Enhanced Medication Histories

A Guide to Implementation in a Health Information Exchange

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Preface

This project was funded as an Accelerating Change and Transformation in Organizations and Networks (ACTION) task order contract. ACTION is a 5-year implementation model of field-based research that fosters public–private collaboration in rapid-cycle, applied studies. ACTION promotes innovation in health care delivery by accelerating the development, implementation, diffusion, and uptake of demand-driven and evidence-based products, tools, strategies, and findings. ACTION also develops and diffuses scientific evidence about what does and does not work to improve health care delivery systems. It provides an impressive cadre of delivery-affiliated researchers and sites with a means of testing the application and uptake of research knowledge. With a goal of turning research into practice, ACTION links many of the Nation's largest health care systems with its top health services researchers. For more information about this initiative, go to [http://www.ahrq.gov/research/action.htm](http://www.ahrq.gov/research/action.htm).

This project was one of seven task order contracts awarded under the Improving Quality through Health IT: Testing the Feasibility and Assessing the Impact of Using Existing Health IT Infrastructure for Better Care Delivery request for task order (RFTO). The goal of this RFTO was to fund projects that used implemented health IT system functionality to improve care delivery. Of particular interest were projects that demonstrated how health IT can be used to improve decision support, automate quality measurement, improve high-risk transitions across care settings, reduce error or harm, and support system and workflow design, new care models, team-based care, or patient-centered care.
Acknowledgments

We are very grateful to HealthNet, Inc. of Indianapolis for allowing one of its community health centers to participate in this study.
Introduction

This Implementation Handbook describes the Enhanced Medication History Project (EMHP). The EMHP was constructed at Indiana University and Regenstrief Institute under the Agency for Healthcare Research and Quality (AHRQ) Contract HHSA2902006000131: “Improving Laboratory Follow-up by Delivering an Enhanced Medication List to Outpatient Physician Practices.” The goal of this project was to design, develop, and evaluate a method of providing Indiana Network for Patient Care (INPC) medication data to ambulatory primary care practices, with the intent of enhancing health care quality and safety.

What Is the INPC?

The INPC is a community-wide electronic medical record (EMR) that was developed in the 1990s, and began to operate in 1995. The Regenstrief Institute, Inc., has developed and implemented all of the software and systems that underpin the INPC, and operates the INPC on behalf of its participants. The participants of the INPC include all five of the major hospital and health care systems in Indianapolis as well as hospitals in surrounding counties. The participants of the INPC also include several large physician practices, two independent commercial laboratories, public health agencies, payors, and the Indiana State Medicaid program. The number of participants grows as new institutions are added.

Currently, the INPC stores over 900 million discrete data items, representing more than 6.1 million residents of Indiana and neighboring States. Important categories of data include: laboratory results, radiology, pharmacy, transcription, coded diagnoses and procedures, and inpatient and outpatient encounters.

The INPC is a centrally managed, federated clinical data repository. Thus, each institution’s data is physically located on separate digital storage media. However, this data is managed in a uniform, standardized way by the Regenstrief Medical Record System. Each patient’s data is protected in accordance with HIPAA guidelines for privacy and security. Such a uniform, standardized approach allows a physician working in an emergency department to view a patient’s previous care information from all participating institutions as a single virtual medical record.

What Is the EMHP?

The EMHP was developed under a contract with AHRQ. It was developed in 2008 and was turned on at the first clinic site in December 2008. Briefly, when a patient arrives for an ambulatory health care visit, the EMHP carries out processes to assemble and print a Medication History for that patient. Although the processes are complex, they occur within seconds, so that the Medication History prints on a printer at the clinic within a minute or so of the patient’s arrival there. These processes are described in the remainder of this Implementation Handbook.

Typically, the clinic staff take the Medication History from the printer and place it on the patient’s chart before giving that chart to the physician. The physician reviews the chart, and the Medication History, prior to the encounter with the patient. Often, the physician discusses the
Medication History with the patient during the Encounter, as part of the general process of Medication Reconciliation. See Figure 1 for a sample Medication History.

A Decision Support Engine searches for aspects of the Medication History that might indicate problems of health care quality and safety. Specifically, there are four categories of decision support:

1. Drugs in the absence of sufficient laboratory monitoring.
2. Drugs in the presence of abnormal laboratory test results.
3. Drugs to be avoided in the elderly.

If any of these categories of problems are discovered, a decision support reminder is printed on the Medication History, under the offending medication.
## Medication History: June 23, 2009

**Pt:** SAMPLEPATIENT, JOHN THE  
**MR#:** 1234567  
**Gender:** M  
**DOB:** 1901-Jan-01

### Medication Details

- **Amlopidine (AMLOPIDINE Bitartrate)**
  - 500 mg tablets: 40 mg, 80 mg, 120 mg, and 160 mg.
  - **Primary Care:** COORDINATED, PREPARED.
  - **Previous處方:** COORDINATED, PREPARED.

- **Furosemide (FUROSEMIDE)**
  - 40 mg tablets: 20 mg, 40 mg, 80 mg, and 160 mg.
  - **Primary Care:** COORDINATED, PREPARED.
  - **Previous處方:** COORDINATED, PREPARED.

- **Gabapentin (GABAPENTIN)**
  - 300 mg tablets: 300 mg, 600 mg, and 900 mg.
  - **Primary Care:** COORDINATED, PREPARED.
  - **Previous處方:** COORDINATED, PREPARED.

- **Glipizide SR (GLIPIZIDE SR)**
  - 5 mg tablets: 5 mg, 10 mg, 15 mg, and 20 mg.
  - **Primary Care:** COORDINATED, PREPARED.
  - **Previous處方:** COORDINATED, PREPARED.

- **Losartan (COVARTAN)**
  - 50 mg tablets: 50 mg, 100 mg, 200 mg, and 400 mg.
  - **Primary Care:** COORDINATED, PREPARED.
  - **Previous處方:** COORDINATED, PREPARED.

- **Metoprolol (METOPROLOL Tartrate)**
  - 50 mg tablets: 50 mg, 100 mg, 200 mg, and 400 mg.
  - **Primary Care:** COORDINATED, PREPARED.
  - **Previous處方:** COORDINATED, PREPARED.

- **Nitroglycerin SL (NITROGLYCERIN)  
  - 40 mg tablets: 40 mg, 80 mg, and 120 mg.
  - **Primary Care:** COORDINATED, PREPARED.
  - **Previous處方:** COORDINATED, PREPARED.

- **Pioglitazone (ACTOS)**
  - 30 mg tablets: 30 mg, 60 mg, and 90 mg.
  - **Primary Care:** COORDINATED, PREPARED.
  - **Previous處方:** COORDINATED, PREPARED.

- **Simvastatin (SIMVASTATIN)**
  - 20 mg tablets: 20 mg, 40 mg, and 80 mg.
  - **Primary Care:** COORDINATED, PREPARED.

### Relevant Lab Results

- **ALT** (Serum alanine aminotransferase)**
  - Value: 27.0 U/L  
  - Reference: [7-40]

- **CFT** (C-reactive protein)**
  - Value: 109.0 mg/L  
  - Reference: [1-118]

- **Hemoglobin (Hgb)**
  - Value: 12.0 g/dL  
  - Reference: [12.0-16.0]

- **Platelet Count**
  - Value: 4.6 x 10^5/L  
  - Reference: [150-400]
A Randomized Controlled Trial is under way to determine how the EMHP affects health care quality and safety. Medication Histories are printed for Intervention patients, but not for Control patients. The research hypothesis is that, gradually, the use of Medication Histories will improve health care quality and safety for the Intervention patients: as measured by the number of decision support reminders. The average number of decision support reminders on those Medication Histories should start to decrease, as the problems are corrected.

**Trigger: Arrival of the Patient**

Figure 2 illustrates the steps taken to activate the EMHP software.

Figure 2. How the EMHP software is activated by the arrival of a patient for a clinic visit

In order to generate and print a Medication History, the EMHP Process requires a trigger. The trigger is the arrival of the patient. When a patient arrives at an ambulatory health clinic, he/she stops at the front desk to register. The front desk staff enter the patient’s information into the electronic registration system.
Each clinic may have its own electronic registration system. Implementation and use of the registration system is beyond the scope of this project. Each clinic may choose whichever electronic registration and scheduling system serves its needs best. From the perspective of the “Enhanced Medication History Project”, the only things that matter are—

- The clinic registration system must be able to generate an electronic message, in a consistent format, at the time of a patient’s arrival.
- That message must contain information allowing us to identify the patient.
- The clinic registration system must send that message electronically to the INPC.

Typically the message follows the HL7 ADT message format (see below); but it is possible to contemplate a system which emits a non-HL7 message. However, such a non-HL7 message would then require an intermediate step for conversion to an HL7 ADT message.

**HL7 ADT Message**

The electronic registration system at each clinic creates an HL7 ADT (“Admission, Discharge, Transfer”) message at the time of a patient’s arrival. See Figure 3 for a sample ADT message.

We recommend using the ADT^A04 message type, and using HL7 version 2.3 or greater. We recommend following the HL7 standard format completely. In reality, however, many institutions do not follow the HL7 standard completely. Some institutions add non-standard segments to carry additional information. Some institutions put the wrong information in the wrong field. If such errors cannot be fixed, a workaround is possible. What is important is that each institution be clear and consistent about the values found in each field; and that the sending application and the receiving application agree about the data carried in each field. Of course, the easiest way to come to agreement is to follow the standard.

As in the above example, the most important segments in an ADT message are the MSH (Message Subject Header), the PID (Patient Identification) and the PV1 (Patient Visit) segments. Each segment has multiple fields, separated by the vertical bar (“pipe”). Important fields in the sample ADT message include the “Sending Application” (e.g., PRACT_MGMNT, as in the above Figure), the “Sending Facility” (e.g., RED_CROSS_CLINIC), and “Location” (e.g., DOWNTOWN_SITE). We use the information in these three fields to determine where to send our reports. This information could also be used to generate different reports for different sites.

Also important is most of the data in the PID segment, as proper identification of the patient is crucial. Note that the clinic registration system is aware of only one medical record number (e.g., 12345). One of the challenges, and features, of our system is the ability to match this
medical record number to the medical record numbers of other health systems. We also use the patient’s name (e.g., DOE^JANE^R), date of birth (e.g., 19700502), gender (e.g., F), ZIP code (e.g., 46202). The Social Security Number (e.g., 123121234) is not essential, but can be used to confirm a questionable match.

**Patient Arrival Message Sent from the Clinic Registration System to the INPC**

The HL7 ADT message described above is sent from the clinic registration system to the INPC over the internet. In order to ensure the privacy and confidentiality of data transferred in real time over the internet, data should be sent through an IPSec VPN tunnel. This requires use of a VPN concentrator, a firewall with VPN capability or any other device capable of creating a LAN-to-LAN VPN tunnel. This also requires a continuous Internet connection with sufficient bandwidth to support the message volume.

The INPC Server receiving this HL7 ADT message is also receiving hundreds of other HL7 messages each minute. The INPC Server runs a Message Processor which decides what to do with each message. The Message Processor examines a few fields in each HL7 message it receives. In this case, the Message Processor examines the Sending Application, the Sending Facility, and the Message Type. If these fields match a predetermined listing, the Message Processor simply routes the HL7 ADT message to the EMHP software. Other messages are routed to other systems: for example, public health reports, laboratory results, hospital discharge notifications, and many more, all arrive to the INPC concurrently, and need to be routed to the appropriate software system.

Under ideal conditions, these electronic messages travel instantaneously: the trigger message is sent out by the Clinic Registration System, forwarded by the Message Processor, and received by the EMHP software in under a second. Unfortunately, some delays—sometimes many minutes long—have been noted. Typically this happens when the forwarding slows down, if it is overwhelmed by a large backlog of messages from other systems.

With one clinic, we found it useful to use Mirth, an open source HL7 integration engine. The Mirth engine examines all messages produced by this clinic’s registration system, applies filters to exclude some messages, and then sends the remaining desirable messages over the internet to the INPC server. The Mirth filters exclude children younger than 18, and exclude messages that indicate an event, other than a patient’s arrival for an office visit (e.g., a rescheduled appointment, or arrival for a blood test). We used the Mirth engine in order to make things easier for the Information Technology personnel at the clinic, to remove as much of their workload as possible.

**EMHP Software Controls Generation of a Medication History**

From this point on, the EMHP software takes control. The EMHP software is completely written in Java. Simplistically, the EMHP software can be viewed as receiving one input: the HL7 ADT message string (described above); and producing two outputs: a printed document, and a database for research analysis. Of course, just as any high quality software, the EMHP software also writes descriptions of all events to a log file, and sends out notifications of any
problems to program developers. The EMHP software has a user interface (see Figure 4 for screenshot) intended for software developers to allow easy investigation of any problems.

The EMHP software takes the following steps (each described in more detail below):

1. Obtains a CCD (“Continuity of Care Document”)
2. Randomizes patients to “Intervention” or “Control”
3. Obtains decision support reminders, and inserts them into the CCD
4. Formats CCD
5. Prints the Medication History

See Figure 5 for an overview illustration of the steps taken by the controlling EMHP software to generate and print an Enhanced Medication History.

Figure 4. Developer interface for the Enhanced Medication History Processor
EMHP Obtains the CCD

The Continuity of Care Document (CCD) is an XML file. It is an HL7 version 3 document, based on the HL7 Reference Information Model. The CCD specification is a standard, developed to allow health care entities to exchange a patient summary clinical document. The CCD specification clearly states the syntax, semantics, and encoding to be used to create a patient summary, which can then be shared with another health care entity. The CCD standard has been further constrained by the HITSP (Health Information Technology Standards Panel) of the U.S. Department of Health and Human Services. This HITSP construct—commonly referred to as the C32 construct—is the one we used to guide our development of the CCD. Please see the HITSP Web site (http://www.hitsp.org) where the C32 construct is freely downloadable.

We use the CCD internally in the EMHP as an “envelope”—a convenient way to store a patient’s demographic, medication, and laboratory information. However, the EMHP does not exchange the CCD with other institutions. At the end, the EMHP transforms the CCD into a printed document, and prints the piece of paper. Nevertheless, it is important to point out that it
would be relatively easy for our software to send the CCD electronically to another institution’s
Electronic Medical Record.

Please note that the EMHP system only requires three limited categories of data: Demographics, Medication, and Laboratory. Therefore, we do not need to use all of the CCD modules available. Only the “Medications” and “Laboratory Results” modules are needed. Patient demographic data is carried in the main body of the CCD. Limiting the CCD to these two modules made the work of implementation easier.

The EMHP obtains a CCD by calling a different (non-EMHP) computer system at Regenstrief Institute: a CCD Generator Web Service. This is a Web Services interchange. The EMHP sends a SOAP request, which wraps the same HL7 ADT patient arrival message, to the CCD Generator Web Service. The CCD Generator returns a SOAP response, which wraps the CCD for that patient.

**CCD Generator Service**

The CCD Generator accepts the HL7 ADT message indicating patient arrival, extracts patient demographic information from the HL7 fields, and creates the shell of a CCD with that information. Then the CCD Generator obtains (1) laboratory results and (2) medication histories, and builds the “Laboratory Results” module and the “Medications” module, respectively. The CCD Generator obtains Laboratory Results by direct query of the INPC database. The CCD Generator obtains Medications by calling the INPC Medication Hub in an HL7 version 2 request/response interchange. See Figure 6 for an overview of how the CCD Generator obtains Laboratory and Medication data.
Figure 6. Overview of How the CCD Generator Obtains Laboratory and Medication Data

Note: CCD Generator Service queries the INPC Data Repository for laboratory test data, and calls the Medication Hub for medication dispensing records. Laboratory and medication data is assembled into a CCD, which is returned to the calling application.
Laboratory Results

The CCD Generator connects to the INPC Data Repository, an Oracle database, and queries it for laboratory results. It does not seek all laboratory results, only the most recent value of each test. For example, a patient may have had blood drawn dozens of times to test the Serum Potassium; but the database query retrieves only the most recent Serum Potassium, whether it was performed days ago, or years ago.

All laboratory results in the INPC Data Repository are coded with a RMRS (Regenstrief Medical Record System) code. These RMRS codes correspond closely to the LOINC (Logical Observation Identifiers Names and Codes) coding system, but they are not identical to it. Ideally, another institution implementing such a project should use the LOINC codes; however, at our institution we have many applications that were originally developed using RMRS codes. The database query returns the RMRS code, the lab value, and the datetime stamp: e.g., “Serum Potassium,” “4.4,” “mmol/L,” “200812312359.”

An important feature of the INPC Data Repository is that it stores laboratory test results from multiple institutions. Yet each institution stores its test results using its own medical record system. Therefore, a patient by the name of John Smith may have visited two hospitals in Indianapolis, and have had a Serum Potassium tested at Hospital A, and a Serum Potassium tested at Hospital B. Both Potassium test results are in the INPC Data Repository, but they are stored under different medical record numbers. It may not be immediately obvious that both test results refer to the same John Smith.

The INPC Data Repository relies on a Patient Matching Algorithm to link the different medical record numbers to the same individual. The identifiers from each institution are compared, and if there is a match—i.e., good evidence that two identifiers refer to the same individual—then those identifiers are grouped together. Strong evidence linking two patient records together includes a common medical record number, or social security number. If such a linking identifier is not present, then other evidence is examined: birthdates, names, gender, and geographic address. The algorithm makes adjustments to give stronger weight to matches with uncommon values, and lesser weight to common values. When two patient records contain evidence that they are linked, then the medical record numbers in those patient records are grouped together, to make subsequent queries easier.

This Patient Matching Algorithm is invoked to search through the laboratory test results maintained by all INPC institutions. For each laboratory test, the most recent result is obtained, even though some lab results may be provided by one health system, other lab results may be provided by another health system. All laboratory test results are placed into the CCD. See Figure 7 for a deidentified example of a laboratory test result in the CCD format.
In this example, this test result is coded as 45 “Potassium SerPl Qn” in the RMRS coding system, and coded as 2823-3 “Potassium SerPl-sCnc” in the LOINC coding system. The value of this test result is 4.10 mmol/L. The date of this test result is 20081231.

### Medication Hub Obtains Pharmacy Data from Three Sources

The CCD Generator obtains Medications by calling the INPC Medication Hub in an HL7 version 2 request/response interchange. The Medication Hub is a complex software system; for a more complete description, please refer to the following reference:


In turn, the Medication Hub calls three other systems to obtain Medication History data:

1. Wishard Pharmacy
2. SureScripts-RxHub
3. Indiana State Medicaid

Wishard Pharmacy is the multisite outpatient pharmacy of Wishard Health Services, which serves the disadvantaged population of Marion County in Indiana. Wishard Pharmacy sends a record of every medication that it dispenses to the INPC repository. The Medication Hub sends an HL7 version 2 request to the INPC repository to obtain Wishard Pharmacy data. The Medication Hub then receives an HL7 version 2 response, with a record of all medications dispensed for that patient by the Wishard Pharmacy in the last 13 months.

This transaction assumes that each patient has a Wishard MRN (Medical Record Number); without it, the Wishard Pharmacy is not able to return any medication history. But a Wishard MRN is not present in the HL7 ADT messages originating from a non-Wishard ambulatory clinic. If the HL7 ADT message does not contain a Wishard MRN, then the Patient Matching Algorithm (described above) is invoked by means of a lookup service. In some cases, a matching
Wishard MRN is found for that patient; if so, this Wishard MRN is used in the request to Wishard Pharmacy.

SureScripts-RxHub (now renamed simply SureScripts) was founded by the merger in 2008 of two separate organizations: SureScripts and RxHub. SureScripts had been keeping records of all pharmacy sales transactions in the U.S.; RxHub had been a consortium of Pharmacy Benefit Managers. Our previous work had been with RxHub and its pharmacy claims records, when RxHub was an independent organization. We continue to query the new merged entity for the pharmacy claims records previously provided by RxHub. At present, we continue to use the same interface developed by RxHub prior to the merger of the two organizations. It is possible that this interface may change, as the technical operations of the two organizations are combined.

The Medication Hub sends a request to the MEDS interface of SureScripts-RxHub. This request does not need to contain any specific medical record number. The identifiers required by SureScripts-RxHub are as follows:

- Last name, first name
- Date of birth
- Gender
- Home ZIP code

SureScripts-RxHub will not release any medication history data unless all four of these data fields match.

Finally, the Medication Hub sends a request for medication histories to a third source: Indiana State Medicaid. Indiana State Medicaid data is stored in the INPC repository, and is accessible by a web services request. Note that Medicaid is not available for all users; however, Medicaid granted special permission for use of its data in this research project.

Medicaid stores pharmacy claims for each patient in its databases; however, that data is indexed by a Medicaid identifier, unique for each patient. This Medicaid identifier is usually not sent in the ADT Patient Arrival message from an ambulatory clinic. Therefore, the Medicaid identifier is looked-up by the NHIN Gateway prior to actual query of the Medicaid database. The look-up of the Medicaid identifier uses the same Patient Matching Algorithm as required for the Wishard Pharmacy look-up, and for the Laboratory Results query across INPC institutions.

Some data sources are more current than others. The Wishard pharmacy can provide medication history data the same day that a drug was dispensed. Likewise, the pharmacy claims available through Sure-Scripts RxHub are usually current within a day. On the other hand, our version of the Medicaid database is updated less frequently, only about once a month. Therefore, a patient’s medications might not be available in the Medicaid database, even if they were dispensed several weeks previously.
Medication Hub Translates, Aggregates, and Filters Pharmacy Records

Pharmacy records are coded. Different drug coding systems exist: e.g., First DataBank, Medi-Span, Micromedex, Multum, RxNorm. However, there is one drug coding system that is ubiquitous in the U.S.: the FDA National Drug Code (NDC) system. Almost all pharmacy records contain this NDC identifier. Unfortunately, the disadvantage of the NDC is that it is not designed for clinical use. For example, in previous investigations, we found at least 227 different NDCs that refer to Amoxicillin 500 mg capsules. Each manufacturer, distributor, and repackager uses a different NDC for the same clinical product. Yet the differences in these NDCs are irrelevant, and even detrimental, for most clinical applications.

Therefore, the Medication Hub translates the NDC in each pharmacy record to a common clinical code. The primary clinical code used is the Regenstrief Medical Record System (RMRS) Dictionary Drug Term. The secondary clinical code used is the RxNorm Clinical Drug Code. The Medication Hub was originally designed for use with other Regenstrief Institute applications which use the RMRS Dictionary Drug Term. The RMRS Dictionary Drug Terms are intended to represent medications in the way clinicians order and prescribe medications, and are modified based on feedback from clinicians. For example, there is one RMRS Dictionary Drug Term to represent oral Amoxicillin (as opposed to hundreds of NDCs). The translated clinical code is inserted into the record for that dispensing event.

The Medication Hub groups dispensing records together if they share the same RMRS Dictionary Drug Term. For example, a patient might have been dispensed Amoxicillin on two different dates. On the first date, the pharmacy used one NDC for Amoxicillin; on the second date, the pharmacy used a different NDC for Amoxicillin. Both of these dispensing events will be grouped together in the Medication Hub output.

The Medication Hub filters out any medication records that are older than 13 months old. We established this cutoff, in order to provide an adequate window on a patient’s medication history, but to avoid cluttering medication histories with old data that is no longer relevant. Nevertheless, the 13 month cut-off is configurable and can be changed. This same 13-month cut-off has been used for other applications, besides the EMHP, and so far no institution has requested changing it.

The Medication Hub also attempts to find and filter out duplicates. When pharmacy records are obtained from multiple sources (i.e., the three sources used in this EMHP project), there is the possibility that some of those sources will send data on the same dispensing event. For our EMHP project, the disadvantage of duplicate data is limited to a confusing display of information on the printed document. However, it is possible to envision future implementations with more complex decision support, and those decision support rules could be affected by duplicate data. The Medication Hub saves only one record, if more than one record is retrieved referring to the same dispensing event. However, we do not yet have a implementation that can eliminate duplicates in a consistent way. Practically, thus far this has not been a large problem, and there has been little overlap between our three data sources. Nevertheless, as more data sources become available, and especially when SureScripts-RxHub provides sales transactions data, increased attention will be required for the identification and removal of duplicate data.

After the Medication Hub retrieves, translates, aggregates, and filters the pharmacy records, it returns them in an HL7 response to the CCD Generator. The CCD Generator maps the HL7 fields in this response to elements and attributes in the CCD. Thus the CCD Generator populates
the CCD “Medications” Module with this medication data, just as the CCD Generator populated
the CCD “Laboratory Results” Module with laboratory data. See Figure 8 for a sample of how
one dispensing event is represented in the CCD.

The CCD Generator returns the CCD to the EMHP software. Assembly of all the laboratory
and medication data into one CCD is undoubtedly the most complex step in the EMHP system.
Fortunately, it is usually accomplished quickly, within several seconds. Nevertheless, when there
are database problems or network problems, this step is affected. Then it may take considerably
longer to return the CCD—in some cases, the CCD Generator fails to return the CCD altogether.
In our experience, failure to obtain the CCD has been the single most common reason for failure
of the EMHP to deliver a Medication History to the clinic.

Randomization of Patients

In its current implementation, the EMHP project is a research study, and is designed to carry
out a randomized controlled trial. Therefore, patients are randomized to intervention or control
status (currently, 80 percent of patients are randomized to intervention). The Java subroutine to
assign intervention/control status has simple logic: one out of every five new patients is
designated a control patient.

However, not all patients are new: patients may have already been randomized during a
previous visit. A table is necessary to keep track of randomization status. This randomization is
indexed by a composite key: the identifier of the clinic, and the identifier of the patient (used by
that clinic system). The patient is defined as a unique combination of clinic identifier and patient
identifier. For each patient arrival, the clinic identifier and patient identifier is extracted from the
ADT message. Randomization status is looked up in the table. If the patient has already been
randomized previously, the same randomization status is used. If the patient has not been
randomized previously, a new randomization status is assigned.
Figure 8. Medication Dispensing Event placed in the CCD

In this deidentified example, the medication is coded as 312615 “Prednisone 20 MG Oral Tablet” in the RxNorm coding system; 00591544301 “PREDNISONE” in the NDC coding system; 140 “Prednisone” in the RMRS coding system. The medication was dispensed on the date “20011231” at the pharmacy “CVS PHARMACY #1234” with a quantity of “15” dispensed.

**Decision Support Service**

The EMHP software then calls a Decision Support Service, using a Web Services protocol. In a SOAP request, the EMHP sends the entire CCD to the Decision Support Service. In a SOAP response, the Decision Support Service returns a list of Decision Support Reminders (i.e., small fragments of XML wrapped in the SOAP response).

The Decision Support Service parses the CCD to extract “facts” (i.e., data in the CCD which may be used to evaluate a decision support rule). The “facts” are instantiated as objects in the memory of a Java program. The list of “facts” usable in our implementation of a Decision Support Service is not extensive:

1. Age of patient
2. List of all dispensing events. For each dispensing event:
   a. Drug dispensed (RMRS Dictionary Term)
   b. Date dispensed
3. List of all laboratory values. For each laboratory value:
   a. Lab test (RMRS Dictionary Term)
   b. Lab value
   c. Date tested
These “facts” are then passed to a Decision Support Engine. In our implementation, we use the Drools Decision Support Engine. Drools (http://www.jboss.org/drools/) is an open-source engine developed by the JBoss community (best known for the development and support of RedHat Linux). Drools is written in Java, integrates easily with our Eclipse development environment, and offers a convenient user interface (allowing decision support rules to be written out as Java-like text, or to be imported from a Microsoft® Excel spreadsheet).

Each time that a patient arrives, and a CCD is assembled, then the Decision Support Service is called for that patient. The Drools Engine evaluates all 786 rules we have written, operating on the “facts” presented to it by the parser. In general, there are two categories of rules. Some rules classify drugs, or labs, into groups. Other rules generate reminders, when their conditions evaluate to “true”. Each reminder generated by the Decision Support Engine is associated with a medication. A more precise breakdown of rule categories follows:

<table>
<thead>
<tr>
<th>Category of Decision Support Rule</th>
<th>Rule Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Classification of drugs into drug groups</td>
<td>18</td>
</tr>
<tr>
<td>Classification of lab results into lab groups</td>
<td>11</td>
</tr>
<tr>
<td>Reminder that lab monitoring is outdated</td>
<td>28</td>
</tr>
<tr>
<td>Reminder that lab test is abnormal</td>
<td>13</td>
</tr>
<tr>
<td>Reminder that drug is to be avoided in elderly</td>
<td>1</td>
</tr>
<tr>
<td>Reminder of potential drug-drug interaction</td>
<td>693</td>
</tr>
<tr>
<td>No reminder, but relevant lab results are displayed</td>
<td>22</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>786</strong></td>
</tr>
</tbody>
</table>

The Decision Support Service responds to the EMHP controlling software which called it. It returns a Web Services SOAP response. The response contains a list of reminders—and each reminder is indexed by a medication. Therefore, the EMHP software inserts each reminder into the proper place in the CCD document. Where previously there was a CCD document without reminders, now there is a CCD document with reminders. It is important to note that the CCD document without reminders is compliant with the HITSP C32 construct. However, after the reminders are inserted, the CCD document is no longer compliant with the HITSP C32 construct. This would have implications for data exchange. However, in our current implementation, we are only using the CCD document to facilitate printing. Therefore, the departure from the C32 construct has no negative ramifications.

**Decision Support Rules**

First, the Drools Decision Support Engine uses rules to classify medications and lab values. A classification is simply added, as an attribute, to the “fact” describing each drug dispensing event. In this implementation, we use these medication classes:

- ACE (Angiotensinogen Converting Enzyme) Inhibitors
- ARB (Angiotensin Receptor Blocker)
- Diabetes
• Diuretic
• Diuretic, Potassium Sparing
• Diuretic, Potassium Wasting
• Fibrate
• Iron Supplement
• Liver (miscellaneous drugs with potential for liver enzyme elevation)
• NSAID (Nonsteroidal Anti-inflammatory Drug)
• Potassium Supplement
• Statin

We use these lab classes:

• BUN (Blood Urea Nitrogen)
• CK (Creatine Kinase)
• Carbamazepine
• Creatinine
• Hemoglobin A1C
• LDL (Low Density Lipoprotein)
• Phenobarbital
• Phenytoin
• Potassium
• TSH (Thyroid Stimulating Hormone)
• Valproate

Second, and more complex, are the rules for generating reminders. The clinical reminders are derived from well-established guideline logic: either the NCQA (National Committee for Quality Assurance) HEDIS specifications, or the same reminders used in the Regenstrief Gopher order entry system for outpatient practices for over a decade. They are written as brief facts. For example, if a patient uses Digoxin, and the most recent Potassium lab result is below 3.5, then the message: “Recent Potassium lab result below 3.5” is displayed next to the medication. The clinical reminders fall into four categories:

1. Drug Lab Interactions
2. Drug Lab Monitoring
3. Drugs to Avoid in Elderly
4. Drug–Drug Interactions

1. Drug Lab Interactions: this category refers to those drugs whose use is less safe in the presence of an abnormal lab value. If a patient has had a medication in the following groups dispensed recently (defined as 182 days), and if one of the following lab conditions is true (defined by the most recent lab test), then a reminder is printed:
Table 2. Drug lab interactions reminder

<table>
<thead>
<tr>
<th>Medication group</th>
<th>Lab condition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Digoxin</td>
<td>Potassium &lt; 3.5</td>
</tr>
<tr>
<td>ACE-I / ARB</td>
<td>Potassium &gt; 5.5</td>
</tr>
<tr>
<td>K-sparing Diuretic</td>
<td>Potassium &gt; 5.5</td>
</tr>
<tr>
<td>K-wasting Diuretic</td>
<td>Potassium &lt; 3.0</td>
</tr>
<tr>
<td>Diabetes (x single-agent Metformin)</td>
<td>HgbA1C &gt; 9.0</td>
</tr>
<tr>
<td></td>
<td>LDL &gt;= 100</td>
</tr>
<tr>
<td>Levothyroxine</td>
<td>TSH &lt; 0.3</td>
</tr>
<tr>
<td></td>
<td>TSH &gt; 6</td>
</tr>
<tr>
<td>K Supplement</td>
<td>Potassium &gt; 5.5</td>
</tr>
<tr>
<td>Metformin</td>
<td>Creatinine &gt; 1.4</td>
</tr>
<tr>
<td>NSAID</td>
<td>Creatinine &gt; 2.0</td>
</tr>
<tr>
<td>Statin</td>
<td>SGPT &gt; 150</td>
</tr>
<tr>
<td></td>
<td>CK &gt; 500</td>
</tr>
<tr>
<td>Fibrates</td>
<td>SGPT &gt; 150</td>
</tr>
<tr>
<td></td>
<td>CK &gt; 500</td>
</tr>
<tr>
<td>Glitazones, Nefazadone, Niacin</td>
<td>SGPT &gt; 150</td>
</tr>
</tbody>
</table>

2. Drug Lab Monitoring: this category refers to those drugs whose safe use requires regular lab test monitoring. If a patient has had a medication in the following groups dispensed recently (defined as 182 days), and if one of the following lab conditions is true (defined by the most recent lab test), then a reminder is printed:

Table 3. Drug lab monitoring reminder

<table>
<thead>
<tr>
<th>Medication group</th>
<th>Lab condition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Digoxin</td>
<td>Potassium: none found in past 12 months</td>
</tr>
<tr>
<td>Digoxin</td>
<td>Creatinine: none found in past 12 months</td>
</tr>
<tr>
<td>ACE-I / ARB</td>
<td>Potassium: none found in past 12 months</td>
</tr>
<tr>
<td>ACE-I / ARB</td>
<td>Creatinine: none found in past 12 months</td>
</tr>
<tr>
<td>K-sparing Diuretic</td>
<td>Potassium: none found in past 12 months</td>
</tr>
<tr>
<td>K-sparing Diuretic</td>
<td>Creatinine: none found in past 12 months</td>
</tr>
<tr>
<td>K-wasting Diuretic</td>
<td>Potassium: none found in past 12 months</td>
</tr>
<tr>
<td>K-wasting Diuretic</td>
<td>Creatinine: none found in past 12 months</td>
</tr>
<tr>
<td>Diabetes (x single-agent Metformin)</td>
<td>HgbA1C: none found in past 12 months</td>
</tr>
<tr>
<td>Diabetes (x single-agent Metformin)</td>
<td>LDL: none found in past 12 months</td>
</tr>
<tr>
<td>Levothyroxine</td>
<td>TSH: none found in past 12 months</td>
</tr>
<tr>
<td>Anticonvulsant</td>
<td>Serum drug level: none found in past 12 months</td>
</tr>
<tr>
<td>Statin</td>
<td>LDL: none found in past 12 months</td>
</tr>
</tbody>
</table>

3. Drugs to Avoid in the Elderly: If a patient is older than 65, and has one of a group of unsafe medications dispensed within the past 182 days, then a reminder is printed. These medications are the RMRS Dictionary Term translations of the medications specified by the NCQA HEDIS guidelines in table DAE-A (Drugs to Avoid in Elderly): Use of High Risk Medications in the Elderly. We use the year 2008 version. This table DAE-A is freely downloadable as a technical resource from the NCQA Web site (http://www.ncqa.org). The broad categories of drugs represented in this table DAE-A are the following:
Drug–Drug Interactions. This rule converts each of the 693 rows of a MS Excel spreadsheet into a rule. Each of the 693 rows has a drug in a first column, and a drug in a second column. If the first drug and the second drug were dispensed within 90 days of each other, then a warning message is generated. These drug–drug interactions are only a subset of all possible drug–drug interactions. They were selected as the interactions with greatest clinical significance and severity, as specified by the Regenstrief Gopher RX.INTERACTIONS table and by Wolters Kluwer Health Facts & Comparisons.

Formatting Creates a Readable Document

The processes described above generate a CCD for each patient visit; the CCD contains medications, lab test results, and decision support reminders. However, the CCD is an XML file, and is almost unreadable by human eyes. Therefore, the controlling EMHP software formats the XML to produce a readable document.

The EMHP software calls the Saxon (version 9) XSL Transformation Engine (free and open source, available through http://saxon.sourceforge.net) and the Apache FOP (version 0.94) Formatting Engine (free and open source, available through http://xmlgraphics.apache.org/fop/). The Saxon Transformation Engine applies an XSLT stylesheet to the CCD document to generate a tree of formatting objects; the Apache FOP Formatting Engine converts this tree into a PostScript document.

Depending on the patient’s randomization status, one XSLT stylesheet is used for Control patients, and another XSLT stylesheet is used for Intervention patients. The Control stylesheet creates a PostScript document without any medications, labs, or reminders. Its only usefulness is to reassure the clinic personnel that the patient visit was processed and that no failures occurred.

The Intervention stylesheet is more complex, because it produces a readable medication history. All dispensing records are grouped by RMRS Dictionary Drug Term, and then
alphabetized by the name of that drug term. If any reminders exist, these are displayed underneath the drug name. For each grouping (i.e., for each drug name), the dispensing events themselves are sorted in reverse chronological order. Each dispensing event includes the following fields (not all fields are always available):

- Date dispensed
- RxNorm Clinical Drug name
- Quantity dispensed
- Pharmacy where dispensed
- Prescriber name
- Instructions (“SIG”) for how to take the drug

Refer back to Figure 1 for a de-identified sample illustration.

**PostScript Document Is Printed**

The PostScript document is readable—when it is sent to a printer and printed. The above steps have described how each patient visit triggers creation of a PostScript document. Intervention patients have a document listing medications. Control patients have a document without medications. Nevertheless, all patients have a document which must now be printed.

The EMHP software accomplishes printing by calling a standard Java “print” routine. The most difficult aspect of printing is specifying which printer should be invoked. The EMHP software is designed to be scalable, and must be able to print to different printers at different remote locations and in different health care system. We constructed a printer configuration look-up table to store the name of which printer to use. This table is indexed by two keys. The first key is the clinic identifier, derived from the “Sending Application” and “Sending Facility” in the MSH segment of the HL7 ADT arrival message. The second key is the visit location, extracted from component 4 of field 3 in the PV1 segment of the HL7 ADT arrival message. The EMHP software extracts the clinic identifier and the visit location from each arrival message, and uses the composite key to look up the name of the printer to use.

Each printer has been manually installed, using the printer management function of the Microsoft® Windows operating system on the server hosting the EMHP software. The name given to the printer, when installing it on Windows, is the same name stored in the printer configuration look-up table. Remote printers, protected by an institution’s firewall, can be accessed; but installing that printer on our server’s operating system requires involvement of the other institution’s IT support personnel.

Printer assignment is relatively inflexible: each location at each clinic is assigned a single printer, and this configuration is stored in the look-up table. In other words, printing cannot vary from one patient to the next. If a clinic truly does want to change its printer assignments, then the printer configuration look-up table must be modified manually.
Lessons Learned (From the Implementation of This System)

As a result of this project, we have learned lessons that we would like to share with others carrying out similar work:

1. Minimize Disruption To Clinic Workflow

This project could only proceed successfully when we designed it so that the workflow of clinicians would not be disturbed. The Medication History is printed and placed on the clinic chart along with other printed encounter forms. No additional effort is required from clinicians, except to look at the document in their hand. However, there is minor additional effort required from registration staff personnel, who must remove the document from the printer and place it on the correct patient’s chart, at the same time that they are assembling the chart.

2. Clinic Liaison Is Necessary

Although workflow disruption was minimal, there were inevitable problems. Therefore, having a clinic liaison was essential. Our clinic liaison drove out to the clinic sites on a regular basis, and spoke briefly to registration staff and to clinicians. In this way we learned of problems earlier, than if we had waited for the clinic personnel to contact us. (Problems included: prolonged delays in printing; patients arriving, but no printout generated; medications very different than those recorded in the patient chart)

3. Organizational Agreements

This project involves multiple organizations sharing data. Data sharing is a complex activity requiring multiple legal agreements and high level of trust and common understanding. This project could only proceed because the organizational agreements to establish and develop the INPC had already been worked out in previous years. Even so, there additional approvals had to be obtained to allow this project to proceed.

4. Patient Identifiers

A project to aggregate data from multiple sources can only proceed if there is a mechanism for linking different patient identifiers together. The INPC has invested effort into developing algorithms for linking patient identifiers, which we were able to make use of. Without such a linkage algorithm already implemented, we could not have carried out this project. Although RxHub pharmacy data did not require a specific identifier, the other two sources of pharmacy data did require specific identifiers. Furthermore, laboratory test results from various institutions required various identifiers. The same linkage algorithm was re-used in all cases.
5. Patient Arrival Messages

We found that the arrival of a patient to an outpatient clinic is a useful event to trigger the creation of medication histories, and potentially other types of patient information documents as well. It seems that many outpatient clinic settings have electronic registration systems (in contrast to electronic medical record systems). It seems that many of those electronic registration systems are capable of sending out standardized HL7-protocol ADT messages to describe the patient’s arrival. (These are impressions which may not be generalizable to all settings.)

HL7 ADT messages can be generated as a by-product of the registration process, without requiring any additional effort from clinic personnel. We believe that this is greatly preferable to any other trigger mechanism, which would require an active request on the part of clinic staff and thus disrupt workflow. However, we also experienced the disadvantage of reliance on an automatic trigger: when connectivity is disrupted, and ADT messages stop arriving, no medication history is triggered—even if the clinician is still seeing the patient and requests a medication history.

6. Careful Filtering of Patient Arrival Messages

Careful planning is required beforehand to determine which ADT messages should be used as triggers, and which ADT messages should be ignored. The ADT message format is used to convey other information, not just the fact of a patient’s arrival to the clinic. Our initial attempts required testing and fine-tuning to make sure that we could filter out those ADT messages which should not be used to trigger generation of a medication history. This definition required guidance and feedback from clinic management.

For example, ADT messages can be generated to indicate blood draw for lab testing, to indicate documentation of a follow-up phone call, or to indicate that a patient’s demographic information has been updated. It requires investigation to determine which data in which fields of the ADT message indicates an event (which should not be ignored) and differentiates it from an event (which should be ignored). Implementing the filter is relatively straightforward, compared to deciding on the semantics of that filter. Although the HL7 standard is well specified, it can be interpreted in different ways by different system developers, requiring an individual approach for each site.

7. Drugs Must Be Identified by a Clinically Usable Coding System

A drug coding system enables aggregation, grouping, sorting, and incorporation of decision support rules. If we had used free-text drug names, this project could not have been possible. However, even if coded, this project would not have been possible if a variety of drug coding systems had been used.

The NDC codes are ubiquitous in pharmacy dispensing data, forcing us to incorporate NDC codes in our strategy. Although they are ubiquitous, we found that they are very inappropriate for clinical use, because they represent distinctions which are not useful for clinicians. For example, there are at least 227 distinct NDC codes to represent Amoxicillin 500 mg capsules. No clinical application would be tolerated by clinicians if medications were represented on such a granular level.
Therefore, a crucial element of our process is the translation of NDC codes to clinical codes: in this project, RxNorm Clinical Drugs and Regenstrief Dictionary Drug Terms. For example, each dispensing event is linked to an RxNorm code, and the dispensing events are grouped and sorted by Regenstrief Dictionary Drug Terms. All decision support rules operate on the level of Dictionary Drug Terms. Our work with drug codes has helped us realize that much research is still needed in the domain of drug codes, in order to improve their use in the clinic setting. Finally, it is important to realize that any translation between coding systems carries the potential for loss of information, if there is any drop-off during the mapping process.

8. Drug strength Is Not Well-Represented

One important realization was that the strength of a patient’s dose of medication is not well represented, when compared to the name of a patient’s medication. Pharmacy data sources do attempt to represent the strength of a medication dose, and this information appears to be reliable in those cases where a patient takes one tablet/capsule at a time. However, this information appears to be less reliable in those cases where patients take half a tablet, or two tablets—or where they use inhalers, or oral liquids, or topical creams. When we tried to incorporate strength information in our medication histories, we produced displayed strengths which we judged to be confusing. We realized that representing strength information is a complex task, and may still require improvements on the part of external data sources and message standards.

However, we were able to represent the strength of medications in a way acceptable to clinicians. We translated NDC codes to RxNorm Clinical Drug codes, and wrote out the text description of the RxNorm code. In other words, we used the strength information carried in the NDC code, instead of obtaining it from any other field in the pharmacy data record.

9. Speed Is Paramount

Our INPC Enhanced Medication History process could not afford delay. Delays were unacceptable to the clinic site staff, and were an important category of complaint. After registering the patient in the electronic registration system (and thereby generating the ADT message trigger), clinic staff took roughly several minutes to assemble a patient’s chart. For the most part, our software could generate and send a medication history to the clinic printer within a minute—fast enough, so that the history could be included in the patient’s chart. However, there were several occasions on which our medication histories were delayed—by only a few minutes. Those few minutes were troublesome enough to the clinic staff. If they had already assembled the patient’s chart, then an inconvenient workflow disruption was necessary to go back and retrieve the delayed medication history.

10. There Continues To Be a Need for Paper-Based Solutions

Although we firmly believe in the benefit of all-electronic health care information systems, we still recognize the need for paper-based solutions. Most outpatient health care sites still use paper, some to a small extent, others to a large extent. This project demonstrates the utility of a process that gathers electronic information and converts it to a printed document, which easily
integrates into clinic workflow. While paper is not a perfect solution, it can be considered a user-interface to an information system, just as a computer monitor is a user-interface.