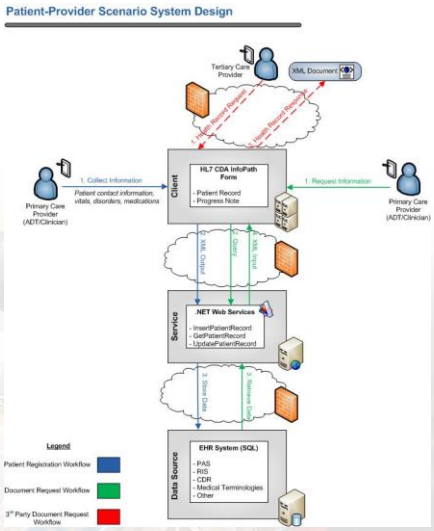
Proof of Concept System

- Terminology: SNOMED CT, LOINC, etc.
- Language: XML
- Grammar: HL7 CDA
- Envelope: SOAP
- Delivery: Web Services (WS-*)



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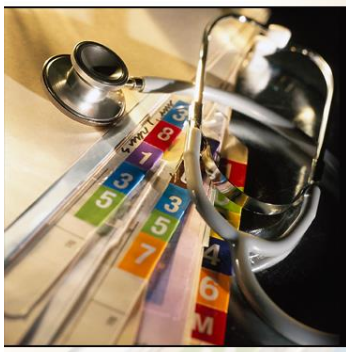

Discussion

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System Results

- Outcome assumes single healthcare provider documenting patient contact information, vitals, disorders, and medications on a local machine
  - Not in line with real scenario, but good for proof of concept and future expansion
- POC designed to interact with EHR SQL database using Web Services
  - Same methods could be applied to clinical forms based on HL7 CDA standard like Microsoft example, although with additional complexities and more arduous coding
- Form could be published to Web portal such as SharePoint using InfoPath Form Services and allow interoperable exchange of clinical data given acceptable permissions across the Web

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System Results (cont.)

- Features
  - Quickly view patient data from previous visits
  - Streamlines entering and tracking of patient data
  - Decentralized so that multiple users can work on the system at the same time (uses a web service and database)
  - Copy forward patient data from previous visits
  - Easy installation
  - Simple workflow for entering, editing, and completing patient visit info
  - Uses auto-correct from Word
- Limitations
  - No billing support
  - No security
  - No error handling
  - No offline caching to allow operation when the network is down

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ROI

- Single-vendor solutions
  - Out-of-the-box integration and EHR certification via the Certification Commission for Healthcare IT (CCHIT)
- Multi-vendor solutions
  - Increase the risks of integration but allow a “best-of-breed” approach
- ROI difficult to measure
  - Existence of legacy systems
  - Business model adaption
  - Difficulty of integration
  - Not enough systems in place to properly measure and each healthcare system is different

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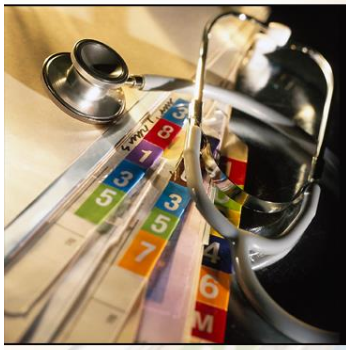

Future Work

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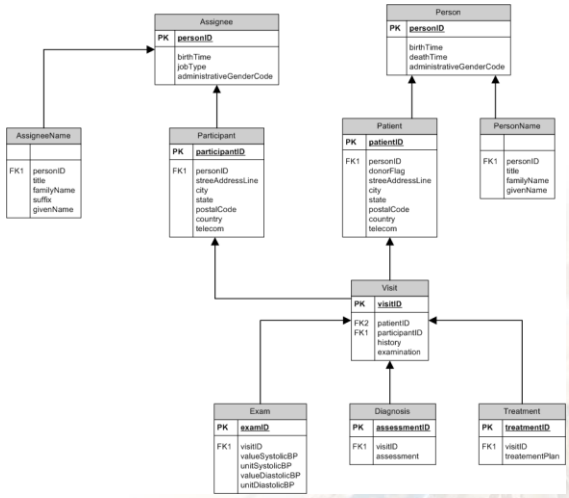
HL7 CDA Data Modeling



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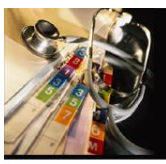

Security

- Microsoft BizTalk Server (orchestration service and software) provides reliable delivery service for messages
- Secure Sockets Layer (SSL) and HTTPS protocol provide message protection and confidentiality
- Lightweight Development Application Protocol (LDAP) provides authentication through user credentials stored in a central directory (Active Directory)
- Digital Signatures of XML-based clinical documents as supported by InfoPath provide protection from repudiation and message tampering during transmission and delivery
- WS-* extensions provide authentication to Web Services and fall under Microsoft Web Service Enhancements (WSE) category

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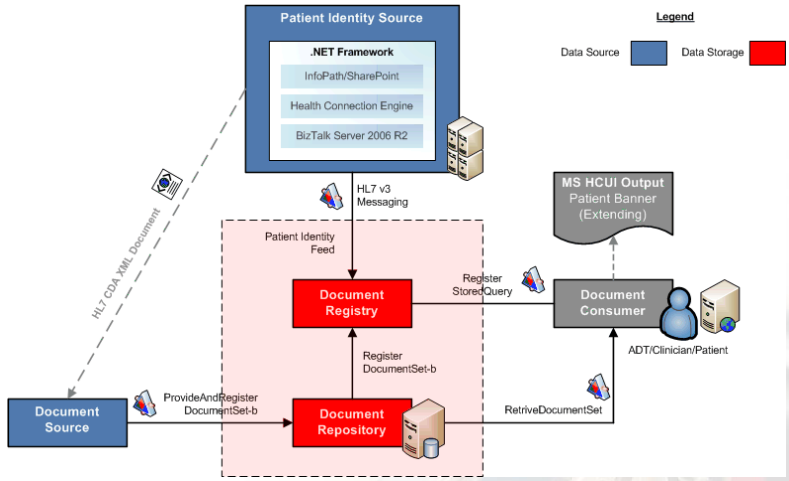
Microsoft CHF Reference Implementations



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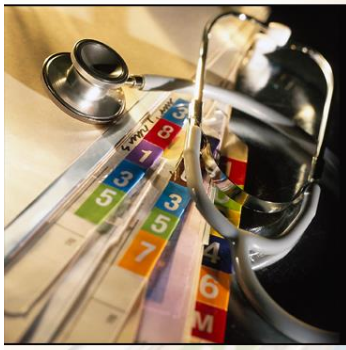

Conclusions

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Conclusions

- Project aligned with SOA, supporting an incremental approach outlining a “proof point” upon which to build further
- Combined with controlled medical vocabularies, SOA methods and Web Service technologies can offer data interoperability in healthcare within and among EHR systems, helping to realize the goal of a nationwide EMR system
- Microsoft-based technologies make implementation easier to realize

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Learning Outcomes

- Setting up multiple machines and operating systems in a networked environment for future use and expandability to support the needs of the Department of Computer and Electrical Engineering Technology & Information Systems and Technology
- Various operating systems including Windows XP, Windows Server 2003, Windows Server 2008, Windows Vista, and Linux
- Setting up a Web Server including installing IIS, UDDI, and other components (although it was not ultimately used in this project)
- Active Directory permissions, network users and groups, and local computer users and groups permissions
- Installing and configuring Microsoft BizTalk Server including prerequisites (SQL Server, SharePoint and SharePoint Services, Visual Studio, etc.)
- Microsoft-based healthcare solutions (HCE, IHE XDS.b, and HCUI) exploration and testing (although they were not ultimately used in this project)
- C# programming in Visual Studio including Web Services and Web Applications
- SQL Server commands, setup, and interactions
- Using healthcare standards and schemas
- Using Microsoft Office InfoPath data connections and form design

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Findings and Lessons Learned

Technology

- Software environment setup is extremely important (BizTalk prerequisites)
- Domain Controllers are not recommended for testing complex software (BizTalk) due to performance drops from additional functions associated with domain controllers
- Compatibility between different versions of software must be considered
- Permissions (both Active Directory and Local Users and Computers) are extremely important for software configurations (different users for IIS, ASPNET, BizTalk, SQL, etc.)
- Microsoft Office InfoPath requires extensive knowledge to design good schemas as the data source and to use dialogs for rules and filters
- Large and complex InfoPath forms require business logic and performance considerations
- Microsoft Connected Health Framework and related Connected Health Platform recommendations are more appropriate for enterprise solutions and situations where infrastructure and business processes are already in place

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Findings and Lessons Learned (cont.)

Healthcare

- Healthcare information technology and methods are constantly changing which presents difficulties in recommending solutions
- Healthcare business models, infrastructures, and politics all work against emerging solutions to interoperability and integration of EHR systems
- Healthcare standards suffer from a lack of an overarching universal framework and without such a framework, interoperable and integrated EHR systems will not be achieved

Directed Project

- Project scope needs to be well defined and based on extensive background research when attempting to discuss a complex problem with no prior experience
- Project plan should be realistic, yet adaptable to unforeseen changes as project progresses

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