The Value of a Domain Ontology for Provider Order Entry

By

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A Capstone Project

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human 'capital' through education.

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ABSTRACT

Building on a previously developed ontology for clinical orders [3], this work undertakes to answer questions about the usefulness of continued ontology development. Three questions were asked initially: Has such an ontology previously been described? Is one being used in the development of present day Computerized Provider Order Entry systems? Are orders processed based on such an ontology contextually linked to decision support tools? We conducted interviews in a semi-structured format with five clinical experts involved in the implementation of various electronic health record systems. We found that while data schemas do form the basis of certain types of orders and allow decision support and workflow management at varying levels, these schemas do not comprehensively represent the domain knowledge. They do not enable all types of orders in all medical disciplines and in all clinical settings to be completely machine-interpretable, shareable and interchangeable among the diverse systems. Our ontology, once further refined, may be better able to allow these functionalities.

INTRODUCTION

Van Bemmel and Musen define ontology as "a set of concepts, the attributes of those concepts, and the relationship among concepts that characterize a given application area" [1]. Alternatively, they define it as "a kind of model of an application area." [1]. Hence,

- "[An ontology] provides a machine-processable representation of how domainspecific content is organized.
- 2) An ontology provides a computable reference of the concepts about which the system 'knows something,' and defines the framework for organizing concepts in a knowledge base.
- 3) When two different systems can reference the same ontology, the two systems have the potential to share knowledge about the application domain and even to work in concert to solve complex problems" [1].

The above considerations led to the development in the Department of Medical Informatics and Clinical Epidemiology (DMICE) at Oregon Health & Science University (OHSU) of an ontology of orders with the expectation that it would lead to definition of a common vocabulary for medical informaticians who need to share information in this domain. An Intensive Care Unit (ICU) order set was already available from work previously done on developing a language model from handwritten physician orders [2]. The ontology was developed as a natural extension of that project using MultiTes [Multisystems, Miami, Florida, USA], which is a commercially available thesaurus construction software [3, 4]. We have been interested in knowing

whether further development of this ontology would be worthwhile. In order to explore this interest, we initially asked three questions: Has such an ontology previously been described? Is one being used in the development of present day Computerized Provider Order Entry (CPOE) systems? Are orders processed based on such an ontology contextually linked to decision support tools?

A comprehensive search was first undertaken of the OVID Medline, Ovid, New York, New York, USA [5] and Web of Science, Thomson ISI, Stamford, Connecticut, USA [6] databases using a combination of search terms such as "ontology", "schema", "orders", "order set", "order entry" and "decision support". No article pertaining directly to the development, use, or application of an ontology of clinical orders was found. We surmised that this lack of findings in search of the literature may indicate a gap in knowledge for this domain. We also considered the possibility that such ontologies may be in existence but are not published because of their proprietary nature.

This study continued the questions previously asked by interviewing clinical experts in CPOE. We hoped to learn whether or not orders in various CPOE systems are processed based on an ontology, whether or not knowledge based on an ontology of clinical orders is already or might be useful, especially if it is contextually linked to decision support tools.

METHODS

Institutional approval to conduct this study was requested and received from OHSU's

Institutional Review Board. We then requested interviews with the following five individuals, who are known to us to be clinical experts with experience in CPOE.

1) Richard F. Gibson, M.D., Ph.D.

Chief Medical Information Officer

Information Services Division

Providence Health System [7]

Portland, Oregon

Dr. Gibson is in the process of implementing the Horizon Expert Orders product by McKesson-HBOC [8] and expects to 'go live' in September 2004.

2) W. Paul Nichol, M.D.

ACOS Clinical Information Management

VA Puget Sound Health Care System

Seattle and Tacoma, Washington [9]

Dr. Nichol has implemented (along with Dr. Payne) the 'home-grown' order-entry system at the VA medical centers and is in the process of upgrading it. (Patty Hoey RPh, who was part of the team for creating order sets, was also present during the actual interview and added some very helpful remarks).

3) Thomas Payne, M.D.

Medical Director, UW Medicine Information Technology Services

University of Washington

Seattle, Washington [10]

Dr. Payne was instrumental in implementing the CPOE at the VA medical centers.

Currently, he is in the process of implementing the electronic health record product by Cerner Corporation [11]

4) Michael A. Krall, M.D., M.S.

Physician Lead

Kaiser Permanente HealthConnect

National Electronic Health Record Project

Portland, Oregon [12]

Dr. Krall is the lead physician in implementation of the Epicare electronic health record by Epic Systems Corporation at Kaiser Permanente facilities nationwide.

5) Jay Eisenberg, MD

Physician Executive, Cerner Corporation

Portland, Oregon

Dr. Eisenberg supports the implementation of clinical solutions, including CPOE, for Cerner Corporation.

E-mails introducing the project and the interviewer (author) were sent to these experts and a request was made to interview them in person. They all agreed to participate.

A semi-standardized interview involves use of a pre-determined set of questions asked in a systematic and consistent order. However, the interviewers are allowed and expected to digress in order to allow them to probe far beyond the answers to their prepared and standardized questions. It is assumed that standardized questions are formulated in words familiar to the people being interviewed (i.e. in the vocabularies of the subjects) [13]. We felt that this type of interview would yield the most meaningful

responses. As a next step, the participants were sent a diagram of the ontology schema [Figure 1] and a list of proposed questions [Table 1]. The experts were interviewed individually. In keeping with the above definition of a semi-structured format, conversation was allowed to digress, and definitions of certain terminologies were addressed to ensure a common understanding. Further clarification (by more examples) regarding the intent of the project or the purpose of the questions was provided as requested. In order to maintain the flow of conversation and depending on the response of the participants, the questions were not necessarily asked in the same order as

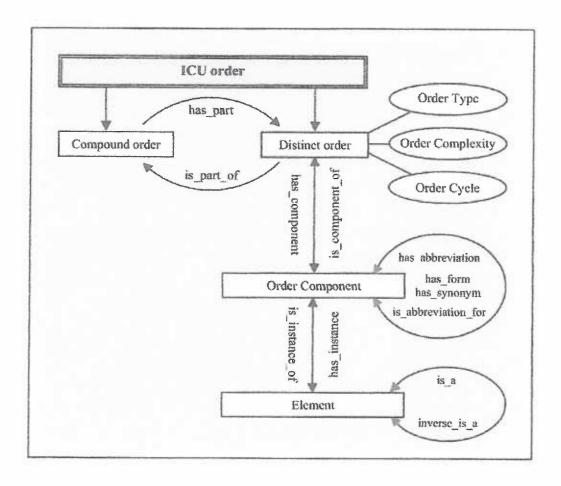


Figure 1: Ontology schema for ICU order ontology project

Table 1: Questions used in the semi-structured interview of clinical experts exploring the usefulness of an ontology for orders.

Is your CPOE based on a particular ontology or schema?

If so, how has it been evaluated?

Is there a syntax of orders of all types?

How in your system are orders structured? Are there pre-defined validated orders? Is there a 'pick list' of components from which orders are synthesized? Is there a 'smart' pick list?

How are conditional orders that require further collection of data, entered and processed? [Example: If pressure (PAP) still low after Albumin give LR 250 cc IV x 1 OR Dopamine gtt – maintain SBP > 140 < 180]

Does your system allow for a 'multi-part' order, and how is such an order 'decomposed'? [Example: Clamp NGT once TFs start, check residuals q 3 hours. Hold TFs for residuals > 150 cc OR Peripheral blood culture, then admin 800 mg ibuprofen PO x 1]

How is a change in a previous order processed? [Example: Decrease Cipro to 500 mg PO q d OR Decrease Prednisone to 40 mg p NGT, starting tomorrow]

Are a certain percentage of orders still being written as free text because no comparable orders are included in the knowledge base or the predefined orders list?

If your CPOE is not currently based on a schema or ontology, do you think that such an ontology would be useful for the construction/population of a CPOE system? If so why or how?

How could an order ontology be used/implemented? How would you test its use?

presented above.

All interviews were taped and some handwritten notes were taken. References made during these interviews to printed information, journal articles, and websites was noted. Taped interviews were then selectively transcribed to extract comments pertinent to the study, and the transcribed documents were further edited and used to compile the results. Words in brackets are this author's and were added to the quotations to clarify meanings.

RESULTS

Since this study was not intended to compare different features of the various CPOEs, and because some concern was expressed by at least one of experts regarding discussion of proprietary products, direct reference to individual products and respondents has been avoided as much as possible when presenting the results. The results are being presented based on list of questions initially proposed [Table 1].

Is your CPOE based on a particular ontology or schema?

One of the experts did not know if the system he was familiar with is explicitly built based on a schema. The other four stated that while the CPOEs they were familiar with are not based specifically on an ontology schema similar to what we had developed, their systems do have some sort of a schema to manage the order process in the order entry system. Therefore, while some sort of schema or syntax to manage the order process in order entry systems is common, at least for some types of orders, there is no

"master" syntax for all orders. Each one of them described it differently. One described each item (such as a medication, a lab test or an imaging study) as an *orderable* having many components – for example, the dose and route of a medication are components of an orderable, as are the type of study and site in the case of an imaging order. He emphasized that each order had to have those components.

A second expert stated that their schema for order entry is one piece of a larger infrastructure (or schema); orders themselves do not have a separate schema independent of that and were not based on a separate knowledge model. He went on to describe, "Some of that logic it is handled externally...there is an identifier for the drug; we order that drug; the identifier is sent along with other information about the patient, the age, the allergy history, etc...that is all sent to other applications...it takes those arguments and runs through a collection of knowledge about that drug and that patient's medications and history, and then it gives back to you the results of that analysis. That's handled externally. It's brought back into the order entry system. It's called the ordering conversation...it's a kind of rule engine; it's actually mostly tables, it's sort of a task mostly handled by tables as opposed to certain rules that you might embed in an older system like Mycin[14]. Drug-drug interactions and drug-allergy are basically large tables... and that is one main form of logic you can apply to orders." The third expert specifically described his order entry system. "How do you manage the terminology, and whether the terminology has these relationships? We manage that in the background, what we call CMT, which stands for Convergent Medical Terminology. We have a large project... creating and managing this terminology that is based on SNOMED [15]. It is actually an extension of SNOMED. And so if you ask

[about] 'is-a' relationship - that is primarily managed in SNOMED and CMT relationships...CMT becomes the source for terminology that we extract to populate files within [our system]. So, for example, [there is] a Procedure master file, or a Diagnosis master file...concepts like orderables would be extracted from CMT, and placed in a flat file that ...doesn't show up those relationships to the user." He explained further, "for example, in terms of the medicines, the terminology that we use for medications comes from First DataBank [16]... so within that database, they have pharmaceutical classes and subclasses...so they know that amoxicillin is an antibiotic for example, and actually amoxicillin is a penicillin. So that kind of a thing is represented within the terminology and that's important of course for a number of things including being able to do drug interactions, allergies and so on. We don't maintain that, we make use of that structure... so that's at one level. The second level, that within the application, each procedure, whether the procedure is a drug or a chest x-ray has a number of facets to it. Essentially, it is a row in a table, and columns in the table include things like - 'Is it a drug?' or 'What type of an image is it?' 'What are the characteristics of that image?', 'What other questions that are attached to that particular image or that particular drug?', 'What other requirements - for example, does it have an expiration date? Is it a future order? Is it a pending order? There are many different columns potentially in each row, and those columns do vary dependent upon whether it's a drug, an image, or a supply or something else."

The fourth expert chose to describe the ontology or schema as a "complex data model."

He stated that the basics [of the data model] are common among all order entry systems. In his words, "...an order catalog...contains orderables. It has different

categories such as medications, labs, diagnostic tests, nursing orders. An orderable is the highest level, for example, dopamine or ampicillin. [There are] order formats. A format describes order details... it determines what is required and what is optional. For example, medication order - you can have multiple formats for medications. What is required in the medication order other than the name? Well, you need a number. That could be called the dose, the unit [milligram], the route, the frequency. You might say that for these medications this is the format that we are going to design, but for these [other] medications the format might be different. But optional fields are things like duration, and duration is actually in duration units. Most of them also require a start date. But the chest x-ray order has a completely different format. It requires the name of the test. It probably requires the reason for the exam. It requires when you want it done - and everything else can be optional. That's a completely different format. What happens is, all this information goes somewhere - pharmacy and nursing, x-ray orders [go] to radiology. When you develop an order it has to go somewhere, it has to tell someone. You have to route it. And you have to enter an activity or a task for the right people. Respiratory orders are for respiratory people [therapists]; pharmacy doesn't have to know about it unless it is dispensing the medications. So these orders have format. You can have a generic order called Nurse Communication and you can have just a free-text instruction field. You type in what you want and as soon as you sign, it goes to the nursing activity list."

If so, how has it been evaluated?

It appears that there is little that is commonly known about the evaluation of these

existing systems. Three of the four experts who stated that their system is based on some sort of schema did not know how it had been evaluated. A fourth expert attempted to express it in a general way. "[Software] engineers do performance evaluation and all that. They'll put a data model together and do 'stress-testing'. They'll populate the database with a lot of queries and see what works the best. That never gets to any of us. What happens is that there are different models and different sorting schema, and the sorting schema then would have advantages and disadvantages. They would test. And then the usability...usability is very complex and because it has to do with the interface and lots of other things."

Is there a syntax of orders of all types?

Syntax was considered synonymous with order structure or order format by our respondents. All of them felt that some sort of a structure is essential for the orders to be processed electronically and be communicated to appropriate personnel. One of the experts felt that even with a possible verbal order system by speech recognition system there needs to be defined structure so that the same thing is said the same way each time for the order to be processed and transmitted safely and accurately.

One of the experts said that "[orders] have formally been presented as a specific syntax." However, he went on to say that "it's clear that each off the different types of orders have to have all those components. And that each of those components is a separate data element."

A second expert stated, "There is a syntax. The syntax is -'this is how we would write

a drug order', or 'this is how one would order a consult'... there is a *consult package*, there is a *laboratory package*, there is a *pharmacy package*... all of those have a tight structure to the forms of orders that will be accepted by them... that's regimented."

A third expert answered "Yes. Even a free text order has *order name* and the *orderable* and a *single free text field*. That would be the syntax for that order. Parts of the order are not seen by the ordering person, such as 'where is it going to'...so there is even a syntax there." He elaborated further – "If you write a completely free text order, it goes to where you decide you want free text orders to go. If you say, the want free text orders to go to the ward clerk, in which case it will be the ward clerk that will process the information and turn it into a formal orderable. They order into the same system you and I would. The way some people implement this system is to have the physicians continue to hand-write and the orders are entered by the department clerk. So you would never build a system where the order has nowhere to go."

How in your system are orders structured? Are there pre-defined validated orders? Is there a 'pick list' of components from which orders are synthesized? Is there a 'smart' pick list?

The answer was 'yes' to all of these by four experts; one of them did not specifically state if there is a pick list of components. He mentioned that there are *pre-defined order sets* based on patients' problem/diagnosis. And the system allows the 'ala carte approach' whereby individuals ordered can be searched for and 'picked'.

Hence, pick-lists or order sets are a universal feature of all the CPOEs in this study. All

the experts felt that order sets are much more practical (i.e. end-user oriented), make ordering relatively easy and quick and therefore facilitate implementation. However, the experts emphasized that on the 'back-end' (i.e. built into the interface but not seen by the users) many of the orders are decomposed into separate data elements. They felt that this is essential for automatic transmission of relevant information to databases that, for example, allow for drug-drug, drug-allergy, or drug-food interactions to be presented. With regard to these issues, these safety features have been installed at various levels in the different Electronic Medical Records (EMRs), some only apparent to the pharmacist, and others actually issuing an alert or reminder to the relevant provider. From the administrative or medical error perspective, standardization and consistency of orders is desirable, as opposed to flexibility/variability in the way orders may be written.

In one system, frequently used orders have been formalized into *Quick Orders*. In this system there is also a *Generic Order Entry Dialogue* whereby [medication] orders can be synthesized from components.

One expert said, "They all [systems] have some way of pre-compiling the orders ... terms that they use are all different." He mentioned the term *Order Sentences*. "Order Sentence, is a choosable, preconfigured order... it may not be complete, but it is partly towards completion... this is what they call a Order Sentence... Almost every order entry system has that concept, and the reason is your main problem with CPOE is time." Offering pre-compiled orders and order sentences for the physicians to complete saves them time in entering the orders.

Another system was presented as having "a database that contains all the valid entries

for all the drugs and all the orders and so on. And that can be presented either as a search or there is a pick list to choose from. In addition [we] can present them as *Order Panels* or *Smart Sets*, or *Templates*."

There was a lot of direct reference to usability and safety issues in response to this question. As one expert summed it up, "What implementation of this kind of system allows is to get rid of a lot of variation in the things that are frequently hard to interpret. So you don't want to give 10 ways to write the same order. And you don't want to allow - you can - but you don't want to allow too much freedom in letting an end-user to order just the way they want. As soon as you do that, you start running into different communication, different terminology - which then breaks down what you are trying to work on - which is some consistency, some standardization, all of that improves safety."

How are conditional orders that require further collection of data, entered and processed?

Conditional orders are often handled as free text orders or in comments which are then printed out for caregivers or patients, although some systems have a rules- or event-engine where events can trigger alerts to prompt for institution of the conditional order. Some of the experts had their own examples to add of *conditional* orders or *multipart* orders. While some of the common conditional orders are part of their order sets or pick-lists, for other orders, the *condition* or *parameter* is left as a blank to be ordered as *free text* electronically; some of the free text orders are not processed externally to be

broken down into separate components. Most of the implementers did not feel that this limitation is negatively affecting usability or compromising safety. They felt that since the conditional orders required human knowledge and judgment, their emphasis has been on *communicating* orders to the relevant personnel responsible for interpreting and implementing the orders – be it the pharmacist, respiratory therapist, bedside nurse or the patient herself - accurately, safely and expeditiously. However, they admitted that classifying such orders as *conditional* and processing them in that context could further improve their EMRs in terms of decision-support and healthcare provider (nurse, therapist) documentation, i.e. facilitate recording the *condition* with the prescribed *intervention*. This discussion also highlighted the fact that representing conditional orders in a terminology is difficult.

One of the experts answered, "There are all sorts of ad hoc combinations of conditional statements...some are complete in and of themselves, others have 'blanks'... and then to make a complete order, the doctor will have to fill in the blank...so it is a template for a conditional order. The order-entry system has 'if-then' rules, 900 of them. And say, when a new [lab] value drops in, it would issue an alert. Now the issue is that this is not an alerting system. It has logic. The difference between this and alerting system is that an alerting system would page you, e-mail you. This doesn't notify you. It's just that as soon as you log in, it says you have this condition. So it has an *event engine*, but it doesn't have an alerting effective on."

Three others stated that most of the conditional orders are 'nursing [free] text orders' or 'comments' linked to a 'simple' order, be it a print out [instructions] for a patient or parameters for a caregiver. It was described this way by one expert, "for the most part,

those are free text in the nursing orders. And the common location for those to be used would be in the inpatient area. For the outpatients, an order that requires a condition to be met could be placed in the comments field and it will be printed on to the bottle, but it's not something that automatically cancels the order automatically in the computer when certain conditions are met. We enter vital signs into the computer. There is not a link between that blood-pressure [a vital sign] that gets entered and something automatically changing the order in the pharmacy. That requires human intervention." "The computerized order system that the provider sees is a little bit different that what the pharmacists sees. Currently, our user interface does not provide for drug-lab order checks. But the pharmacy package does. So the pharmacists who is filling and acting on the prescription can make the appropriate intervention. I personally would prefer that information is all also displayed at the time that the clinician is ordering it. We are in the process of reengineering our computerized record and those are some of the capabilities that I would like to see be included."

Another expert answered, "Most of these are handled as either comments or a text order ... this sort of thing would require more knowledge or judgment... it would be written down as a text order." A third expert said, "Some of the compound or conditional orders that you described, for the most part, that are not represented today in the system. Now if it is a 'standard' conditional order that is always handled the same way conditionally - that might be represented - but as an ad hoc [it] is not standard.

Currently that is handled in text. And that's something that should be, or could be improved. But today we don't have a way of representing that with the terminology."

The fourth expert described their inpatient system in the following manner. "There are

some conditional orders within the inpatient system that I do know about. For example, I know that you can order cultures for temperatures greater than 105. So that order is sent in a queue, so when [the nurse] enters the temperature of 105, an alert or a reminder pops up ... so at least some of that exists today. And I understand that you could utilize the same logic to do other types of orders of that nature. There is a whole alerting system that is not part all the order entry system per se, and sits over and on top of it and could respond to orders all the various kinds. There is a condition or a rule that's attached. So it might be that this is the way you are going to implement some of these things."

The fifth expert had a different perspective. Using the example that was presented to him along with the question, he said that such orders go "under the nursing task as as needed (prn) order. And it is administered when the parameters are met. This is communicated to the nurse. And the medication orders can be designed so that they are required to enter the data by which they made the decision. What ends up happening is that number [parameter] and then becomes a result. And you can see [it] when you look at the medication administration record...some sort of a flow sheet manner that would work very well in critical care units because the nurse doesn't have to go and chart that vital sign elsewhere...you can do what is called a BMDI(bedside medical device interface)."

As is evident, all of the experts made a distinction between CPOE and an *Alerts and Reminders* system which they regard as a separate product.

Does your system allow for a 'multi-part' order, and how is such an order 'decomposed'? Multipart orders can be handled as a text nursing order, chosen from a predefined list in some cases with discrete data points behind the choice or as an order set. Tapers and sliding scales are special types of multipart orders. These are commonly handled by special modules in the CPOE such that they look like discrete orders, but they end up at the end of the ordering process as free text orders (i.e. are not computationally available).

Multi-part orders are important to include in discussions of CPOE usability and structure. In general, two disparate (i.e. apparently unrelated) orders are not allowed as a single order statement. If a set of orders is related, then it must be pre-built as an order set. Providers are encouraged (or required) to use – pick and choose, if need be – two (or more) simple orders from a pick-list instead of placing a multi-part order.

One of the experts felt that he could not respond to this question adequately because he was more familiar with the outpatient ordering system. Since 'multipart' orders fall within the domain of inpatient care, which they were still in the process of implementing, he felt it had some capability but he could not give a complete description.

The responses by the other four experts were varied. One said, "We could really represent any logic in a written order. But again, you would need to search for that order based on a 'search' word...and you would need to accept the text as it is written. Or, just write a new free text order yourself."

Another described their system in the following manner. "The way we would handle that order currently, would be to put it into a nursing text order and then they would transfer it into their 'cardex'. Now in this system that we use, there is a way to

decompose that order into separate orders using *orderable items* if we found the need to have that kind of data. The way to do that is through *order sets*. So, what you described there would be actually be broken down (into more than one order). So, for instance, starting heparin [is seen as] seven different orders...and then there is the heparin sliding scale...the values are modifiable...so this would actually come out as a text order that gives you ranges. We haven't built that for data elements behind that text order, but we have the capability to do that. I'm not sure what we would do with them as separate data elements. The other thing we could do with is to put as separate alerts, for example, for PTT values...but PTT is a data element in the lab...we could use that in our decision support to fire off a reminder...this is a feature that we don't have. We also have the Barcode Medication Administration System. The Barcode Medication Administration System and the lab don't 'talk' to each other. We have the ability to generate alerts, and I think the ability to display lab work (related) to orders is also within the realm of possibility, and the pharmacists already have that."

A third expert used another scenario for a 'multipart' order. "Another example of a multipart order would be taper...those could be handled as – 'day one', 'day two', 'day three' put together as components of a parent order. Another example, which of course has fallen out of favor, is that of the sliding scale, but most systems have a way of creating them. And the interesting thing is, when you are all done with that, what spits out the other end is often a text order. So, it looks great! It has the very, very atomic components, and we can do all sorts of stuff with it, but really, you push "OK.", and then what? So it is wasted from the point of view of its computational potential. The example you gave here "clamp NG tube..." would be a text order. May be a table is

used to enforce completeness...but, when you're done with it, it is a text order. If the order is going to the lab, it is transmitted electronically, but if it is going to the nursing station, it is often printed out. There is no machine that is going to put the NG tube down...so it helps to have a record."

The final expert answered, "In general, this would be an *order set*. This would be a collection of orders that would be ordered and signed as a group. There is a better way of doing this. Most hospitals have protocols. A *prn* order that generates a task so the order is given and it is carried out based on certain parameters that are given. Let me explain one other kind of order. It's what's called *linked orders*. For example, an oncology order – 'Give [the chemotherapeutic agent] for ANC greater than 500' what happens is that, that order can be activated as soon as the condition is met. If it is phase one, then as soon as phase one is complete, phase two orders are activated. That's done manually because it has to do with nursing assessment. So the nurse says 'target met, activate phase two' and the next set comes up that has already been ordered."

"What you don't do is to have a single order [for example] to draw blood culture and give ibuprofen. You don't do that in electronic orders. This gets back to usability. There are ways of grouping orders that you frequently use together. These kinds of things can be saved in a *folder*."

How is a change in a previous order processed?

Change orders present a potential for double orders, which have then to be detected by some external system. Change orders are being processed, for the most part, in a

order, [on the interface] there are options - is it a 'NEW' order, or a 'RENEW' order, or a 'CHANGE' order so that it can be handled differently."

The third expert explained, "You would find the order, you would go up and press on 'CHANGE', make your changes, and do 'OK' and then you sign. What happens behind the scenes is that it would create a new order, using the prior order as a template for it, and then it would cancel the old one and put in the new one... except for a text order of course. Because of the possibility that you could be sending this to any pharmacy, any system, so they give you the possibility to do any of these."

The fourth expert stated, "Modifying is to take the existing order and go back and change the frequency, change the route, the dose, etc. 'CANCEL' actually cancels the previous order, and 'MODIFY' brings up the previous order for rewrite. While it is important in the pharmacy system and sometimes with nursing, the advantage of a modifier, especially in the ICU, is that the history of that order is available right there. For weaning orders, you can have protocols. All those orders have different formats. ICU orders usually tend to be single line orders and they are usually modifications. And then the 'sliding scale' - there is a sliding scale tool."

Are a certain percentage of orders still being written as free text because no comparable orders are included in the knowledge base or the predefined orders list? In these systems, very few orders are written as free text. However, many orders, especially nursing orders, are preconfigured and many do not contain computationally available (i.e. discrete) data. In all of the above cases, an organizational decision has

been made to minimize and, if possible, eliminate the need for creating ad hoc orders that cannot be processed electronically. However, certain orders in the Emergency Department and narcotics orders (because the DEA has not yet begun to accept electronic signatures) are still being written on paper. Greater than 95% of orders entered into these CPOE systems are not extemporized 'free text'. Some of these have a "free text component" or there are validated "nursing free-text" orders, or there is a "comments" field to which any instruction can be added ad lib. Most of this 'free text' is not processed any further to fit into any schema. For example, one expert explained, the phrase "times 14 days" in free text is not computable, but entering a *start date* and a *stop date* (to calculate the duration of the therapy) is. He implied that being able to derive meaning out of such 'free text' would be desirable. None of the respondents viewed the lack of these features as a drawback or a significant hindrance to implementation. Hence, allowing *free text* entry of orders and electronically transmitting them seems less of a data modeling issue and more of an organizational decision on how much *liberty* to give to the ordering provider.

One expert answered this question by stating, "My guess would be...less than 2-3 percent." A second expert elaborated, "Next to none. [Some of the] nursing orders are in free text, but for the most part, to write an order in [our system] requires that you find an order in an orderable item. The nationwide last statistics that I saw was that 95% of medication orders are directly entered by the providers. And then there are some categories that are excluded from that such as, what are referred to as, *Policy Orders...* we currently have some orders on paper [for] some of the narcotics medications, because the Drug Enforcement Administration (DEA) does not allow

electronic signatures. We also have a number of protocols in oncology, so those, are in large part still on paper. What that means is that the pharmacists or someone else has to enter it. They all get entered into the computer at some point. When you say, "turn the patient" that is a nursing text order. I don't know for nursing text orders how many are entered and how many are picked off a pick-list of predefined orders. But we do have many nursing text orders that are used frequently that we can just check or pick off a list. We have a variety of different order sets that we have set up - those that are offered on a menu - have an orderable item in the back end. We also have the generic nursing care orders that the doctors write and those there's no way for us to capture. Radiology orders are computerized. Requests for consults are computerized. Some orders are still being written on paper, such as in the ER."

The third expert stated, "I would say there are pretty small percentage of orders that are put in because there are no comparable orders - I would say 1-2 percent. Another interesting question is what percentage of orders is written as free text because they couldn't find the order? That's probably higher. "

The fourth expert, who is more familiar with outpatient than inpatient order entry systems, said, "Orders themselves...in the outpatient, zero orders in free text...so every order has a unique identifier. For example, [in the inpatient setting] if I was to order Demerol injection, and I wanted it be repeated in three hours for a pain scale of 6, I may have to order a Demerol injection for now, and I may have to order a second one as a *future order*. In the *sig* it would say, in free text, "Give if pain scale is greater than 6". That would not be discreet coded information in the sig. In the outpatient setting, my guess is it would be less than 2%. There are some settings in which, such as giving

oncology drugs in the outpatient settings, those kind of conditional orders might be free text. I do know that [the vendor] actually is in the process of developing a specific oncology module in which they are controlling more of those variables and they can be more discreet but I'm not sure where that is right now. We are in the process of implementing [our system] in the inpatient setting."

The fifth expert had a slightly different perspective. He viewed the percent of orders entered in a structured manner as an implementation challenge rather than as a software design issue. "[How many orders can be entered] depends on what the [organization] wants. You have to decide what the goal is. If the goal is a specified percentage of patients, or a specified location or locations, or you want 70% of the medication orders of outpatients, or you want your hospitalist group to use the CPOE. There are advantages or disadvantages to doing just about any one. So it's not because no comparable orders are included or there are no predefined orders. But it is an organizational decision. So this is usually not a limitation of the system but an organizational culture decision. So what that tells you is that 80% of this isn't the software. Software can usually be designed to fit to do the necessary thing. That's why there are best-of-breed systems that are very good for an individual domain. But they don't talk to anyone else. So how do you solve that? So you come back to the concept of a single database. Number two, you have a lot of options for all the formats. But then that is 20% of the work. 80% of the work is sitting down with the cardiac surgeon, neurosurgeon, and pediatrician and saying 'you are all ordering the same thing', and have them agree on a syntax. Some orders have to be developed specially for certain specialists."

If your CPOE is not currently based on a schema or ontology, do you think that such an ontology would be useful for the construction/population of a CPOE system? If so why or how?

Almost universally, the experts thought that the schema we have developed is more comprehensive, generalizable, and transferable than the schemas for the systems with which they are familiar. They said it has a better potential to be machine-interpretable, and therefore, is likely to further facilitate the automation, speed, accuracy and versatility of the order-entry process. Most importantly, they realized that a schema such as this at the lowest level could serve to bridge the various CPOEs together. At the same time, they felt that development of such a schema at the present time is an academic exercise, and that it needs further refinement before being accepted and implemented widely.

The expert who was uncertain whether or not his CPOE is based on a schema commented, "I think it has value and it has more intelligence and you don't have to be so explicit. The issue is this – in our system you have to write an explicit rule to check contradictory orders. Whereas, if you a have system that is based on hierarchy of concepts then you could embed the intelligence in a more generalizable fashion instead of requiring a programmer to write a specific code. It's a smarter system no question, so I am sure that all systems in the future would be built on that. But it's not going to hold me back. I have 900 rules to choose from. So my problem is not that I don't have enough rules but that I have too many rules. How do I bring them into the environment to provide patient safety, and not make it miserable day for all the physicians without all these pop-ups coming up? So my challenge is how few [rules] to bring up and still

offer patient safety. So I think your system is a system for the future, but its not going to hold me back now because I have explicit rules. I have more rules than I can possibly use right now. So for now it is an academic exercise. But the academic exercises of today lead to the products of tomorrow. I see even greater value in having orders based on concepts in the clinical data repository. That if a person is on heparin, then they probably have these conditions - if they have a compression hose on, they probably have these conditions. If they have both the likelihood of them needing a PT, or a PTT or coumadin is very high, let's roll up that rule and see if the doctor will use it. Therefore there is some value in processing an order but there is more value, I think to clinicians in offering them a subset of all the orders in the system that are particularly pertinent to their patients. Then the system looks smart. Anyway, that's where the real value is." He added "The Internal Medicine discipline has the most to gain by having an intelligent system like that because they are faced with more and different treatments and diagnostic paths. In our EMR, 500 [order sets] are in oncology alone - about half the order sets are in oncology - so there you are faced with a complicated regimen with doses based on a number of different physiological parameters. So there that organization would be very smart. My expectation would be that the more complicated the medical care the more likely this system would be of help."

The remaining four experts felt that any CPOE has to be built on some sort of a schema or data model. One of them did not address this question further, and the other three had the following comments. "I think our order is pretty much following this type of schema. I think that a schema like this could help to ensure that when a new order is written, or is developed for use by the computer, that all the aspects that need to be

considered are covered. So it is like a preflight checklist for developing a new order and this is something we don't do... and we should look at, for instance, to promote patient safety. You have a schema for developing computerized patient orders, and this would be particularly useful for developing Quick Orders and even the Generic Order Dialogue that I showed you. So by identifying the components that need to be associated with each order...so that there is a routine for people to look at when developing orders...that's one way, I would use it. Also, you could also look at it retrospectively, for instance, how often we violate our orders, how often we adjust the doses because of drug -drug interactions. It would also allow you to do some assessment of your ordering practices. Another scheme that seems to facilitate orders is to be sensitive of context in which the orders are being written. This sort of a schema would be useful for the people who are developing our system. Any of these items could be used to trigger other things. If they developed orders that would follow this it would provide the baseline functionality with which we could do that. So what you would want to know is 'Is a syntax and ontology that you've come up with, applicable to orders that are created in various electronic medical records systems?' We might not have syntax, but we have a formalized structure to each of the orders. I don't think we've necessarily talked that through, although it was provided for us by the way the EMR was developed. I don't know if the developers actually have a document that calls it that. All the medication orders follow a similar structure; all the lab orders follow a similar structure. I don't know if anyone has come up conceptually with a master syntax. I think it's interesting to have this discussion, because what you are doing now is to formalize this. In our system, what we are using now was developed a long time

ago and I have not seen a formal description, not that it would be a bad idea to describe how the system is set up. The way we could use this is to describe our system. I think one of the things that developing this kind of the schema does is that it allows you to describe what you're doing in a common language so that when we talk about components, elements, and things like that, others who are looking at their own system know what you're talking about. We need communication among disparate EMRs." The second said, "I would say, yes, it would be useful. And I should say, some developers do use schema or ontology. It may be transparent to me; they may have some really smart people who have a beautiful ontology all set up that they use every day...they [may] have chart or a poster behind the wall. But in my view, it would be useful. It kind of helps you learn from the very basics - how you're going to go about creating this enormous collection of orders. And you can educate people on making [their own] distinct orders. What we were missing is, we could say they have things here in column E, those are order components, you can see we have labeled the columns 'has form', 'has abbreviation', 'is synonym of', etc. You understand the schema and the spreadsheet is completely clear to you. It's very explicit. So, sharing is another potential advantage."

The third expert commented, "I think there are many aspects of that. From the processing end of it, knowing what type of an order and what the attributes of that order are allows you to automate much more than you otherwise the would. Obviously it also decreases the risk of errors, the more discrete it is and the more knowledge that is incorporated in it. If it is set up appropriately, it might also increase the usability and increase the speed because the more is known about it, the less needs to be entered in it.

It not only allows automatic processing but it also allows decision support, interaction checking and so on and so forth. Finally, it allows maintenance much better. If you wanted to change some attribute, for example, of all the penicillins or all of the pneumonias, you have this parent-child relationship. So that gives you tremendous maintenance capability."

How could an order ontology be used/implemented? How would you test its use?

Recommendations for testing our schema had a variable focus – safety and accuracy for one, cost-effectiveness (in terms of less human labor) for another, and usability from a third expert. An RCT to measure correctness or success of an ontology or system based on it would difficult. Success could be measured in one of several ways:

- a. When linked with a rules engine, look at all of the rules fired for correctness.
- b. Ask "smart users" to rigorously test the system.
- c. Build use cases to make sure it performs as expected.
- e. Look for evidence of cost savings, simplification of processes, and system speed.
- f. Measure the effect on workflow, especially on duplication of actions.

Four of the five experts answered this question in some detail. One of them said, "One way would be to keep a log of all the rules that fired, all the times logic was used. Now that's tedious. If I was to examine those and at least feel comfortable that every rule that was fired was appropriate, that would give me confidence in the system. One way to do it would be to look at every rule of logic. The other way to do it would be look at every rule that did fire, and look at the clinical context – also quite difficult to do – and after a while you get confident that the system worked as designed."

"The other thing would be to put it out in an environment of smart users and say [to them], 'Your job is to test drive the order expert system. We don't want you to take any computer suggestion without inspection because you will be determining the safety of this.' The FDA has interpreted [these systems] not in terms of product liability but in terms that these are intended to be used by a smart user, as an aid to treatment, not a replacement for processing the treatment. So it places the burden on the doctor to use the system effectively, and you don't get blanket product liability."

A second expert stated, "In my view, the process of implementing would be easier. Right now the barriers are primarily financial. So if the ontology simplifies the process, and makes it faster and therefore less expensive, you need fewer people in the process. If those differences were important enough, then I would say that would be a measure of success. You might also say how many errors occurred in the process? Did we avoid double work, triple work and end up with fewer problems, [fewer] mistakes using this ontology? Randomized controlled trials for this process are going to be tricky. I think it has the potential [to be machine-interpretable], but the history of this sort of approaches has been that they take a while to succeed, and take many attempts and their adoption is not as rapid as you might want; if we come up with the new schema, we have to be open to the possibility that whatever benefit it may be, it is not going to be broadly adopted. And then you are going to have to talk to the vendors. They don't have a strong interest in interchangeability and exchange. It's a good idea, but it's going to take a while to percolate through. It certainly would be a good academic project. It would be a good idea at some point, if you have the time to talk to the vendors and I mean their engineers, and see what they think."

"The way I would think about testing such a thing would be through 'use-cases'. A use-case would be a description of the ways in which the terminology would be used. For example one use-case might be – 'the doctor enters orders into the system'. Second use case would be – 'doctor changes orders'. So you have to come up the scenarios or use-cases. Another way would be that some people who are familiar with the layout of that particular environment...have them come up with all the use cases to make sure that it performs the way you expect it to."

The fourth expert responded, 'Vendors are not interested in data models. In their mind it is an academic exercise. But the engineers of those companies - that's what their interest is."

DISCUSSION

Since our study is unique, it is not possible to discuss it in reference to any other work done previously. The response of our experts suggests that most of the current CPOEs in their present stage of evolution are based on some sort of schema or data model. Two of the respondents also emphasized that the schema of their CPOEs was actually part of the larger schema on which their EMR (an integrated suite of 10 or 11 different applications) was built. Judging from their responses, it appears that while they were conceptually aware of the basis on which their respective schemas were built, as implementers, they did not have immediate access to the formal description of the data model used by the software engineers and developers. Therefore, when one expert claimed that their schema was conceptually similar to ours, we had no way to compare. It was difficult, at times, to separate CPOE design issues from implementation and

usability issues during the interviews. Hence, a next step in our quest may be to approach the engineers involved in designing these CPOE systems.

Given the remarks and responses of the five experts that we interviewed, it is evident that developing and refining a schema such as ours is worth pursuing as the next step in establishing ontologies in the medical domain. Academic as the exercise may seem, it is not distantly futuristic in its applicability. Indeed, some of the communications gleaned recently from the list-servs of the Knowledge in Motion Working Group [17] and Clinical Information Systems Working Group [18] of the American Medical Informatics Association [19] suggest heightened activity in this direction.

We learned that an orders ontology and syntax derived from it would have the following advantages:

- Maintenance: Having an order ontology should improve ease of maintenance of orders and order sets.
- Safety: An order ontology and syntax help all aspects of an order to be considered, "like a preflight checklist" to promote safety. This could occur during the ordering process or when preconfigured orders are being developed.
- Decision support: Inherent in an ontology are terminological relationships. If an "orderable" comes from a common terminology, the relationships inherent in that terminology may be useful in decision support systems.
- Assessment of ordering practices: Increase in discrete data in orders should
 occur with use of an order ontology and syntax, which then may allow for better
 assessment of ordering practices.

- Interfaces: Increase in discrete data in orders should facilitate use of interfaces with other systems, such as medication administration and bedside monitoring devices.
- Shareability: An order ontology could facilitate shareability such that disparate proprietary CPOEs could communicate and exchange data with each other.

We became aware of a number of issues and ideas that will direct future work. For instance, it is evident that there are administrative or transactional aspects of an order that our schema ignores but which are essential data elements or components of an order. Examples include the cost of a drug, which may be visible to the pharmacist, or the CPT code of a procedure visible to a coder but not necessarily to the ordering healthcare provider. These transactional aspects of an order may need to be incorporated into our schema.

It is also apparent from this study that our schema does not have a provision to explicitly identify to whom the order is being communicated – for example, a drug order could be for the pharmacist to dispense, a nurse to administer, or a patient to take. An improved version of our schema will need to incorporate this field.

Order types that we did not model well include weaning *orders* and *titration schedules*, which are more that just compound orders as we have allows. Instead, they are specific protocols and may need to be modeled as a separate order type.

Some of our experts view CPOE from an outpatient or from a subspecialty viewpoint.

Since our schema was derived from the inpatient intensive care domain, it seems that it will likely need further modification to enable it to encompass wider medical and

surgical domains.

It appears that in present CPOEs *smart sets* (lists of orders related to a particular clinical condition or diagnosis) are a first attempt at associating some sort of clinical context to the orders. Future efforts to extend our ontology should also include relationships to dynamically link orders to concepts in the clinical data repository or physiological parameters to provide the context.

Finally, two of the experts questioned our choice of certain terms in the schema and found them confusing. During the interviews, they asked for further explanation of our usage of those terms. Hence, a future version of our schema may require the use of completely unambiguous terms.

CONCLUSION

Many orders and sets of orders, especially those requiring discrete and predictable data elements are indeed based on some sort of a schema or data model. They are also linked to a varying extent to decision support tools. On the other hand, many orders that are deemed to require subjective human interpretation and judgment, while being entered electronically, are not being semantically processed in CPOE systems. Further insights into the existing schemas will require contacting engineers and developers of these products. Our schema, once further refined on the basis of this study, may be the next step in further automating the order entry process and in capturing and analyzing more and different kinds of order entry data.

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