

Maintaining the enterprisewide continuity and interoperability of patient allergy data

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Adverse drug events (ADEs) are estimated to cause morbidity or mortality in more than 770,000 hospitalized inpatients annually in the United States.¹ Twenty-eight percent of ADEs are associated with a medication error and are therefore preventable.² A large percentage (56%) of preventable ADEs occur at the time the drug is ordered.² Failure to avoid known allergic reactions represents an important cause of preventable ADEs, particularly since allergic reactions can be devastating when they occur.³ In a study of inpatient medication errors, Leape et al.⁴ found that 8% of errors were preventable because it was known that the patient was allergic to the medication at the time it was ordered. Computerized provider-order-entry (CPOE) systems have been shown to significantly reduce preventable ADEs related to allergy errors.⁵ CPOE is frequently integrated with clinical decision support (CDS), which serves as an important tool to prevent allergy-related medication errors.⁶ In a study measuring the

Purpose. The efforts, results, and challenges of a large tertiary care, academic health care system to standardize and integrate allergy information across clinical information systems are discussed.

Summary. The University of Michigan Health System and its Information Technology Strategic Advisory Committee recognized the necessity for storing and maintaining allergy information in a single repository; therefore, the clinical data repository (CDR) was named as the central database for coded allergens and reactions for the University of Michigan Hospitals and Health Care Centers (UMHHC) electronic medical record. The Enterprise Allergy Project (EAP) began in June 2005 with the formation of a steering committee that included representatives from clinical departments with order-entry systems. The initial phase of the EAP consisted of several components. One component was a one-time conversion of existing free-text allergy information into coded allergens and reactions. Before the implementation of the EAP, the order-entry system only

supported the entry of uncoded allergen and reaction information. An initial process of allergy matching reduced the list of uncoded allergens from 272,519 to 29,500 by using terms that indicated no allergies were present and trimming and modifying free-text strings that closely matched or easily translated to a coded allergen counterpart. Another component of the EAP consisted of the interface and technical build to support allergy information processing between the CDR and University of Michigan (UM)-Carelink. One goal of the EAP was to transfer data bidirectionally, but that goal could not safely be accomplished.

Conclusion. Implementing a strategy for enterprise allergy integration at UMHHC has improved the quality of allergy information documented as measured by a significant decrease in the amount of uncoded allergens.

Index terms: Allergies; Computers; Hospitals; Information; Quality assurance; Records; Standards; Technology

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impact of CPOE systems on the prevention of serious medication errors in

a large tertiary care teaching hospital, Bates et al.⁶ found a significant reduc-

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tion of 56% ($p = 0.009$) in medication errors secondary to known allergies following implementation of CPOE with CDS.

While growing evidence indicates CPOE with CDS can substantially improve patient safety, clinician efficiency, and the quality of health care, research suggests that CPOE can introduce unintended adverse consequences and potentially facilitate medication errors.^{1,7} Koppel et al.¹ indicated that these CPOE-facilitated medication errors can be grouped into two categories—(1) information errors through fragmentation and systems integration failure, and (2) human-machine interface flaws reflecting machine rules that do not correspond to work organization or usual behaviors. Poor design or flaws in the user-allergy-entry interface and other elements of allergy documentation and decision support contribute to problems and errors associated with both of these categories. Examples of errors resulting from fragmentation include isolated patient-allergy databases contained in disparate systems that are inaccessible to CPOE and other enterprise electronic order-entry or clinical systems. Furthermore, the allergen dictionaries, or lexicons, used in CDS for translating a patient's allergens to the ordered drug are not standardized and cannot be readily mapped from one proprietary lexicon to another. These dictionaries contain information (e.g., active medication ingredients, chemical compounds) stored in coded form and are typically provided by an integrated module by third-party vendors, such as Multum (Denver, CO) and First DataBank (San Bruno, CA).⁶ Ultimately, the ordering clinician may not have all the information needed at the time of medication ordering. Presentation to the user of complex, unclear, or incomplete allergen and reaction pick lists are examples of human-machine interface flaws

that may promote inappropriate allergen selection or failure to find the intended allergen or reaction. Poor design of the user-allergy-entry interface may encourage entry of free-text (uncoded) allergens, which would then defeat decision support. Many systems may not be able to support entry, or can support only very little entry, of coded allergens and reactions.

Given the importance for avoidance of allergy-related medication ADEs, and the role that CPOE plays in promoting optimal allergy documentation and decision support to prevent patient harm, it is critical that health care institutions and organizations take a thoughtful, structured, and standardized approach in unifying allergy information across their electronic clinical systems. With a goal of implementing a CPOE system and recognizing this importance, the University of Michigan Hospitals and Health Care Centers (UMHHC) set out to create a strategy and implement a process for effective integration of enterprise allergy information. This integration effort is called the Enterprise Allergy Project (EAP). The purpose of this article is to describe the UMHHC EAP and provide an evaluation of its success and performance. Specifically, this article focuses on the initial phases of the project, including the incorporation of the inpatient pharmacy system, new CPOE system, and enterprise clinical data repository (CDR) (Web-based clinical patient record) into the integration process. Meeting proceeds and abstracts that describe efforts to share and consolidate allergy information among clinical systems have been published.⁸ However, we have not found any published articles that are of the scope of this article, are similar to the design goals of this project, or describe the impact that improving the quality of electronic allergy information documentation has on health care.

System description

Clinical information systems at UMHHC. UMHHC, part of the University of Michigan Health System (UMHS), is comprised of 150 regional outpatient facilities and clinics across Southeastern Michigan and a 865-bed tertiary care and teaching facility in Ann Arbor. The inpatient facilities are comprised of a 550-bed adult university hospital and a 315-bed women's and pediatric hospital. Of the total licensed beds, 84 are adult intensive care unit (ICU) beds, 40 are neonatal ICU beds, 31 are pediatric ICU beds, and 40 are maternity beds. The hospitals see 44,490 admissions annually. All staff, including physicians, are employed by UMHS. Teaching affiliation and faculty appointments are maintained with the University of Michigan.

Key electronic clinical information systems at UMHHC, specifically at the university hospital and the women's and pediatric hospital, include the following:

- CareWeb—an internally built, enterprise-wide, Web-based system for the entry of outpatient visits, encounter information, results, discharge information, pharmacy orders, and inpatient progress notes.
- Centricity (GE Healthcare, Chalfont St. Giles, England)—a clinical reporting system for documentation and results used in the operating room, emergency department, trauma center, and burn center.
- IDX (GE Healthcare)—an order-entry system used by radiology.
- Cerner Classic (Cerner Corp., Kansas City, MO)—an order-entry system used by laboratory and pathology services.
- WORx version 2.8 (Mediware Corp., Lexexa, KS)—an inpatient medication order-entry system used by the pharmacy department.

Information is not shared among systems with the exception of laboratory and radiology results and

pharmacy-order information, which can be viewed in CareWeb. The CDR serves as the centralized storage database for enterprise clinical information, receiving information directly from the CareWeb user interface and from Centricity and the radiology, laboratory, and pharmacy systems through Health Level Seven (HL7) (Health Level Seven Inc., Ann Arbor, MI) compliant interfaces.

In late 2004, UMHS launched the Orders Management Project to bring CPOE to the women's, children's, and university hospitals. UMHS uses Sunrise Clinical Manager (Eclipsys Corporation, Boca Raton, FL) as its CPOE system. UMHS internally "branded" Sunrise Clinical Manager, referring to it as UM-CareLink. The Orders Management Project is a multiyear initiative with rollout of UM-CareLink scheduled over a three-year time frame. Initial activation of UM-CareLink in the women's hospital occurred in October 2006. Phase 2 of the rollout occurred in the neonatal ICU in February 2007, and the remaining units in the children's hospital were activated on June 4, 2007. UM-CareLink was activated at the university hospital in April 2008.

UM-CareLink is primarily an electronic order-entry and results-reporting system. Orders from all order-receiving departments (e.g., pharmacy, laboratory, nursing, radiology, dietary) are entered directly into UM-CareLink. Medication, diet, laboratory, and radiology orders are transmitted using HL7-compliant interfaces to the corresponding order-receiving department's order-entry systems (e.g., WORx in pharmacy for medication orders). Laboratory and radiology results are transmitted back to the CPOE system for result-reporting purposes. Documentation of medication administration and other tasks also occurs within UM-CareLink. The CDR receives and stores all order information entered into UM-CareLink.

Development and initiation of the EAP. Before the formal launch of the EAP, and simultaneous to the start of the UM-CareLink project, UMHS and its Information Technology Strategic Advisory Committee set a goal for standardizing and coding allergy information across the health system. The committee recognized the necessity for storing and maintaining allergy information in a single repository; therefore, it named the CDR as the central database for coded allergens and reactions for the UMHHC electronic medical record. The EAP formally kicked off in June 2005, with formation of the multidisciplinary Enterprise Allergy Steering Committee. The steering committee includes physician, pharmacy, and nursing representatives from major clinical departments with order-entry systems (e.g., pharmacy, radiology, emergency department). Representatives from outpatient areas, UMHS medical center information technology, and UM-CareLink system are also on the committee. Additionally, a project team was formed with representatives from UM-CareLink, CareWeb, CDR, and the interfaces team.

The steering committee meets monthly, and the project team meets weekly and is a "working" group that is in charge of coordinating design-build specifications and other clinical and technical details for the project. Recommendations from the project team primarily go to the steering committee for approval. The project team's initial work focused on standardization in allergy architecture through drafting of the project scope document and by developing business rules, goals and objectives, guiding principles for EAP processing, and the design build for each phase of the EAP. The goals and objectives for the EAP include the following: (1) to improve the quality and completeness of the medical record necessary for quality care across the organization, (2) to improve clinician productivity,

(3) to improve patient satisfaction and comfort by eliminating repeated requests for known information, (4) to increase compliance with the Joint Commission standards and medical records policy for the problem summary list (policy 03-090-050), and (5) to communicate the expectations and methods for clinical systems integration, particularly with regard to critical continuity data elements. Additionally, the steering committee approved the following key guiding principles and design goals for other electronic clinical systems participating in enterprise allergies: (1) the CDR is UMHS's authoritative resource for patient allergy data, (2) the CDR will transmit electronic messages to other automated clinical systems with new allergy information, (3) the transfer of allergen data will occur in a bidirectional process between the CDR and other clinical systems, (4) allergy data will be codified using the Unified Medical Language System (UMLS), except where no code is available, and (5) there will be core required data elements to support improved quality care and patient safety.

Standardization provides for uniformity in data processing among systems and ensures better quality data for decision support, ultimately improving patient safety. To help ensure standardization, EAP architecture specifies core and extended data elements for allergy information processing. To participate in enterprise allergies, clinical systems supplying allergy data to the CDR must store and provide the allergen, reaction, allergen creator name (i.e., user creating record), source system name (e.g., UM-CareLink, CareWeb, ADT), and allergy status (i.e., active or inactive). Elements (extended data elements) that may not exist within a clinical system and are optional but desirable include allergy type (e.g., drug, substance, environment); authorizing doctor's number (i.e., pager number); onset date; additional allergy description, comment, or free

text to further describe detail of the allergy or reaction; and visit number. In addition to the core and extended data elements, certain technical fields exist to ensure that the application and database work correctly. Some examples of this technical information include indexes for data tables, source-system information, and date and time stamp information for each allergy record.

The project team defined phases for the design build and enterprise allergy integration. Phase 1 included a one-time recoding of free-text allergen and reaction entries to a coded equivalent, modifying and enhancing the CareWeb user interface to support core allergy data elements, and integrating the pharmacy system (WORx) into the new allergy model. Phase 2 included integrating UM-CareLink, and phases 3 and beyond included integrating other source systems into enterprise allergies.

EAP phases

EAP phase 1. The initial phase of the EAP consisted of several components. The first component was a one-time conversion of existing free-text allergy information into coded allergens and reactions. Before the implementation of phase 1, CareWeb only supported the entry of uncoded allergen and reaction information. The inpatient pharmacy system (WORx) supports entry of coded allergen information and transmits this information to the CDR for display in CareWeb. However, a majority (53%) of the existing allergy information was from outpatients entered from CareWeb. As a result, the CDR contained approximately 272,519 uncoded allergen records out of a total of 519,986 records entered from the time when CareWeb was implemented until the start of phase 1. An initial process of allergy matching reduced the list of uncoded allergens down to 29,500 by using terms that indicated no allergies were present (e.g., “no known drug

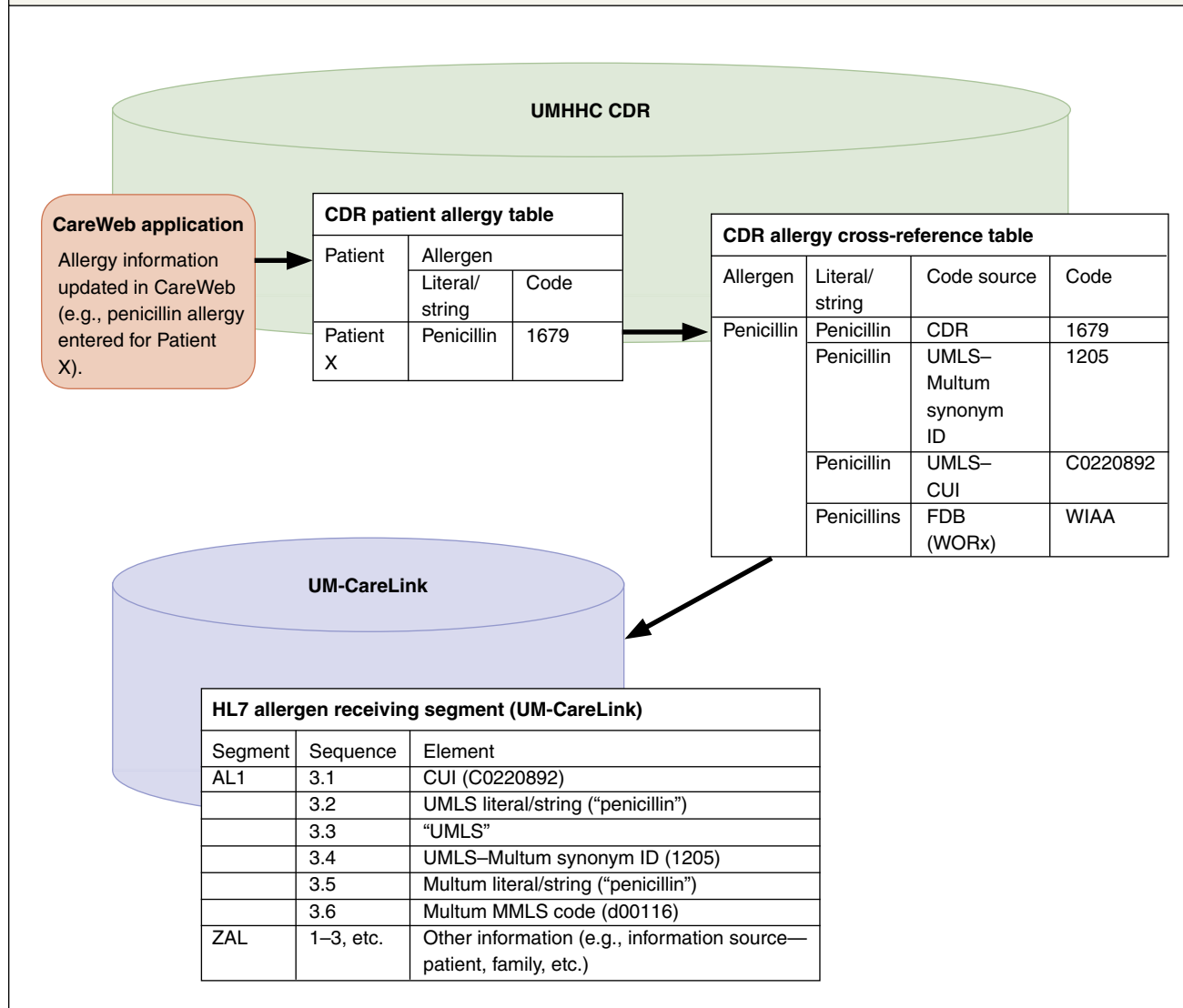
allergies,” “none reported,” “none,” “not reported”) and by trimming and modifying free-text strings that closely matched or easily translated to a coded allergen counterpart (e.g., PCN = penicillin). The final conversion process resulted in 17,000 coded allergens (conversion rate = 58%) and required about 320 hours of effort. Multum is the reference database used by UM-CareLink for its allergy decision support. In view of the initial project scope with UM-CareLink as the primary inpatient order-entry system and the resultant anticipated patient volume impact this system would have, it was decided that Multum would be used for coding drug allergens. The Multum dictionary of approximately 12,000 allergens can be extracted to facilitate the coding process. For nondrug allergens, the top 15 food allergens, 12 contact and environmental allergens, and 4 substance-type allergens were selected to be included in the CDR and enterprise allergen dictionary. Based on the frequency of reaction data, the top 30 reactions were chosen as coded terms.

Given the future potential for changing allergen dictionaries based on selection of alternative vendors or their conversion to other proprietary dictionaries, the project team decided to map each allergen to a universal type of dictionary to facilitate mapping to alternative allergen dictionaries if needed. Ultimately, the UMLS was selected. The UMLS is a large, multipurpose, multilingual vocabulary database that contains information about biomedical and health-related concepts and the various names and relationships among them.⁹ The UMLS is built from many different thesauri, classifications, code sets, and lists of controlled terms used in patient care, health services billing, public health statistics, indexing and cataloging biomedical literature, and basic, clinical, and health services research.

The purpose is to link alternative names and views of the same concept together and to identify useful relationships between different concepts. The UMLS connects different names for the same concept from many different vocabularies. Each concept has a concept unique identifier (CUI). The UMLS also contains a unique proprietary code for each drug term that is mapped to a CUI. The proprietary code can then be linked to codes from other proprietary vocabularies via the CUI. This will help translation to other allergen dictionaries should the need arise. Figure 1 provides a visual representation and working example of the allergen translation process and information transmitted between the CDR and UM-CareLink.

The other two aspects of phase 1 included modification of the CareWeb graphical user interface (GUI) to better support entry and the selection of coded allergens and core elements. The user is required to enter an allergen and reaction with the new design (Figure 2). An important feature of the new GUI supports rapid allergen selection with a pick list of the top 20 allergens from each category, which represents 80% of the allergens entered. Since UM-CareLink will ultimately be the primary source for inpatient order entry, the decision was made to only pass allergy information directly into WORx and to disable the ability to send allergy information back to the CDR. A one-way interface greatly simplifies the allergy processing between WORx and the CDR. WORx uses First DataBank as the allergen master for decision support, and its allergens were mapped to most appropriate counterparts in the CDR allergen dictionary. The allergen mapping and translation allow allergy decision-support features in WORx to function. Entry of allergy information was disabled in WORx. The CDR-to-WORx interface began operating on

Figure 1. Allergy translation between clinical systems. An update in allergy information or a patient admission triggers the interface to request allergy information from the clinical data repository (CDR). The interface will format an HL7 message according to the downstream recipient with appropriate allergy information (e.g., if sending to UM-CareLink, the elements from the HL7 allergen receiving segment will be transmitted; elements from the cross-reference table and other additional elements required by UM-CareLink for decision support [Multum MMLS code] will be sent). UMHC = University of Michigan Hospitals and Health Care Centers, HL7 = Health Level 7, UMLS = Unified Medical Language System, ID = identification, CUI = concept unique identifier.



November 15, 2005, one month after the implementation of the CareWeb allergy GUI to support entry of coded allergens and reactions.

EAP phase 2. Phase 2 of the EAP consisted of the interface and technical build to support allergy information processing between the CDR and UM-CareLink. Originally it was envisioned that allergy information would flow bidirectionally

between the CDR and UM-CareLink. However, the present version of UM-CareLink (i.e., Sunrise Clinical Manager version 4.0) only accepts the full “snapshot” of active allergens and reactions on its inbound interface. There is potential for allergy information to become unsynchronized under the following sequence of conditions: (1) there is latency (slowness or downtime) in the

UM-CareLink outbound interface, (2) the patient’s allergy accessed through UM-CareLink is updated, (3) an update is made in CareWeb, (4) the CDR broadcasts its updated allergen information from CareWeb (without an update from UM-CareLink given latency) to UM-CareLink and downstream systems, and (5) UM-CareLink accepts all allergy information as is from the

Figure 2. Revised CareWeb allergy add screen (pop-up window from UM-CareLink) to support entry of coded allergens and reactions.

Allergies and Intolerances: [Edit] [History] [?]

Step 1: Select Allergen

Select Type of Allergen

☒ Drug ☐ Drug Category ☐ Food ☐ Contact/Environment ☐ Substance

Select from a list of frequently used allergies

☐ amoxicillin	☐ Bactrim	☐ codeine	☐ meperidine (Demerol)
☐ ampicillin	☐ cefaclor (Ceclor)	☐ Compazine	☐ morphine
☐ aspirin	☐ cephalexin (Keflex)	☐ Darvocet	☐ tetracycline
☐ atorvastatin (Lipitor)	☐ ciprofloxacin (Cipro)	☐ erythromycin	☐ vancomycin
☐ Augmentin	☐ clarithromycin (Biaxin)	☐ ibuprofen (Motrin)	☐ Vicodin

- OR -

Browse the list of allergens by letter

A | B | C | D | E | F | G | H | I | J | K | L | M | N | O | P | Q | R | S | T | U | V | W | X | Y | Z |

- OR -

Search the list of allergens

Other [Search]

Select one of the following allergens based on your search:

☐ Lansinoh for Breast Feeding ☐ Mother's Friend ☐ Nuts (other)

☐ Tape (other) ☒ Other Allergen

Step 2: Select Reaction

Select Reactions: [Deselect All]

- ☐ Unknown
- ☐ Anaphylaxis
- ☐ Bleeding
- ☐ Blood Abnormalities
- ☐ Constipation
- ☐ Contraindication
- ☐ Cough
- ☐ Diarrhea
- ☐ Dizziness
- ☐ Dystonic Reaction
- ☐ Edema
- ☐ Fever
- ☐ GI Distress
- ☐ Headache
- ☐ Hives
- ☐ Hyperkalemia
- ☐ Hypotension

Allergen: []

Warning: "Other" allergies DO NOT TRIGGER ALERTS for ordering Clinicians or Pharmacists. Please carefully search for a listed (i.e. coded) allergy prior to using "Other".

Allergies and Intolerances last reviewed by OMPQAT33 on 10/25/2007 at 8:26 AM for visit 7777

[Save New Allergy] [Save and Mark Allergies as Reviewed] [Close]

CDR (i.e., active information only) and inactivates the change that was made previously on the patient's allergy. Therefore, allergy information could be temporarily unsynchronized until the interface caught up or came back online.

The potential for unsynchronized information was deemed to be a significant patient safety issue and alternative solutions were investigated. One solution included modification of the UM-CareLink inbound interface to accept the IAM segment, which is a component of the HL7 2.4 interface standard but can be supported by version 2.3. Version 2.3 is used by UM-CareLink. Use of the IAM segment allows real-time allergy processing and can distinguish between additions, deletions, and inactivations made in other systems and

within UM-CareLink. However, the vendor could not support modifications in the interface to include the IAM segment in a timely manner before the activation of UM-CareLink.

The most feasible solution, and the one ultimately implemented, was the incorporation of a CareWeb allergy entry pop-up window opening directly from UM-CareLink. A custom allergy tab was programmed into the UM-CareLink application which prompted the pop-up window. This window contains the allergy information entry and editing feature of the CareWeb application. It is in context with the patient who is currently in view in UM-CareLink (i.e., the same patient who the user is currently viewing in UM-CareLink will be linked to the same patient's allergen informa-

tion brought up for viewing in the CareWeb window). An HL7 message will transmit allergy information back to UM-CareLink from CareWeb and the CDR for decision support. Accordingly, the allergy entry features of the UM-CareLink application were turned off. The advantages of this model are that it supports a single-source model (CDR) for allergy data entry and updates and ensures data are synchronized to all receiving systems, it simulates entry of allergy information directly into the UM-CareLink application, it is less complicated and prone to fewer points of failure from an interface standpoint (only a one-way interface is needed), and it reliably provides allergy data across enterprise systems (i.e., there are no data integrity issues). Most im-

portantly, these attributes have the highest impact on promoting patient safety. However, this model has two potential significant disadvantages: (1) dependency on CareWeb or CDR downtime and (2) possible latency in transmission and updating of allergy information in the UM-CareLink database. Although annual unscheduled downtime for CareWeb and the CDR is anticipated to be less than one hour, scheduled downtime could negatively impact end users as well.

A description of the system latency issues is a bit more complex and requires a detailed explanation. Although the CDR is the single source for allergy information, updated allergy information is also concurrently stored in the UM-CareLink database for allergy decision support. A customized alert (hard stop) has been programmed into the UM-CareLink application to allow order entry only if allergy information has been entered and reviewed. The UM-CareLink application supports a process in which the user indicates that he or she has reviewed allergy information on newly admitted patients (i.e., clicking on the “mark as reviewed” button). For newly admitted patients, the user is required to update allergy information and click “mark as reviewed” initially before order entry can take place. Otherwise, an alert would prevent the user from continuing until allergy information had been entered or updated as appropriate. A similar type of “mark as reviewed” button for allergies was programmed into the CareWeb window to mimic the process used in UM-CareLink. As a result, latency occurs if the user marks allergies as reviewed through the CareWeb window and the “mark as reviewed” or allergy information has not yet been updated into UM-CareLink. By the time the user attempts to enter the order, the user will get the hard-stop alert. The user will not be able to enter

orders until the information comes across the interface and populates the UM-CareLink database. The hard-stop alert and allergy-decision-support features of UM-CareLink only query data within the UM-CareLink database. Thus, a delay or latency in allergy transmission time from the CDR to UM-CareLink could have a big impact on user adoption given the potential for inappropriate hard-stop alerts (i.e., alerts that occur following entry and review of allergy information).

Significant effort was put toward ensuring the highest speed possible in transmission of allergy data across the interfaces, including adjusting the messaging queues in the UM-CareLink application (e.g., adding more HL7 workers). Extensive performance and load testing determined that inappropriate hard stops or slowness in allergy data transmission should not be an issue during the first several phases of UM-CareLink activation. System performance and inappropriate hard-stop alert data are evaluated in an ongoing manner.

Efforts to reduce uncoded allergens

During phase 2, the project and steering committees focused on reducing the amount of uncoded allergens. Although the new CareWeb allergy-entry-user interface promoted selection of coded allergens and reactions, it was discovered that approximately 3000 uncoded allergens had been entered in the 10-month period following phase 1 activation (November 2005–August 2006). Consequently, the project team focused on two efforts to further reduce the amount of uncoded allergens. The project team first investigated the opportunity for further refinements in CareWeb allergy-entry and editing screens (Figure 2). Additionally, the allergen search feature was enhanced to find the closest matches based on whether the allergen term

started with or contained the requested search string. Thus, a greater search hit would further result in the user successfully finding the desired coded allergen.

Focus was also placed on an ongoing process to evaluate and code free-text allergens entered into CareWeb and the CareWeb allergy window accessible from UM-CareLink. Many of the uncoded allergy data had been entered by health record analysts (HRAs) who primarily transcribed information into CareWeb from physicians' handwritten clinic documentation of their patient assessments and workup. Given the difficulty of deciphering physicians' handwriting and recognizing the information as a coded allergen from CareWeb, a list of allergen synonyms that included the most commonly encountered uncoded allergens and the associated recommended coded alternatives was created. This list helps the HRAs translate a physician's documentation into an allergen available from the enterprise allergen dictionary. To further evaluate and provide an ongoing opportunity for coding free-text allergens, reports of uncoded allergens entered into the CDR were obtained on a monthly basis initially and then weekly starting approximately 10 months following phase 1 activation. The HRAs assess these reports and convert free-text allergens to their coded counterparts as appropriate. A pharmacist on the project team double-checks and validates the conversions made by the HRAs.

Status report

As described above, phase 1 of the EAP (CDR to WORx) was implemented on November 15, 2005, and phase 2 was activated on October 16, 2006. Operationally, both activations went well with no major technical issues. Feedback from users on the new CareWeb user interface was also positive.

Given the dependency on a hard-stop alert to prevent users from en-

tering orders into the UM-CareLink system, interface transmission and processing speeds were highly scrutinized and monitored following the launch of phase 2. In January 2007 (approximately three months following phase 2 activation), the transfer time from the CDR to UM-CareLink for allergen information was a mean $\pm$ S.D. of 5.6 ± 2.2 seconds. Although these data represent only 40 active inpatient beds, simulating a full patient load on the system results in identical transfer time figures. In translating the transfer time to impact on the end user, the number of inappropriate hard-stop alerts was examined from November 2006 through March 2008 (approximately 1.5 years following phase 2 activation). Out of a monthly mean $\pm$ S.D. of 826.1 ± 395.4 alerts, the mean $\pm$ S.D. number of inappropriate alerts was 10.4 ± 8.2 , which represented approximately 1% of all hard-stop alerts.

As of March 31, 2008, the CDR contained 756,340 patient allergen records, of which 19,904 (2.6%) were uncoded. Approximately 60% of the 3,000 free-text allergens that occurred during the 10-month period following phase 1 were converted to coded allergens. Subsequently, since weekly review of uncoded allergens started in August 2006, a mean $\pm$ S.D. of 300.9 ± 77.1 uncoded allergens are entered on a monthly basis with a mean $\pm$ S.D. conversion rate of $53.9\% \pm 5.3\%$. The CDR also contains 486,300 reaction records to date, which include 244,333 reactions documented as "other" (free text) and 40,932 documented as "unknown." Approximately 60% of the total reaction records are coded terms. The ongoing maintenance process for gathering and changing uncoded to coded allergens requires approximately 15 hours per month (5 hours for the allergy project coordinator to gather and tabulate uncoded allergen reports and statistics and 10 hours for HRAs to recode allergens).

Discussion

Recognizing the importance for enterprise allergy integration, the EAP was formed to address and ensure the continuity of allergy information and maximize its usefulness in patient care between the new CPOE and other information systems. This effort was essential given UMHC's strategic initiative of implementing a completely electronic medical record by 2010, which includes the rollout of all major clinical information systems (e.g., UM-CareLink as the inpatient CPOE system) over a several-year time span. The design build for phases 1 and 2 met all project key guiding principles with the exception of transferring allergen data bidirectionally between the CDR and other clinical systems.

The goal of transferring data bidirectionally is desirable for several reasons. Most importantly, entry of allergy information in each source system simplifies user workflow. Users can use the native allergy-entry and editing functions with each source system and do not have to leave one system and enter another to access, edit, and enter allergy information. In our case, bidirectional transfer of allergy information between UM-CareLink and the CDR could not be safely accomplished given the vendor-specified HL7 inbound interface configuration for UM-CareLink. Ideally, the IAM HL7 segment would safely allow real-time explicit allergy modifications. It is important to point out that organizations attempting enterprise allergy integration should investigate this requirement of a vendor-purchased system early in the planning phase. Given the dilemma of the inability to use a bidirectional process and the additional requirement of a hard-stop alert on electronic order entry if allergy information has not been declared or reviewed, the team spent several months examining alternatives. Fortunately, the final solution—the use of a CareWeb allergy edit-

and-entry pop-up window through UM-CareLink—seemed to provide the best option in terms of mimicking current allergy entry through UM-CareLink while supporting the hard-stop alert requirement and guiding principles specified by the project. Additionally, a one-way process for allergy entry and modification is the safest. Although latency or downtime between systems could interfere with user workflow, we have not found this to be a problem given fast allergy processing and transfer times and a minimal number of inappropriate hard-stop alerts.

Another facet of the project was to reduce the number of uncoded allergens to maximize the number of coded allergens that are available for decision support. The number of free-text allergens converted during Phase I resulted in a significant reduction (94%) in the number of uncoded terms. The amount of uncoded allergens has remained low (2.6%) through ongoing allergen conversion. Although a significant amount of resources went into the initial conversion, we feel that the time invested in this process is worth the return on improved quality in patient care data and facilitates its availability for decision support. A prospective conversion process could also minimize the time needed for conversion if the conversion process was done in bulk at a later time.

This project faced many challenges, and the greatest of these consisted of determining alternatives for the bidirectional process between UM-CareLink and the CDR. It was discovered late in the process that UM-CareLink could not support a safe bidirectional allergy transfer process, and the team spent several months formulating a new plan. The bidirectional allergy transfer process specification should have been clearly delineated to the vendor at the time of request for proposal. This could have potentially decreased the

time commitment to later rework the plan. Related to this aspect, the initial project-scope documentation included a specific technical solution by identifying a bidirectional interface. However, during the testing phase, the project team learned that this solution was flawed and not feasible; therefore, this expectation was set prematurely. Given heightened steering committee and customer expectations, the team found it difficult to refocus on the core business and clinical requirements (i.e., sharing real-time allergy data between systems). While project-scope documentation for systems-integration projects should contain business and clinical requirements, it should not identify specific technical solutions in order to maintain clarity of project goals and scope.

Another significant challenge was the conversion of uncoded to coded allergens. The use of a system that only supports entry of uncoded allergens and that has a time delay in conversion to coded allergens created a huge burden on the project. Previous use or design of systems that only support coded allergens and minimize uncoded allergen entry would have greatly lessened the time commitment for this conversion task.

The composition of the steering committee should also be carefully considered and include a full representation of physicians, nurses, pharmacists, patient safety experts, outpatients, inpatients, health information managers, and information technology leaders. The membership should be revisited throughout the project as needed. The highest-level management (i.e., program manager, director) should be part of the committee during the system integration. Attendance to the steering committee is vital for clear communication and project success.

In September 2006, the National Committee on Vital and Health Statistics (NCVHS) proposed standards for exchanging allergy data across

the federal health enterprise (federal agencies).¹⁰ The primary components of the standard include using HL7 (version 2.4 and higher) to exchange allergy information among systems and using several related vocabulary standards for allergen code, allergen group or class, allergy type, allergy severity, and allergen reaction. The unique ingredient identifier (UNII), developed by the Food and Drug Administration and Environmental Protection Agency, and RxNorm, developed by the National Library of Medicine, will be used to standardize the nomenclature for allergens. The National Drug File Reference Terminology will be used to specify the vocabulary for allergen group or class, and the Systematized Nomenclature of Medicine Clinical Terms will be used to specify allergy type, severity, and reaction. Given that these standards were announced in the midst of the second phase of the EAP and UM-CareLink rollout, it was not feasible to retrofit the UMHC allergen vocabulary to conform to the NCVHS standards (e.g., UNII codes). However, UNII codes are contained in the UMLS, and it would be possible to map and translate allergen codes via the CUI to the designated UNII code should the need arise. Vendors (e.g., Eclipsys, Multum, First DataBank) supplying information to support UMHC allergen vocabulary have not announced support of NCVHS standards to date. Thus, the steering committee still plans to continue using the existing approach to code allergy information until the need for converting to the NCVHS standard can be clearly demonstrated.

The new NCVHS standard is the first major effort to promote standardization in allergy nomenclature and help facilitate interoperability between systems. Additionally, the standard underscores and emphasizes the need for use of the latest version of HL7, which is needed for true bidirectional transfer of allergy information.

The next steps for the project are to further evaluate the performance of integration efforts as UM-CareLink continues to rollout to the university hospital and to assess other UMHC clinical information systems for inclusion into enterprise allergies. For example, the EAP team is currently evaluating the requirements for the radiology order-entry system and the Centricity clinical information system.

Conclusion

Implementing a strategy for enterprise allergy integration at UMHC has improved the quality of allergy information documented as measured by a significant decrease in the amount of uncoded allergens.

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