

# HEALTHCARE INFORMATION INTEGRATION: CONSIDERATIONS FOR REMOTE PATIENT MONITORING

## Contributors

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## Index Words

Remote Patient Monitoring (RPM)  
Semantic Interoperability  
Service Oriented Architecture (SOA)  
Healthcare Informatics  
Chronic Disease Management (CDM)  
HL7 Clinical Document Architecture (CDA)

## Abstract

Modern healthcare is no longer practicable without data integration. Without standards, integration costs soar and threaten the effectiveness of healthcare delivery. With standards, information becomes accessible in computable form, driving new levels of clinical research, patient-empowered healthcare, and innovative business models. In this article we examine a few of the latest developments in healthcare informatics standards with respect to remote patient monitoring, review recent learnings in deploying a remote patient monitoring solution, and identify key considerations and areas for further development.

## Introduction

Simple interventions can save lives and reduce the cost of healthcare. Home care for patients with co-morbidities can mean the difference between life and death. For example, with ongoing monitoring of vital signs, patient condition, and medication levels, sudden changes outside of the patient's established thresholds can be detected, which can mean the difference between extended hospitalization and rapid decline in health, versus maintaining a quality of life in the patient's home, surrounded by family and friends.

Similarly, maintaining tight control over blood glucose levels during gestational diabetes can mean the difference between premature birth with a whole host of medical complications for both mother and child, versus a stable healthy maternity and normal delivery.

RPM can be significant to both examples just cited, and the effectiveness of RPM depends directly on the availability of standardized information from a variety of healthcare data sources, including patient health summary, prescriptions, lab results, daily vital signs collection, and functional assessments.

*“Home care for patients with co-morbidities can mean the difference between life and death.”*

We first explore the standardized representation of RPM information by using the Health Level 7 (HL7) v3 CDA Release 2 [4] and the Personal Health Monitoring Report (PHMR) Draft Standard for Trial Use (DSTU) [10]. Then, we consider recent developments with the American Health Information Community (AHIC) Use Cases and Healthcare Information Technology Standards Panel (HITSP) Implementation Guides for Remote Patient Monitoring [6, 7], Consultation and Transfer of Care [5], Long-Term Care Assessments [13], and the resulting HL7 Implementation Guide for CDA 2: CDA Framework for Questionnaire Assessments DSTU [8]. We review several SOA principles and considerations critical to healthcare integration. Next, we discuss several technical and workflow considerations when designing and deploying a RPM solution. Along the way we identify multiple areas suitable for further development.

## Remote Patient Monitoring Use Case

In this section we discuss a typical RPM use case, in order to set the context for applying healthcare informatics standards and to explain how subtle nuances in clinical workflow and system interactions can have a profound impact, both on the design of the end-to-end information integration as well as on future enhancements to informatics standards.

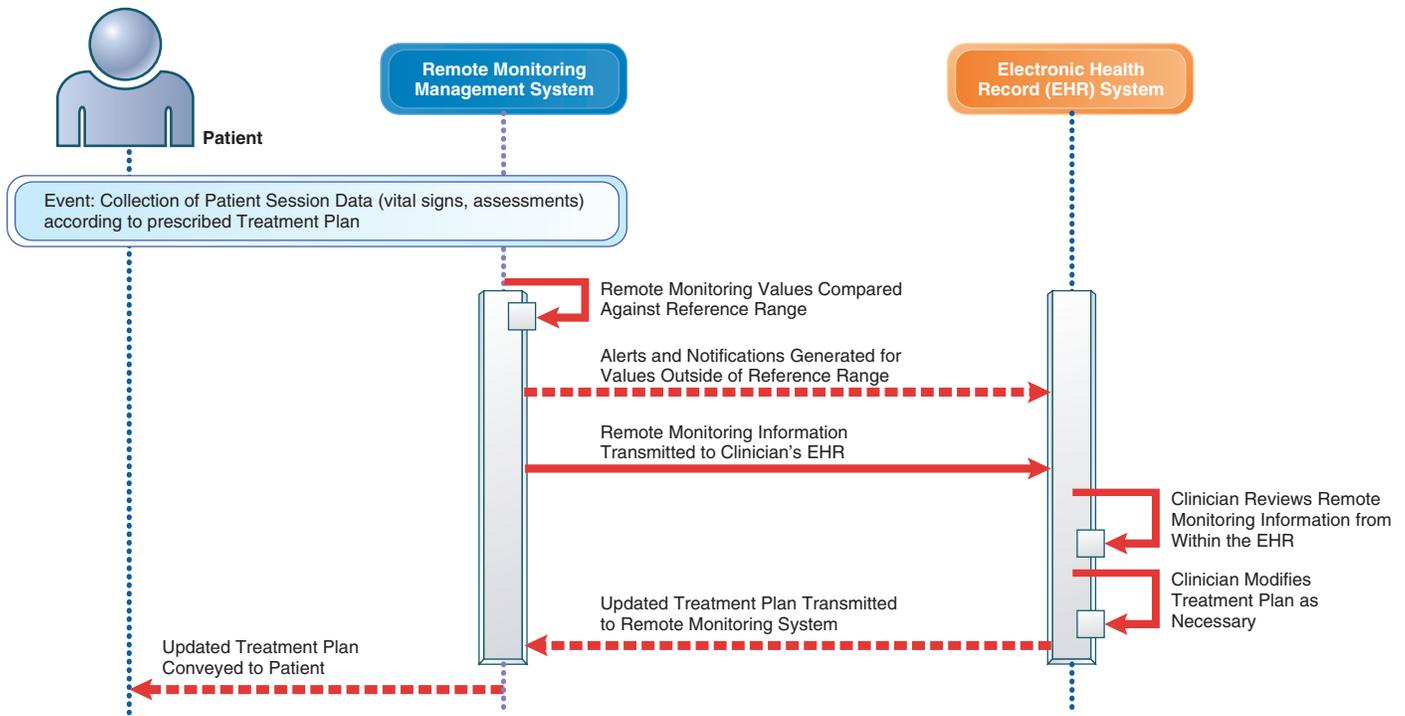
The sequence diagram depicted in Figure 1 was adapted from the HITSP RMON Business Use Case [6], representing a superset of actors, steps, and functionality across a number of finer-grained but related use cases. We currently work with clinicians in a variety of regions worldwide but primarily based in the United States and the United Kingdom. Clinical delivery and reimbursement models are very different between these two regions. Some healthcare delivery models rely upon visiting nurses, community outreach, and clinical call centers to perform primary patient engagement, monitoring patients remotely and within the home, and only referring the most acute cases for physician or hospital intervention.

Other delivery models rely upon physician practices to monitor patients directly, at times delegating these tasks to trained staff that operate as part of the practice under their clinical supervision. These two models exist in both regions regardless of patient acuity, frequency of monitoring, or reimbursement models. (In the healthcare context, patient acuity refers to the type and severity of illness, with acutely ill patients requiring emergency care.) It is important that use cases and the supporting informatics standards comprehend these types of variation in order to deliver an effective RPM solution.

Founded in 1987, Health Level Seven (HL7) is a not-for-profit, ANSI-accredited standards development organization dedicated to providing a comprehensive framework and related standards for the exchange, integration, sharing, and retrieval of electronic health information that supports clinical practice and the management, delivery, and evaluation of health services.

AHIC is a federal advisory body, chartered in 2005 to make recommendations to the Secretary of the U.S. Department of Health and Human Services on how to accelerate the development and adoption of health information technology. AHIC specifies prioritized healthcare use cases, for which the HITSP then develops interoperability specifications, leveraging, harmonizing, and further constraining existing internationally-recognized standards. HITSP identifies gaps in coverage and forwards new development areas to Standards Development Organizations (SDOs) for consideration in future revisions. While both AHIC and HITSP are entirely U.S.-centric in focus, similar organizations exist in each major region worldwide and their common goal is to achieve standards harmonization. The process of international standards harmonization is covered separately in this issue by Jaffe, et al.

*“We currently work with clinicians in a variety of regions worldwide but primarily based in the United States and the United Kingdom.”*



**Figure 1: RPM Sequence Diagram**

Source: Intel Corporation, 2009. Adapted from HITSP RMON Business Sequence Diagrams [6]

Figure 1 represents three primary actors of concern – the Patient, the Remote Monitoring Management System (RMMS) that operates the RPM solution, and an external Electronic Health Record (EHR) system, which might represent anything from a clinical electronic medical record system to a purpose-built system developed specifically for chronic disease management (CDM) or home health monitoring. The primary monitoring of a patient’s wellbeing by a clinician can occur either within the RMMS itself or by extension, from within the EHR system. The sequence diagram is triggered by the event of patient data collection, including vital signs and assessments defined by a treatment plan, which specifies not only what data to collect but also the frequency and schedule.

Typical patients are asked to collect vital signs anywhere from one to four times per day (an average of eight vital sign readings per day), ranging anywhere from three to seven days per week. Patients work with a variety of peripheral device types including blood pressure cuff, glucose meters, weight scales, and pulse oximeters. Vital sign measurements are combined with assessment questions that are geared to assess patient adherence to the treatment plan, functional status, and coping mechanisms with regard to their specific set of co-morbidities, such as congestive heart failure, diabetes, and chronic obstructive pulmonary disease (COPD).

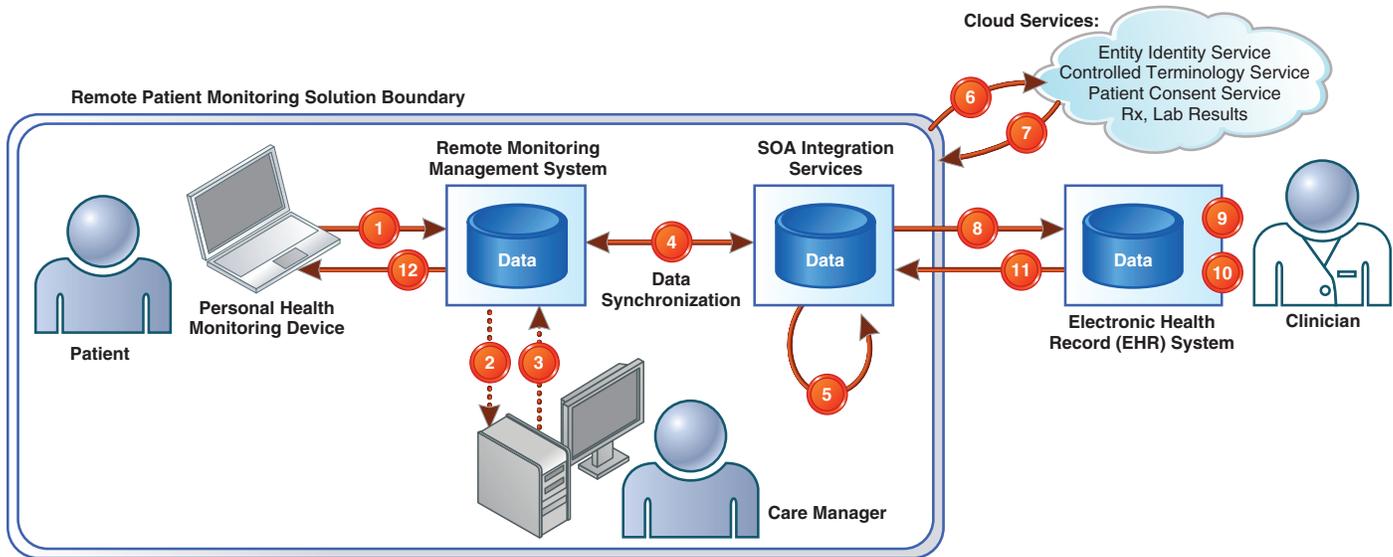
*“Patients work with a variety of peripheral device types including blood pressure cuff, glucose meters, weight scales, and pulse oximeters.”*

Once the RMMS aggregates the vital sign and assessment data, it compares the values against a pre-established reference range or threshold to identify those readings that are out of normal range. Optionally, alerts and notifications may be generated to the EHR system and members of the clinical team, notifying them of the abnormal readings. Next, both normal and out-of-range information is transmitted to the EHR system, either in raw or summary format. The clinician reviews the information, makes clinical notes, and as needed, generates referrals and modifies the treatment plan. The updated treatment plan is transmitted to the RMMS and subsequently communicated to the patient and the patient-local devices.

The significance of the use case and sequence diagram just described are as follows:

- There is a high degree of variability in where patient data are maintained. The clinician and clinical support team review and annotate patient information in multiple systems of record. The RMMS is generally deployed in addition to multiple legacy systems used to manage patient healthcare, and typically, little to no integration exists.
- Some healthcare use cases and informatics standards assume that a clinician event is responsible for triggering the transfer of information from one clinical team to the next; however, this use case underscores several examples where data transmission is triggered instead by system events, and it is important for informatics standards to comprehend both scenarios.
- The type, frequency, and schedule of the information collected is also highly variable, which must be comprehended by informatics and system deployment designs alike. The more standardized the information, the more it will drive machine computability, advanced analytics, and improved healthcare at lower costs. However, informatics standards must always balance the goal of perfect information requiring every data element, with a pragmatic approach to incremental adoption, relying instead on implementations to deliver best effort results in populating standard data elements with carefully designed constraints.
- A consistent, appropriately encoded specification of the treatment plan is just as important as the data collection itself. Initial focus is rightfully on capturing and transmitting RPM data, yet to truly measure patient adherence and prognosis over time, we also need a consistent method to specify the treatment plan in a semantically meaningful way.

*“Optionally, alerts and notifications may be generated to the EHR system and members of the clinical team, notifying them of the abnormal readings.”*



**Figure 2: RPM Interaction Diagram**

Source: Intel Corporation, 2009

Figure 2 reveals several additional deployment considerations with respect to RPM. Step 1 represents the transmission of patient session data to the RMMS. The RMMS aggregates trend information, compares vital signs against reference ranges, and generates alerts and notifications. It has its own data repository, consisting of historical patient treatment plans, reference ranges, clinical notes, patient monitoring data, and customer-specific configuration information. The RMMS is necessarily designed to be an online transaction processing (OLTP) system, since its primary goal is to drive RPM in a high-performance, transaction-oriented manner.

Optionally, Step 2 and 3 depict a care manager who reviews the patient’s status from within the RMMS. The care manager may modify the treatment plan directly, or annotate the record and refer to a clinician for review and follow-up. The care manager may also play a key role in assessing the viability of the data collected prior to escalation. For example, in the case of a very low weight reading generating an alert, the care manager might confirm that the patient’s grandson had in fact triggered the scale.

Step 4 represents some form of data synchronization between the RMMS and the Integration Services environment. The primary goal of the Integration Services environment is rapid query, retrieval, translation, transformation, and guaranteed delivery (push/pull) of healthcare information between a number of participating entities (Step 5). Integration Services, therefore, are commonly a mix of online analytic processing (OLAP) combined with logical mechanisms of extract, transform, and load (ETL). Trend analysis and summarization may also be performed at this stage. The Integration Services environment is best developed according to SOA principles, largely due to the complexity and

*“The RMMS is necessarily designed to be an OLTP system, since its primary goal is to drive RPM in a high-performance, transaction-oriented manner.”*

number of end points, the variability of legacy and standard interfaces, and the number of different workflows and external services required. We discuss the rationale and benefits of applying SOA to RPM in more detail later. The mechanism of data synchronization depends upon patient acuity, data latency, and a number of other considerations, also discussed later in this article.

As a part of the transformation that occurs in Step 5, multiple calls may be made to services across the Internet (Steps 6 and 7) in order to complete the healthcare dataset, including identity match; terminology encoding; record locate; patient consent; or data enrichment, incorporating the latest lab results, prescription history, or drug-to-drug interaction checks.

Finally, the RPM information is transmitted to the EHR (Step 8), where it is reviewed and annotated by the clinician (Step 9). Note that many providers will require manual review of the data for clinical accuracy prior to committing it to the EHR. This review requirement poses significant workload and process implications to the future viability of RPM, discussed in more depth later.

The clinician enters modifications to the treatment plan and generates requests for consultation (Step 10). Changes to the treatment plan are returned to the RMMS (Step 11) and transmitted to the patient-local devices (Step 12). The inbound data flows undergo similar decomposition and transformation as outbound flows (Steps 5-7), remapping identity and terminology to local code sets.

System designers should anticipate the need to support a large number of end points with a high complexity and variability of transforms (e.g., HL7 v2.x, HL7 v3, proprietary XML, proprietary delimited files) and translations (e.g., SNOMED CT, LOINC, RxNORM, ICD9/10) required across an array of different transport protocols (e.g., SOAP over HTTPS, SFTP, MLLP, and proprietary sockets). A powerful approach is the implementation of the HL7 v3 CDA [4] in the Integration Services environment (Step 5) as a normalized view of RPM information, leveraging the full richness of the HL7 v3 Reference Information Model (RIM). The CDA becomes in effect a Rosetta Stone, making the subsequent translation to legacy, proprietary, and standards-based systems predictable, reliable, and semantically correct. The incremental adoption model inherent in CDA ensures the relative ease with which we can populate optional segments with new information, such as Plan of Care, while the SDOs work through the optimal encoding scheme. It also ensures straightforward compliance with new CDA document types, such as the Continua Health Alliance Personal Health Monitoring (PHM) Report [3], as a minor transform from the baseline CDA.

*“Note that many providers will require manual review of the data for clinical accuracy prior to committing it to the EHR.”*

The HL7 v3 RIM is an abstract healthcare informatics model, generated by using Uniform Modeling Language (UML) and consisting of a set of classes, attributes, and relationships. The HL7 CDA and other v3 specifications are derived from the RIM and encoded by using XML. The RIM is capable of representing Acts, Entities, Relationships, Roles, and Participants, and it is refined by using standard code sets and controlled medical vocabulary.

Continua Health Alliance is a non-profit, open industry coalition of more than 200 healthcare and technology companies collaborating to improve the quality of personal healthcare. Continua is dedicated to establishing a system of interoperable personal health solutions, with the knowledge that extending those solutions into the home fosters independence, empowers individuals, and provides the opportunity for personalized health and wellness.

*“The standard is both precise and adaptable, as demonstrated by the Continua xHR Implementation Guide.”*

## Using HL7 to Encode Telehealth Data

The HL7 v3 CDA Release 2 [4] is the ideal vehicle for healthcare data integration. It is an informatics standard based on years of industry expertise, it represents healthcare documents in their purest form, ranging from a progress report, to a discharge summary, to capturing an MRI study as a standard image set. The HL7 CDA can scale easily from early to advanced stages of adoption: it can represent a container with basic summary information (such as basic patient demographics, ordering physician, and a facsimile of a lab result stored as an attachment), to a container with a longitudinal health record. The standard is both precise and adaptable, as demonstrated by the Continua xHR Implementation Guide [3], a variant of the CDA developed to define the Personal Health Monitoring Report (PHMR) [10].

The real ingenuity of the CDA is the overlay of a series of templates or constraints to the v3 RIM, to uniquely identify and encode sections of a clinical document in a standard and semantically meaningful way. The HL7 v3 Continuity of Care Document (CCD) [9] was one of the first broadly implemented set of constraints applied to the HL7 CDA Release 2 [4], and it was selected by HITSP as the basis of their implementation guides. There are now a whole complement of implementation guides based on either the umbrella CDA or on the further constrained CCD, all of which aim to deliver both human-readable and machine-consumable clinical information in a systematized fashion.

### Assigned Author

The HL7 CDA supports the concept of the Assigned Author being either a human or a device, as depicted in Code Listing 1.

*“The real ingenuity of the CDA is the overlay of a series of templates or constraints to the v3 RIM, to uniquely identify and encode sections of a clinical document in a standard and semantically meaningful way.”*

```

<!-- when the CDA is compiled/reviewed by a Clinician -->
<author>
  <assignedAuthor>
    <assignedPerson>
      ...
    </assignedPerson>
  </assignedAuthor>
</author>
<!-- when the CDA is created by a system or device -->
<author>
  <assignedAuthor>
    <assignedAuthoringDevice>
      ...
    </assignedAuthoringDevice>
  </assignedAuthor>
</author>

```

**Code Listing 1:** Machine-Computable XML: Assigned Author

Source: Intel Corporation, 2009

In some cases, a summary report of RPM is generated along with clinical notes, as part of a transfer of care or a request for consultation, and the use of a human Assigned Author makes perfect sense. In other cases, information is automatically collected by RPM devices, compiled into an HL7 CDA, and forwarded to other healthcare systems for subsequent clinical analysis. In this latter case, there is no human author who can be assigned, as the information has yet to be reviewed by any clinical personnel. Similarly, while some regions may require legal authentication of a clinical document, other regions may delegate legal authentication to a device or system, and still others may opt to release a clinical document prior to legal authentication. The HL7 PHMR does an excellent job of both considering and supporting each of these variations in usage models [10].

### Medical Equipment

The HL7 PHMR [10] (based upon the work of the Continua Health Alliance [3]) does a thorough job of specifying required peripheral manufacturer information. Table 1 and Code Listing 2 show the Medical Equipment section from the HL7 PHMR [10], depicting both the XML-rendered table and a subset of the machine-computable section for a single device, respectively.

*“The HL7 PHMR does an excellent job of both considering and supporting each of these variations in usage models.”*

Medical Equipment					
System Type	System Model	System Manufacturer	System ID	Production Spec	Regulated
Blood Pressure Monitor	Pulse Master 2000	Nonin	1F-3E-46-78-9A-BC-DE-F1	Unspecified: Serial Number: 584216 Part Number: 69854 Hardware Revision: 2.1 Software Revision: 1.1 Protocol Revision: 1.0 Prod Spec GMDN:	Regulated

**Table 1:** XML-rendered Table: Medical Equipment

Source: Health Level Seven, 2009 [10]

*“Systems can transform the terminology to other standard and proprietary formats, precisely because the standard is encoded in the first place, just like the Rosetta Stone.”*

```

<title>Medical Equipment</title>
...
<!-- Note the use of the IEEE EUI-64 unique peripheral DeviceID, used
to establish a link between Medical Equipment peripheral and reference
measurements in the Vital Signs section -->
  <id root="1.2.840.10004.1.1.1.0.0.1.0.0.1.2680"
    assigningAuthorityName="EUI-64" extension="1F-3E-46-78-9A-BC-
    DE-F1"/>
...
<!-- standard device encoding via SNOMED CT -->
<playingDevice>
  <code code="32033000" codeSystem="2.16.840.1.113883.6.96"
    codeSystemName="SNOMED CT" displayName="Arterial pressure
    monitor">
<!-- translated device encoding via MDC -->
  <translation code="MDC_DEV_SPEC_PROFILE_BPM"
    codeSystem="2.16.840.1.113883.6.24" codeSystemName="MDC"
    displayName="Blood Pressure Monitor"/>
</code>
  <manufacturerModelName>...</manufacturerModelName>
</playingDevice>

```

#### **Code Listing 2: Machine-computable XML: Medical Equipment**

Source: Health Level Seven, 2009 [10]

*“Semantic interoperability is the highest form of data integration.”*

Note the significance of the use of standard terminology in Code Listing 2, which leverages both SNOMED CT and MDC code sets (refer to “code/code system...translation code/code system”). This semantic encoding is what makes the information machine-computable and enables interoperability. Systems can transform the terminology to other standard and proprietary formats, precisely because the standard is encoded in the first place, just like the Rosetta Stone. Semantic interoperability is essential to enable clinical research and to facilitate queries across a wide variety of data sources; however, semantic exchange is only possible if the terminology has been first normalized to one of a few dozen international healthcare terminology standards.

#### **Levels of Interoperability**

Semantic interoperability is the highest form of data integration, such that receiving systems can readily and precisely consume information, encoded with standard terminologies and code sets, with no loss of meaning or context for abstract terms and concepts. This is the goal of the HL7 v3 RIM.

Syntactic interoperability, the next lower form of data integration, exchanges information by using agreed-upon syntax. A set of fields are specified along with their syntax, but nothing is specified as to the possible range of values or meaning. Prior messaging standards tended to stop short at syntax: they did not address the crucial last step of semantics, and therefore left an incomplete data standard wide open to conflicting interpretation and incompatible

*“Prior messaging standards tended to stop short at syntax.”*

implementations. For example, the earlier versions of HL7 v2.x messages focused almost exclusively on syntax, and hence the expression “every v2.x interface is a new v2.x interface.” Each implementation added proprietary interpretations and extensions over time.

Integration at the lower five levels of the OSI model focus on standardizing transport, protocol, and security, which is also the primary focus of such groups as W3C, Continua, IHE, and IEEE. Technology standards are optimal to address the exchange *on the wire*, while healthcare domain expertise is optimal to address the syntax and semantics of the exchange.

### Vital Signs

Table 2 shows a sample of the Vital Signs section of a PHMR, depicting the XML-rendered table, while Code Listing 3 depicts a subset of the machine-computable section for a single measurement. This example highlights the dual role of the CDA construct: to provide highly accessible information viewable by clinicians in a concise, easy-to-read format, along with a fully encoded, machine-consumable version of the same information, capable of supporting any degree of advanced analytics and clinical workflow. It is common in fact for information in the machine-consumable section to be richer than that depicted in the XML-rendered table. For example, the XML-rendered table might present only summary or trend information, whereas it is perfectly acceptable for the machine-consumable segment to include both raw and summary information.

*“It is common in fact for information in the machine-consumable section to be richer than that depicted in the XML-rendered table.”*

Vital Signs					
Date Captured	Peripheral	Measurement	Value	Condition	Reference Range
2008-01-07 13:55:14.000	Blood Pressure	Systolic	137 mmHg	Alert	89-130
2008-01-07 13:55:14.000	Blood Pressure	Diastolic	85 mmHg	Normal	59-90
2008-01-07 13:55:14.000	Blood Pressure	Pulse	89 BpM	Normal	59-100

**Table 2:** XML-rendered Table: Vital Signs

Source: Intel Corporation, 2009

```

<title>Vital Signs</title>
...
<!-- standard encoding for Systolic readings -->
  <code code="271649006" codeSystem="2.16.840.1.113883.6.96"
    displayName="Systolic"/>
...
<!-- actual Systolic measurement -->
  <value xsi:type="PQ" value="137" unit="mm[Hg]"/>
<!-- interpretation code indicates reading is Abnormal, based upon
referenceRange cited below -->
  <interpretationCode code="A"
    codeSystem="2.16.840.1.113883.5.83"/>
...
<!-- Note the use of the IEEE EUI-64 unique peripheral DeviceID, used
to establish reference between a measurement in Vital Signs to originating
peripheral details in the Medical Equipment section -->
<participant typeCode="DEV">
  <participantRole>
    <id root="1.2.840.10004.1.1.1.0.0.1.0.0.1.2680"
      assigningAuthorityName="EUI-64" extension="1F-3E-46-78-9A-
        BC-DE-F1"/>
  </participantRole>
</participant>
<!-- referenceRange cites the lower and upper measurement thresholds
considered out-of-range or abnormal -->
<referenceRange>
  <observationRange>
    <value xsi:type="IVL_PQ">
      <low value="89" unit="mm[Hg]"/>
      <high value="130" unit="mm[Hg]"/>
    </value>
  </observationRange>
</referenceRange>

```

**Code Listing 3: Machine-computable XML: Vital Signs**

Source: Intel Corporation, 2009

*“Inclusion of this information is crucial to be able to quickly perform patient triage as well as trending analysis and population management.”*

Note also the use of Observation/interpretationCode and Observation/referenceRange in Code Listing 3, to indicate whether a particular reading is considered within or outside of the reference range for that measurement type. These data elements are optional, but are strongly encouraged as industry best practice (i.e., “SHOULD”) by the HL7 PHMR [10]. Inclusion of this information is crucial to be able to quickly perform patient triage as well as trending analysis and population management.

## Functional Status

Remote patient monitoring has a clear need for including questionnaire assessments as a part of Functional Status. Assessments can range from standard question-answer sets, recognized regionally as the authoritative protocol for a given disease condition, to proprietary question-answer sets, designed by particular institutions along with customized care plans. The standard assessments are routinely used by payers and providers alike to gauge individual patient functional status and assess overall population trending. The HITSP Long Term Care–Assessments AHIC Gap/Extension [13] lists several assessments applicable to the United States, including the Long-Term Care Minimum Data Set (MDS), the Continuity Assessment Record and Evaluation (CARE), the Outcome and Assessment Information Set (OASIS), and the Inpatient Rehabilitation Facility–Patient Assessment Instrument (IRF-PAI). There are widely recognized instruments worldwide for managing chronic disease conditions such as diabetes, congestive heart failure, asthma, or depression. Assessments can also be utilized as part of pre-qualification and patient recruitment for clinical trials.

AHIC and HITSP acknowledged the gap in the lack of specifications related to assessments, and worked with HL7 to develop the CDA Framework for Questionnaire Assessments DSTU [8]. Standardized information, templates, guidelines, schedules, and scoring mechanisms are all needed to fully comprehend assessments within the HL7 CDA. Currently, work is divided amongst several different teams, including HITSP Consultation and Transfer of Care; Quality; and Long Term Care Assessments: all are working in conjunction with the HL7 Patient Care Work Group, the HL7 Structured Documents Work Group, and a broad array of clinical and technology industry experts.

Some assessment instruments have the concept of weighted points associated with particular question responses, which can then be used to triage patients who require immediate intervention. An extension of this is the concept of a Scored Care Plan Report, with higher patient acuity associated with higher points assigned to more significant health indicators. For example, Congestive Heart Failure patients might score a 0 if they are coping well on a particular day, versus a 5 or 6 if they suddenly put on additional weight or notice swelling in their legs. The ability to encode this information by using standard CDA templates, constraints, and appropriate terminology would be extremely powerful to drive both analytics and clinical workflow.

*“There are widely recognized instruments worldwide for managing chronic disease conditions such as diabetes, congestive heart failure, asthma, or depression.”*

*“An extension of this is the concept of a Scored Care Plan Report, with higher patient acuity associated with higher points assigned to more significant health indicators.”*

*“The framework is very thorough and nuanced in its handling of diverse use cases.”*

The great news is that both the CDA and specializations such as the HL7 PHMR permit the addition of optional sections such as Functional Status to represent this type of information. However, for a system to accurately consume and mediate the information, it would still require extensions to the specification. The work to date from the CDA Framework for Questionnaire Assessments DSTU [8] is outstanding in this regard, in making such rapid progress in such a short period of time. The framework is very thorough and nuanced in its handling of diverse use cases, both enabling early adoption while parts of the specification are yet to be finalized, as well as demonstrated capability to instrument very complex assessments, as evidenced by the derivative work on the Minimum Data Set Version 3 (MDSV3) [8]. We urge the SDOs to continue to aggressively pursue work in this area, essential to all forms of RPM, long-term care, and other clinical settings.

In Table 3, we show an example of how we might render assessment responses in human-readable form.

<b>Functional Status</b>		
<b>Session date/time: 2008-01-07 13:53:04.000</b>		
<b>Assessment</b>	<b>Answer</b>	<b>Score</b>
How are you feeling today compared to yesterday?	Worse	5
Have you taken all of your prescribed medication over the past 24 hours?	Yes	0
Did you need to take any extra diuretic medication in the past 24 hours?	Yes	10
Did you need to use any extra oxygen in the past 24 hours?	Yes, more than normal	5
<b>Total Score:</b>		<b>20</b>

**Table 3:** XML-rendered Table: Functional Status  
Source: Intel Corporation, 2009

High priority should be placed on standardizing the templates to encode patient assessments, including terminology, along with the concept of assessment scales or scores where relevant.

**Plan of Care**

Multiple SDOs and HITSP working groups are planning to address Plan of Care as it relates to Consultations and Transfers of Care [5]. This is another example of the power and flexibility of the CDA architecture. While a traditional treatment plan might be best characterized by a set of multidisciplinary protocols and a follow-up planned upon hospital discharge, in RPM it takes on a different character altogether. Plan of Care includes functional and other nursing assessments (not to be confused with physician assessments of patient status, which are located in the CDA “Assessment and Plan” section).

*“A Plan of Care is used to capture ‘What did we ask the patient to do?’ whereas the combination of daily assessments and vital sign collection is the answer to ‘What did the patient actually do?’ ”*

A Plan of Care is used to capture “What did we ask the patient to do?” whereas the combination of daily assessments and vital sign collection is the answer to “What did the patient actually do?” Thus, the combination of Plan of Care, Functional Status, and Vital Signs can be used to gauge patient adherence to the agreed-upon treatment plan, and can be used as a basis for long-term outcomes analysis with respect to RPM. We would like to see the SDOs create Plan of Care section constraints that cover both definition and scheduling of standard assessments and vital signs collection. Such constraints would be machine-consumable by different systems and encoded, by the use of international terminology standards, to promote advanced analytics.

*“We would like to see the SDOs create Plan of Care section constraints that cover both definition and scheduling of standard assessments and vital signs collection.”*

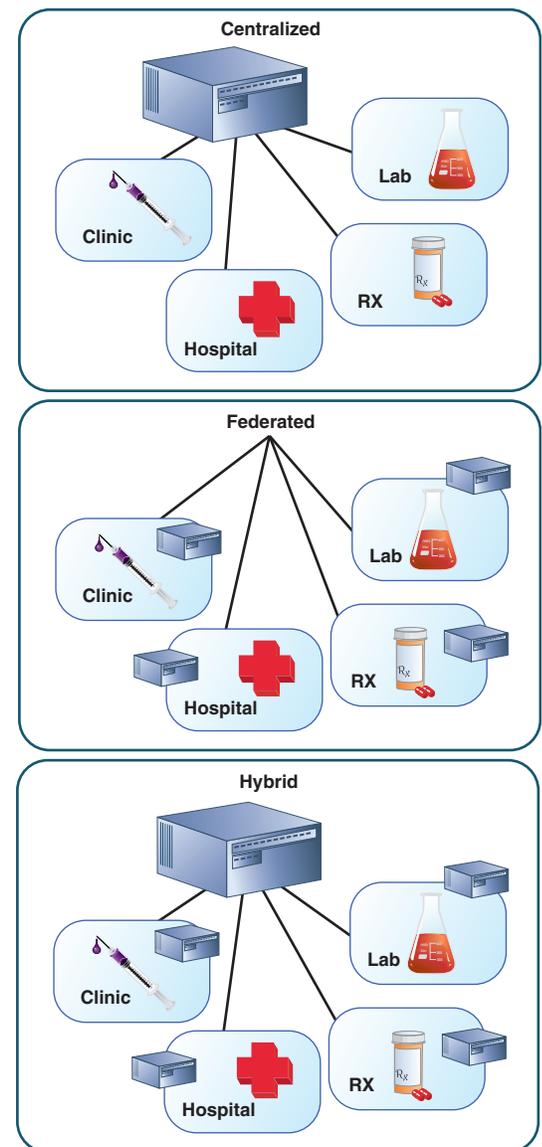
## Service Oriented Architecture (SOA) Principles

Remote patient monitoring truly represents a superset of healthcare integration use cases, sitting at the hub of a complex coordination of care — across clinical specialists, home care, lab, pharmacy, hospital, and assisted living facilities. Chronic disease management adds a further layer of complexity, given that most home-care and remote monitoring systems were developed as proprietary systems with only a passing acquaintance with healthcare and technology standards. Also, it is not uncommon for these CDM systems to be used alongside one or more of the major commercial EMR systems.

SOA provides the essential grounding, agility, and extensibility to manage and reduce complexity when integrating healthcare systems, services, and information. It is adaptable to a challenging and ever-changing business climate, and represents a proven return on investment [1, 2, 11, 12]. SOA provides the necessary bridge between legacy and proprietary environments and moves us towards standards-based deployments that can scale to handle many network end points and a rich diversity of healthcare data services. In this section we outline key considerations and SOA principles when establishing an RPM solution.

## Flexible, Scalable Architecture to Support Any Deployment Model

With healthcare integration, it is important to leverage architecture that is flexible across different deployment models and data-use agreements. Figure 3 depicts three common deployment models, wherein health information is maintained in a centralized, federated, or hybrid database model. The model selected largely depends upon data-use agreements in the region — whether to maintain data centrally to a given region, remotely (federated), or as a hybrid model of the two. The centralized model is optimum both in terms of performance and access to a consistent, normalized data set, suitable for both healthcare delivery and clinical research. However, the centralized model requires the political will by all participants, public and private alike, to agree to centralized data sharing and data-use agreements.



**Figure 3: Data Origin Flexibility**  
Source: Intel Corporation, 2009

*“Due to concerns over performance and availability, deployment models frequently shift over time from federated to hybrid.”*

Due to concerns over data sharing, ownership, and local control, the federated model is frequently chosen over the centralized or hybrid. When a discharge summary or lab report is required, a record locator service query is issued from the center to each of the federated or member organizations. If the federated service is available and the appropriate agreements are in place, one or more relevant documents are returned that pertain to the patient in question. Due to concerns over performance and availability, deployment models frequently shift over time from federated to hybrid, maintaining a small set of demographic data and centralized pointers to records maintained at the perimeter.

The federated model can be quite effective for very large, distributed data sets, but the records must be normalized at the edge by the use of agreed-upon terminology standards. The political will to use such standards can be even more challenging to achieve than that required for the centralized model. An excellent example of the federated model is the caBIG (Cancer Biomedical Informatics GRID at [cabig.nci.nih.gov](http://cabig.nci.nih.gov)), which links physicians, patients, and researchers to clinical, cancer, and genomics repositories distributed worldwide in a standard normalized fashion.

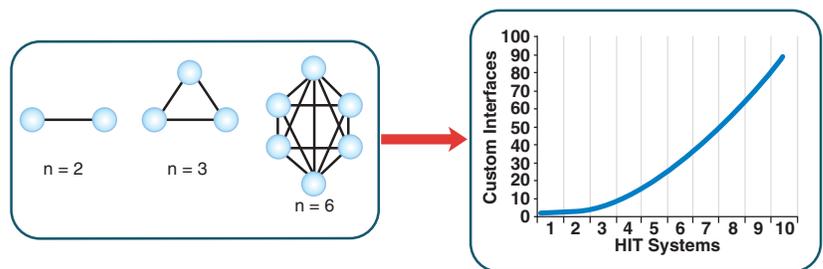
*“A key success factor in deploying RPM is to leverage a flexible architecture which can scale from small institutions, to regional health information exchanges, to national networks.”*

Remote patient monitoring requires the integration of health information from a variety of disparate sources. SOA is well suited to adapt and extend to this level of service, data origin, and terminology complexity. A key success factor in deploying RPM is to leverage a flexible architecture which can scale from small institutions, to regional health information exchanges, to national networks. Finally, the deployment model and technology selected must readily scale to processing at the core or at the edge of the network.

**Service Extensibility, Virtualization of End Points**

Traditional peer-to-peer approaches to integration lead to the  $N^2$  problem as depicted in Figure 4, in that each and every application requiring integration causes a geometric expansion of up-front cost and ongoing maintenance. In healthcare integration, the  $N^2$  problem is made manifest by the inconsistent adoption of healthcare and technology standards by legacy and proprietary systems. When a new application joins the network, each and every adapter has to be modified, in addition to the new application.

*“In healthcare integration, the  $N^2$  problem is made manifest by the inconsistent adoption of healthcare and technology standards by legacy and proprietary systems.”*



**Figure 4:  $N^2$  Problem in Healthcare**  
Source: Intel Corporation, 2009

Integration Brokers change the cost model from geometric to linear, but have their own share of challenges, with the risk of establishing heterogeneous “islands” of integration. Integration Brokers rely upon a hub-and-spoke architecture, creating a single point of failure by routing all messaging traffic through a central hub. Only with a standardized information model, service extensibility, and virtualization of end points, provided by an Enterprise Service Bus (ESB), can one completely address the  $N^2$  problem.

The heart of the  $N^2$  problem lies in the simplistic framing of integration as a two-dimensional use case. When we frame the exchange of health information as a simple, bidirectional exchange between a total of two points, we obfuscate the actual complexity involved. In reality, the RPM exchange requires multiple data sources, or network end points, in order to complete the CDM view of the patient, including vital signs, assessment responses, functional status, lab results, prescriptions, diet, exercise, treatment plan, and clinical notes, to name just a few. The information needs to be addressable by using a standardized information model, and over time, each of the data services should be exposed by using a standard set of query and retrieval methods.

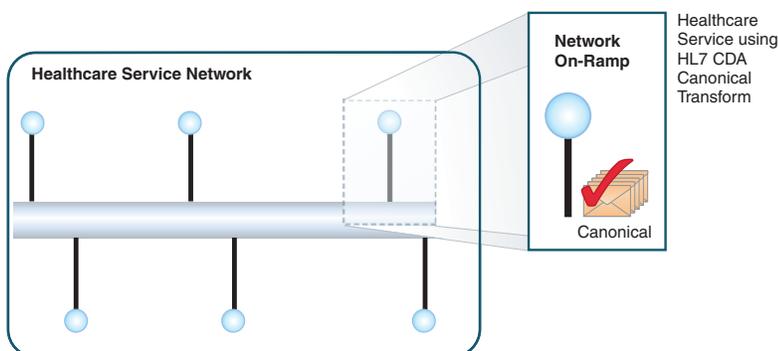
A service network architecture allows for building the “on-ramp” once, with no adapter maintenance required, as other applications join or leave the network. Service extensibility serves to virtualize the end points, abstracting the details of transport protocols and peer-to-peer connections. Services can be dynamically registered, discovered, and rerouted to scale as performance and reliability needs dictate.

### Network Compute Model

The HL7 v3 CDA Release 2 [4] constrains the v3 RIM and leverages the full richness of its healthcare informatics model and standardized terminology, delivering computable, healthcare information as well as human-readable clinical documents. By first composing all of the telehealth data to the HL7 v3 CDA Release 2 (i.e., the network *on-ramp* in Figure 5), it becomes a repeatable exercise then to perform any secondary transforms to legacy or proprietary messaging protocols and local terminology (i.e., the network *off-ramp*).

*“The heart of the  $N^2$  problem lies in the simplistic framing of integration as a two-dimensional use case.”*

*“Services can be dynamically registered, discovered, and rerouted to scale as performance and reliability needs dictate.”*



**Figure 5:** Service Network Architecture

Source: Intel Corporation, 2009

This integration pattern accelerates adoption of the latest healthcare informatics standards, while lowering the barriers of adoption for smaller organizations that need to proceed at their own pace.

A robust network informatics exchange model can be used to establish trust at the network level — a healthcare *dial tone*. Peer systems may validate, authenticate, and audit the encrypted XML payloads at any point in the network. Moreover, the network compute model enables the ability to route, compose, and decompose fine-grained business objects according to national and regional, legal and regulatory, privacy, data protection, and patient consent requirements.

*“Since the service location is virtualized, and the service implementation is encapsulated, a service can be readily created or replaced without impacting existing service consumers.”*

### **Pluggable Services in the Cloud**

SOA provides the ability to leverage services available within the data center or across the Internet. New services can be brought online and directly utilized by network participants, without requiring additional modifications to each end point. Since the service location is virtualized, and the service implementation is encapsulated, a service can be readily created or replaced without impacting existing service consumers. The OMG/HL7 Healthcare Services Specification Project (HSSP at <http://hssp.wikispaces.com/>) is working to define standard Web service methods to access critical healthcare infrastructure services, including entity identity, controlled terminology, record locator, decision support, and clinical research filtered query services. Similarly, there is a need for advanced healthcare data services, such as drug interaction checks, adverse event reporting, clinical trial recruitment, and public health reporting. SOA design methodology allows for incremental implementation, at first utilizing simple data match routines and then, when the complexity of exchange dictates, readily switching to industry-strength identity and terminology services, all without changing the service interface.

*“What is required, however, is deep healthcare domain expertise, a keen sense of customer requirements, and an understanding of the context in which the system will be used.”*

### **Deployment Considerations**

Effective RPM deployment requires the application of industry best practices with respect to information technology, data center operations, enterprise service delivery, and robust security and privacy measures. The technical challenges in healthcare are not insurmountable; rather, they can be solved by using well-known solutions and design patterns. What is required, however, is deep healthcare domain expertise, a keen sense of customer requirements, and an understanding of the context in which the system will be used. In order to fully realize the potential of RPM, we must arrive at the right combination of technology and process.

### Patient Acuity and Mode of Healthcare Delivery

Patient acuity and the concomitant mode of healthcare delivery are arguably the most important determinants of RPM requirements. Patient acuity determines the level of monitoring and likelihood that intervention will be required, the frequency of data collection, the criticality of reference ranges and alerting mechanisms, and the relative intolerance for data latency. The mode of healthcare delivery — whether it be a wellness coach, a visiting nurse, community outreach, an assisted living facility, hospital discharge monitoring to avoid readmission, population management, or patient-empowered healthcare — tends to be matched to patient acuity and provider service level agreements. Contact with the patient, and the relative need to process the clinical findings, will therefore range from occasional, monthly, quarterly, daily, hourly, or perhaps even more frequent when a sudden decline in health is detected. The duration of RPM deployments could be measured in weeks in the case of hospital discharge monitoring, months in the case of high-risk pregnancies, or years when monitoring elderly patients with co-morbidities.

### Data Latency and Modes of Transmission

As discussed earlier, tolerance for data latency is largely determined by patient acuity of the target population. Relatively healthy patients, coupled with wellness coaches, can tolerate high data latency with summary reports over periods as much as a few months at a time. High-acuity patients require more frequent monitoring, with data latency approaching *near real-time*. High data latency can readily be accommodated by scheduled, file-oriented, and store-and-forward processes to perform data integration. In contrast, low data latency requires end-to-end integration performed via Web services every few minutes, where the incremental transmission is closer to a single patient session, containing the latest raw measurements and assessment responses, rather than a complete trend analysis of the past period. Alerts and notifications can be generated via real-time, event-driven triggers, whereas batch operations and monthly summary reports can be scheduled to occur during off-hour processing.

### Volume and Quality of Data

RPM involves significantly more data than what is typically anticipated for an EHR, such as a clinical encounter. Patients may be instructed to take vital sign measurements multiple times per day in addition to responding to various assessment questions. One of the chief areas of ongoing investigation is the optimal level of summarization of the PHMR. Different clinicians will likely want a full range of options, from daily, monthly, or quarterly to a filtered summary, depending upon patient acuity and the mode of healthcare delivery.

*“The mode of healthcare delivery tends to be matched to patient acuity and provider service level agreements.”*

*“Alerts and notifications can be generated via real-time, event-driven triggers, whereas batch operations and monthly summary reports can be scheduled to occur during off-hour processing.”*

*“Different clinicians will likely want a full range of options, from daily, monthly, or quarterly to a filtered summary, depending upon patient acuity and the mode of healthcare delivery.”*

Once the report design is optimized, additional adaptations may be necessary to the recipient system in order to fully leverage the additional rich data types, process alerts, and triage patients based on clinical findings. In particular, it is unlikely that recipient systems are prepared to work with patient-specific reference ranges, threshold violations, assessment questionnaires, or weighted scores for industry standard protocols. Some systems are unprepared to process datetime stamps on individual measurements, because of the prior exclusive focus on clinical encounters in office settings. In other words, while a given office medical system might record the date of the office visit, it rarely records the time of an individual measurement. While the concept of an RPM “patient session” can be likened to an office visit, the recipient medical system is unprepared to process the sheer volume of RPM sessions and measurements.

*“All points along the end-to-end data flow should be instrumented and monitored for effective operation and patient safety.”*

As clinical systems and processes evolve to process data from RPM, the need for more sophisticated methods of patient triage, alert, and notification will also be required. For example, a large number of normal readings from a moderately-sized patient population will quickly outpace the most efficient of care-manager organizations, if workflows require the manual acknowledgement of all readings, rather than triage based on out-of-range measurements. Conversely, if an organization becomes overly dependent upon the direct integration of RPM data without also developing adequate means for systems monitoring, an undetected outage or transmission failure might inadvertently create a false impression that patient readings are within normal limits. It is critical, therefore, to develop adequate systems monitoring and failsafe methods. For example, reports should be appropriately annotated with synchronized datetime stamps, indicating both the time of report generation and the time of the last data transmission. All points along the end-to-end data flow should be instrumented and monitored for effective operation and patient safety.

*“We have identified the need to define tiers of thresholds to separately drive patient and clinician workflows and modes of intervention.”*

Threshold violations, especially life-threatening ones, need to trigger specific workflows that are customizable by practice, by co-morbidities, by target populations, and by individual patients. We have identified the need to define tiers of thresholds to separately drive patient and clinician workflows and modes of intervention, ranging from patient education, to clinician referral, to emergency hospital admission. There is also the need to capture both the trigger event and the clinical intervention as part of analytics. For example, a patient’s oxygen saturation falls dangerously low, which triggers an alert and results in some form of patient intervention — whether a phone call, an SMS text message, a video conference with a clinician, or a house call from a visiting nurse. The clinical intervention may result in a change in protocol, a lab order, a medication change, or hospitalization. Each of these events needs to be associated with a standard measure of outcomes in order to support analytics for evidence-based medicine and drive further improvements to healthcare.

### Clinician Workflow and Reimbursement Model

Another important consideration in the integration of RPM information is clinician workflow and the reimbursement model. Some jurisdictions require that a clinician manually review and accept each and every measurement prior to importing the data into the institutional EHR. This follows standard clinical practice of signing off when reviewing external lab results, yet again, the volume of data is fundamentally different when considering RPM.

Some institutions extend the system boundary of the EHR to encompass any automated data capture but draw the line at information that is *patient-reported* or otherwise manually entered, such as a PHR containing diet and exercise journal entries. Data that are grandfathered in as *automatic data capture* might not require the manual approval step, whereas patient-reported data may be reviewed but perhaps not incorporated into the institution's legal record. Annotating the data stream with the source and method of reporting helps to account for these differences in policies.

Accommodations are required for both the level of summary and raw information in a given report. Streamlined mechanisms are required to process messages through the clinical *inbox*, along with careful consideration as to what level of clinical staff might be able to process what level of data on behalf of the doctor, in order to potentially offload this manual step.

Further, the clinical reimbursement model is frequently called into question with respect to RPM. Some reimbursement models attempt to equate RPM with an office visit, while others only reimburse when the patient establishes and maintains good tolerance of pre-established thresholds. Each of these considerations will have an impact on the rate of adoption of RPM, especially when combined with additional processing overhead on the part of the physicians to periodically review the results.

### Trans-border Data Flow Considerations

Careful attention to detail will be required for any deployment in which integration is planned across borders of state/provinces, regional, or national boundaries. Privacy and data protection laws are rapidly changing worldwide, with significant penalties for mishandling of data and breach of privacy. Advanced workflow, transformation, and routing engines will be required to comply with local data protection regulations and policies. Special consideration is due when determining where to locate a primary or alternative data center hosting patient data, since a number of countries require that protected health information (PHI) not cross national boundaries. To manage and track patient consent and negotiate appropriate data use, business associate and data controller/supplier agreements are all essential, regardless of whether or not information crosses any recognized governmental boundaries.

*“Annotating the data stream with the source and method of reporting helps to account for these differences in policies.”*

*“Some reimbursement models attempt to equate RPM with an office visit, while others only reimburse when the patient establishes and maintains good tolerance of pre-established thresholds.”*

*“Privacy and data protection laws are rapidly changing worldwide, with significant penalties for mishandling of data and breach of privacy.”*

*“While clinical data might be easily segregated between different systems of record, it is highly likely that every system maintains its own copy of demographic data.”*

*“Provisions are made to disable manual edits in the recipient systems, or at least ensure that processing detects, logs as an exception, and overrides any unauthorized changes.”*

*“Common identity mismatch errors tend to require a small staff to resolve and maintain on an ongoing basis.”*

### **Identifying Systems of Record**

Identifying a single system of record (i.e., a single authoritative source for each and every data element) is essential to any successful integration project and frequently overlooked in applications such as RPM. It is typical for even small organizations to already have multiple systems in place for purposes of chronic disease management, population management, a primary EHR data repository, a separate system for lab results, etc. The addition of telehealth data likely represents the addition of one or more systems to an already complex and disorderly mix.

A key area of concern is patient and clinician demographics. While clinical data might be easily segregated between different systems of record, it is highly likely that every system maintains its own copy of demographic data. Considerations must be given both from a systems and a workflow perspective to demographics synchronization, import, and ongoing maintenance. The older systems likely do not have a method to disable manual edits to demographics, yet one must ensure that clinicians are always working from an authoritative source of patient and clinician demographics and contact information.

In an advanced integration deployment, the demographics system of record updates the recipient systems with the latest information, including translation of identity to the recipient system, via an entity identity service (EIS). Provisions are made to disable manual edits in the recipient systems, or at least ensure that processing detects, logs as an exception, and overrides any unauthorized changes.

In mixed environments with both legacy and newer systems, a complex scheme of automated demographics integration along with a carefully designed business process is required. A central system can be configured to synchronize demographics to each of the recipient systems. When manual edits in each system cannot be disabled, they must be controlled via business process, training, and careful oversight to ensure that changes in demographics are only entered into the central system. Common identity mismatch errors tend to require a small staff to resolve and maintain on an ongoing basis.

As healthcare systems integration becomes more complex, encompassing multiple end points and service providers, each with their own independent systems of record, it becomes paramount to employ an industry-strength EIS to accurately address the identity match problem. Industry leaders in EIS leverage advanced stochastic algorithms for matching against multiple demographics attributes to disambiguate identity. The OMG/HL7 Healthcare Specifications Services Project (HSSP) is working to define standard Web service interfaces for common capabilities like EIS, such that different commercial services may be deployed without requiring a change to the implemented interface.

## Customization Requirements

There are a number of deployment considerations when establishing a remote patient-monitoring solution. The AHIC use cases are foundational to defining routine healthcare interactions and processes, required data elements, and terminology constraints to standardize the exchange. It is also important to distinguish the areas of *local variation* and future development, such as those identified in the RPM sequence and interaction diagrams (Figures 1 and 2, respectively). It is important to control the level of customization required for any given solution to something that delivers real value to the customer, both in the short-term and in the reasonable future, yet is practical enough to represent low maintenance over time. While anything is technically feasible, it is not practical for a business to develop a system to be all things to all people. It is critical to establish up front some of the key business drivers, including patient acuity, target mode of healthcare delivery, and the relative tolerance for data latency. From this baseline, customization mechanisms can be established to allow for local variation, leveraging codeless configuration changes to metadata, rather than requiring a code recompile and system overhaul for each deployment.

*“While anything is technically feasible, it is not practical for a business to develop a system to be all things to all people.”*

## Conclusion

Remote patient monitoring represents a critical intersection of healthcare information integration, embodying the need for healthcare informatics standards, careful consideration of workflow and system deployment tradeoffs, and direct engagement with the patients and clinicians who work with the system. The use of HL7 CDA helps to accelerate adoption of healthcare standards by properly constraining the rich schema and vocabulary of the HIM, and lowering the barriers of entry through incremental evolution. The use of SOA design principles enables us to respond to changes in business drivers and adapt to the complexity of healthcare integration end points. Terminology standards drive computable information which in turn enables advanced analytics, clinical research, and transformational healthcare delivery. We are actively working with the SDOs in pursuit of future enhancements to the existing healthcare informatics standards.

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## Acknowledgements

Special thanks to Dr. Robert H. Dolin, co-chair of the HL7 Structured Documents Committee, who assisted us in developing our initial CDA models.

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