

Vocabulary Task Force Public Hearing Draft Transcript September 1, 2010

Presentation

Judy Sparrow – Office of the National Coordinator – Executive Director

Good morning, everybody, and welcome to the Vocabulary Task Force. This is day one of a two-day hearing. We're operating under the auspices of the HIT Standards Committee, which is a FACA committee, a federal advisory committee, which means there will be opportunity at the end of the hearing for the public to ask questions, and a transcript of this meeting will be on the ONC Web site. Just a reminder for workgroup or taskforce members to please identify yourselves when speaking.

Let's go around the table now, and I'll ask you to introduce yourselves beginning on my right with Mr. Vreeman.

Daniel Vreeman – Regenstrief Institute – Research Scientist

Hello. I'm Dan Vreeman from the Regenstrief Institute. I head up the LOINC development activities there.

Stuart Nelson – NLM – Head, Medical Subject Headings Section

I'm Stuart Nelson. I work for the National Library of Medicine, and I produce vocabularies.

Betsy Humphreys – National Library of Medicine – Deputy Director

Betsy Humphreys, National Library of Medicine.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Jamie Ferguson, Kaiser Permanente.

Floyd Eisenberg – Siemens Medical Solutions – Physician Consultant

Floyd Eisenberg, National Quality Forum.

Christopher Chute – Mayo Clinic – VC Data Gov. & Health IT Standards

Chris Chute, Mayo Clinic.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer

Stan Huff, Intermountain Healthcare and the University of Utah in Salt Lake City.

Patricia Greim – VA – Health System Specialist: Terminology

Patti Greim, VA.

John Klimek – NCPDP – VP Industry Information Technology

John Klimek, NCPDP.

Marjorie Rallins – AMA – Director, Clinical Informatics

I'm Marjorie Rallins from the AMA.

Judy Sparrow – Office of the National Coordinator – Executive Director

I believe we have a number of taskforce members on the phone. If you're there, would you please identify yourself? Okay.

Eric Strom – DoD Military Health System – Program Management Support

Eric Strom for Nancy Orvis.

Judy Sparrow – Office of the National Coordinator – Executive Director

Anyone else from the taskforce? All right. With that, I'll turn it over to Jamie Ferguson.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Thanks very much, Judy. We're here today to explore the set of infrastructure requirements for the vocabularies required for meaningful use. The context for this meeting is that it's a follow-on to a hearing we had back in March that resulted in a set of recommendations from this taskforce that were then debated, discussed, and approved by the full HIT Standards Committee and transmitted to the National Coordinator.

One of the themes that came out of that previous work, which, overall, it was focused on governance for vocabularies for meaningful use. But one of the themes that came out of that was the need for so-called one-stop-shopping. And we heard from a wide variety of implementers of the vocabularies who may potentially be eligible and interested in obtaining the meaningful use incentives through that program, folks who are implementing EHRs using controlled vocabularies to meet those meaningful use objectives.

We heard an overwhelming theme of make it easy for the implementers. We want one place to go. We want one coordination point, and we're here today to further explore the set of requirements, and so we've asked a series of questions. And so we have a number of panels here from a variety of stakeholder perspectives. We'll hear from a total of 23 panelists today and tomorrow.

In the first place, we want to address and understand what does one-stop-shopping mean to you, and get an understanding of that. We want to understand if there are some functions or requirements that need to come first, what's most urgent? What's most useful in the context of meaningful use? And what would be a phased plan to achieving the ideal end state?

In order to address those questions, we have a number of much more detailed questions that'll be addressed by the panelists. We expect to hear from their perspective how they run their operations today, how value sets and subsets are created, maintained, distributed, operationalized, and used from a variety of perspectives.

Let me turn it to Betsy and see if you have any other opening comments.

Betsy Humphreys – National Library of Medicine – Deputy Director

I don't think I do. That's a very good summary. Thank you.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Well then, without further ado, we do have one of our panelists on our first panel called in stuck in traffic, so we do expect Lisa Miller to appear soon. Let me start out by introducing Sundak Ganesan from the Centers for Disease Control and Prevention. A couple of our panelists have others who will help them answer questions. Sundak, if you don't mind, I think, introducing Dr. Lipskiy

Sundak Ganesan – CDC- Lead Vocabulary Specialist

Sure.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

If you could just say who you have with you.

Sundak Ganesan – CDC- Lead Vocabulary Specialist

Nikolay Lipskiy is the CDC standards lead for interoperability and standards, so we jointly coauthored this testimony.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Thank you. As I said, we do expect Lisa Miller from X12 to come in just a few minutes late here. We also have Ted Klein representing HL-7. We have Floyd Eisenberg representing the National Quality Forum, and Marjorie Rallins representing the American Medical Association.

Marjorie, do you have others who are going to help with ...?

Marjorie Rallins – AMA – Director, Clinical Informatics

Yes. I also have Kendra Hanley and Delane Heldt from the AMA.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Then I think, without further ado, I think we'll start in with the oral presentations. Sundak, if you can start us off, that would be great.

Sundak Ganesan – CDC- Lead Vocabulary Specialist

My name is Sundak Ganesan, and I'm a Northrop Grumman contractor representing for Centers for Disease Control and Prevention. Thanks to the vocabulary taskforce members for giving me an opportunity to testify. I've been working at CDC for the past six years as a vocabulary specialist lead managing the value sets in CDC vocabulary server. I'm also a co-lead for the public health vocabulary and messaging community of practice, which provides support and training for the implementers.

The CDC has at least 15 years of experience managing the value sets, and I wanted to briefly comment about some of the training and support that's very crucial for the implementation. I think it will be very useful for the implementers to have a national and regional support team, assisting in the implementation of messaging and vocabulary standards. The national support team could ... request and forward it to the appropriate domain experts or organizations responsible for the meaningful use measure. Training regarding the standard vocabulary, mapping tools, and Web services are very crucial for the adoption of standard vocabulary.

So the vocabulary of messaging community of practice has been conducting Webinars to provide information and technical support about the HL-7 implementation guides related to the population health meaningful use measures. These Webinars also provide a brief overview of the vocabulary and messaging tools that will facilitate the implementation. And I just wanted to briefly mention about some of the experience of managing the value sets using the CDC vocabulary server PHIN VADs. The CDC has already published the value sets associated with population health meaningful use measures such as ELR to public health, as well as immunization.

PHIN VAD is a CDC vocabulary server, and it stands for Public Health Information Network Vocabulary Access and Distribution System. Our PHIN VAD's value set ... based on domain recommendations and HITSP CAD value sets. And PHIN VAD's value set metadata is based on HL-7 domain and value set definitions and binding document provided by the HL-7 vocabulary. The PHIN VAD's application has been developed using the HL-7 CTS2 guidelines. And the main purpose of PHIN VAD is really to distribute the value sets, not really the focus of the core system that needs to come from the actual source or the distribution source.

PHIN VAD has grouped all the value sets associated with the particular implementation guide and host them as a vocabulary view. This allows implementers to download and search all the value sets associated with an implementation guide efficiently. Currently, PHIN VADS has almost 600 value sets supporting 60 different HL-7 messaging and CDA implementation guides. PHIN VADS hosts the past, current, and future versions of value sets. An example would be ICD-9. Right now we host the fiscal year 2010, as well as the fiscal year 2011 value sets based on ICD-9 yearly updates. PHIN VADS value set download includes all the metadata that are needed for implementing the HL-7 messaging or CDA implementation guides.

And I also want to briefly mention about how we manage these value sets and what sort of framework we have for authoring these things within CDC and outside CDC. PHIN VAD uses the universe of ... framework, which is a Web-based tool, to manage the core systems and value sets in VADS. UAF is currently available only within CDC Intranet, but it'll be available to the value set creators and measure developers outside CDC later this year. And most of the implementation guides use at least 20 different standard core systems, so UAF provides all the latest versions of the core system that are needed for

creating the value sets. The biggest challenge in creating the value sets is the timeliness of getting the new standard vocabulary concepts from SDO. Sometimes it takes about three to six months to get the concepts to be included in the value set.

Our PHIN VADS release notifications are currently sent to the implementers via listserv and mail. I think it'll be nice to have a good subscription mechanism. Value sets ... by CDC are primarily used to support electronic laboratory reporting immunization, healthcare associated infections, public health case reporting, and notification. PHIN VADS can be easily integrated with any application using Web services, and CDC really supports the vision of vocabulary taskforce on development of the one-stop-shopping infrastructure for updating value sets related to meaningful use. Thanks again for giving me an opportunity to testify.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Next I want to introduce Bron Kislner from CDISC, who I did not introduce before, and just came in. Thank you very much for joining us here today, and please go ahead.

Bron Kislner – CDISC – Director of Terminology & Strategic Alliance

First of all, I appreciate the opportunity to share CDISC's perspective and experiences with controlled terminology and value sets, as well as the vocabulary taskforce idea of moving towards a one-stop-shopping environment. CDISC completely agrees with that approach.

Just a little bit about my experience, I'm the CDISC senior director for terminology and strategic alliances. I've been working in the data standards world since helping co-found CDISC back in the year 2000, so I've been doing this for a long time. I hope to share some of my experiences today to help the vocabulary taskforce.

One of the things I want to do, there are a lot of specifics in my written testimony, but what I want to do in my verbal is kind of step back a little bit. In order to have shared terminology and value sets, the key ingredient of any standard is collaboration. For example, early on when you're developing a standard value set, you need to make sure you have the key stakeholders at the table to provide expertise in development of that standard. Then you need various points along the way in the standards development process to make sure you're bringing in larger groups and perspectives. In the standards development process, the public review and the comment on the draft standard created by experts creates that opportunity, so there are different steps of collaboration and different types of collaboration you need to look at.

The other thing that we want to do is, CDISC, it was really important that we took collaboration to another level. We wanted the ability to actually share standard terminology and value sets with other stakeholders, so beyond standards development. And what we needed to do is, for example, we knew FDA had standard terms and definitions that we wanted to reuse.

We wanted to be able to point to those and tag to those in the same environment. And so what happened is we needed a central, shared, and secure terminology space with which to do this, and NCI EVS has provided that infrastructure. It was also important to us that there's central terminology services wrapped around terminology or terminology reviews and wrapped around the different stakeholders you're working with. It creates consistency and continuity. NCI also provides the framework and services to bring other stakeholder organizations to the table, so we've tested this collaborative framework, so we can bring other organizations to the table. For instance, we're talking with Floyd at NQF right now and seeing how we can share value sets and terminology in that environment.

Another important aspect of a terminology infrastructure is the actual business model that wraps around it. You can't risk being susceptible, a business model being susceptible to fluctuations in funding or politics, especially if you're delivering a standard through that mechanism, and a very large, global use agreement becomes accustomed to that infrastructure. We can't risk that. That's why CDISC partnered with a federal organization that had a long history of consistent funding. That was really important to us.

Looking back at the standards itself, when you create a standard or a value set, the first version of that is really just the beginning of the standard. That standard has a much longer lifecycle after it was developed. Development may take six months to a year, but it's going to live out there and be implemented for many, many years to come. Therefore, it's important to have a clear, flexible, and well controlled mechanism wrapped around the standards to support terminology and value set evolution and versioning without an established mechanism and services addressing requests for adaptation that come in from the industry is not possible. So you need a governance structure with that terminology that helps you control change management.

The other aspect that's important in the life of a standard is a user community. You need to make sure that that standard has dedicated resources that address feedback from the end users, so you want to partnership with your end user community, so you're addressing that feedback. You want to make sure you create a low barrier of entry for access, download, and use of the standard. And in that partnership and feedback from the end user community, you want to continue to lower that bar of implementation. Also, through implementation experiences, you can glean valuable knowledge about the standard and how it's being used in ways you may need to change it.

CDISC currently has about 8,000 terms in production that are tagged and coded in NCI at the source. Many of these, I think, are applicable to meaningful use. But what we want to do now is actually build on this terminology framework, so CDISC actually seeks to electronically represent data elements and data models in conjunction with value sets and controlled terminology. This is also about improving the end user experience. Just because we have terminology in a central space for the end user, which works well, we now need to figure out a way.

The standard is much more in control terminology and value set. You have a data elements layer and the data modeler. How do you connect all those together for a single end user experience? That's one of the things that we're evaluating in the share project, which was mentioned in the last testimony.

I won't go into it in detail today, but CDISC share is intended to be a globally accessible electronic library of common standards and common data elements that can be easily used by applications and clinical research studies. The other idea of share is to link together clinical research with healthcare through the bridge model, and the bridge model has recently been successfully validated through CDISC, HL-7, and ISO.

The goal is to provide a common record standard to be used by clinical research and across other clinical use cases. Regarding share, CDISC has developed in-depth user and system requirements and governance requirements. We conducted a detailed stakeholder analysis with over 100 interviews cutting across many clinical use cases. Then we also conducted a pilot with Mayo using LEX EVS. What we've done is we've taken all this information and all these experiences and lessons learned, and we provided them to NCI to incorporate in their semantic infrastructure.

One last thing I want to bring up is in working through various collaborative models, finding a model that brings clinicians into the fold is very important, and we've identified that disease specific activities really help us to do this. They prove very effective in bringing together very diverse communities and including clinicians, so these projects are designed to make clinicians an integral part of the standards development process, assuring the creation of useful end products for the clinical community and that the clinicians can actually understand and use.

There's one final ingredient I want to point out that I recently discovered. I knew these disease projects were working very well, but I couldn't really step back and understand why until I was actually at a tuberculosis meeting in Ethiopia recently. In the opening part of my written testimony, I mentioned the tuberculosis initiative launched by the Gates Foundation, Global TB Alliance, USFDA, and others. This is a very ambitious initiative that seeks to cut the development of four critical TB drugs and drug regimens from 24 years down to 6 years. That's a cut of 75% in the development and approval time working with regulators from all across the world.

The speed at which they're able to achieve this is because of one reason, and I realize that's why the disease projects at CDISC are successful because everybody is focusing on the same end goal. Everybody has the patient in mind. So you have industry competitors sitting at the table. You have regulators from all over the world, but they're all focused on the goal of providing timely patient access to new TB drugs and vaccines for patients that need it most. So they've created a sense of urgency and purpose by focusing on a disease and population with a public health imperative, so the needs of the patient come first and front and center, creating the actual drivers, so the patients are the glue for the project, and they're the accelerator.

You may wonder why I'm sharing all this. I think that clinicians and patients being a part of the process is critically important. While attending the TB meeting in Africa, I can't tell you how many times African health officials said publicly that they are looking to the United States for leadership, even in these projects that are focused on emerging and developing organizations. I think standards is a very important piece of the puzzle of the whole medical, clinical research and clinical care paradigm, and it's something that not only do we need to get right for the United States, but we need to keep a global perspective in mind. Thank you very much.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Next, we'll turn to Ted Klein from HL-7.

Ted Klein – HL7 – Vocabulary Cochair

Hello. My name is Ted Klein. I'm with HL-7. I'm also the principle of Klein Consulting, a medical informatics-consulting firm. I know many of you through activities in clinical LOINC and ISO, and I'm also one of the co-leads of the CDC's vocabulary community and vocabulary messaging community of practice. I want to thank the taskforce very much for this opportunity to present the HL-7 perspective, so I'll keep my HL-7 hat on for this talk on value sets and vocabulary and, most important, requirements for infrastructure to enable meaningful use and kind of to improve our clinical delivery system.

We've been working on value sets and the vocabulary model at HL-7 for quite a long time in the late 1990's. We began to redesign the vocabulary model specifically to address many of the weaknesses we have seen in the use of vocabulary and standards in the world at that time. It's been under continuous development, including authoring and distribution of value sets for that entire time. We now have over 1,750 value sets that have been authored and are versioned and are distributed through the HL-7 publishing process.

In all of this time of building standards and doing it very iteratively, HL-7, the version 3.0 process, which is where the vocabulary effort is primarily focused, has an iteration cycle of three times a year, so three times a year, all of these are versions. They're updated. Many of them are updated. New things are added, and vocabularies are distributed, so that's pretty frequently a four-month cycle for thousands of value sets to be put out, along with all of the other published standards.

A couple of things that I want to bring up that we've learned in that time, we found that expressing a value set as a list of terms falls apart fairly quickly, as your complexity and sophistication of systems goes up. So HL-7 has developed a robust model of value sets ... actually formalisms for referencing underlying terminologies. HL-7 doesn't want to author or distribute terminology. We have no interest in republishing SNOMED, LOINC, ICD, CPT, ICF, or any of the other hundreds of terminologies out there.

We strongly believe that value sets should reference these underlying terminologies with formalisms that allow rich sets of metadata, descriptions for business purposes, usage, all kinds of versioning, and other kinds of things that are separate from the terminology and specific to the business use of the collection of terminology representing the value set. We make an explicit differentiation between this formalism of expression, which we call a value set definition, and the actual list of codes that you have to put in a pick list, or you have to populate in a system, which needs infrastructure to be generated from the formalism. So a key component to all this is the infrastructure.

Back in 2003, the first version of common terminology services was published by HL-7 and adopted as an anti-standard. More recently, the second generation of that, CTS2, was published two years ago now as a draft standard for trial use. And as we heard from some other panelists, the requirements expressed in CTS2 have already been picked up by other infrastructure development around not only the country, but also worldwide, as it's a very robust and useful set of requirements. It's not in active work by the OMG and ISO and lots of other organizations. I can give you more detail on that if you would like.

A couple of other key components that we've also learned, mapping is absolutely required. You can't get by without mapping. We have historical data. We have local extensions that require mapping. We also have statutory requirements that sometimes flies in the face of standard names and standard usage, and HL-7 is an international organization. So it has to develop standards with a very, very high number of degrees of freedom to be able to cope with the statutory differences in 50-some-odd countries around the world in which it's used. So mapping, also the local extensions, you cannot have terminology services and infrastructure that do not explicitly deal with local extensions.

There are local extensions for lots of reasons. Some of them are just because it's the way it's always been done. Some of them are statutory. Some of them deal with the timing issues that were alluded to before, taking months to get something new added to a release terminology, but somebody needs to use it immediately. And that also brings up the requirement of version and version tracking and what versions of terminology, not only the release terminologies, but also local terminologies, critical to track the versions and to have your infrastructure, which must be centrally accessible. It has to be very, very high reliability, and it has to be very high availability. It requires very, very straightforward and simple access.

We've found that making very clever tools and clever technologies that are all whiz-bang and very creative and everybody thinks they're really flashy, falls apart when they have to be deployed widely. And people have a browser. They need something to deal with, with any one of a number of browsers. No, it's not just IE and Firefox. It's Chrome, Safari, and on and on it goes. Browsers, we know, have PDAs and smart phones that people are using to gather data in the field that have special purpose browsers. Everything has to be conformant to the standards – the W3C standards, the XML standards, the HTTP protocol standards – so that none of this stuff requires anything special. Although, I suggest, gets in the way of getting the work actually done.

The common terminology services model, HL-7 has not built a CTS. HL-7, we try not to build any tools at all, but we're forced to, to get our ballots out the door, and we try to get them replaced with standard or industry specific tools whenever we can. So HL-7 distributes all of its vocabulary as a set of XML files. The schema is available for the XML. Although the world at large is only beginning to become comfortable with XML technology, it has been around for quite some time. And off-the-shelf tools are able to pretty easily deal with XML files if they're very well documented with schemas, and they're easily available.

You can edit them with specific tools or any text editor. For old Unix folks, you could even use VI on these files if you're using 30-year-old tools. That's kind of a summary of a distillation of the details in my written testimony, and I want to thank the vocabulary taskforce again very much for this opportunity to present HL-7's viewpoint.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Next we'll turn to Floyd Eisenberg from the National Quality Forum.

Floyd Eisenberg – Siemens Medical Solutions – Physician Consultant

Good morning, chairs and members of the taskforce. Thank you for the opportunity for the National Quality Forum to provide comments regarding value sets. NQF is a public and private partnership with more than 400 members representing virtually every sector of the healthcare system operating under a mission to set national priorities and goals for performance improvement, endorsing national consensus standards for measuring and publicly reporting of performance, and promoting the attainment of national goals through education and outreach.

Recently NQF has had the opportunity to work directly with measure stewards to retool a set of existing measures to address data obtained through meaningful use of electronic health records, to allow flexibility in those implementations, and provide guidance for the future. Concepts for these value sets have been provided in terminologies now recommended by certification rules, but also future recommendations that have come from the standards committee, for example, ICD-9 for now, but also providing I-10 and SNOMED.

So in this process, for the first 57 measures, that has led to approximately 802 value sets across 3 measure developers with approximately 20% overlap, each one developing their own value sets, so each is separately listed in the 802. So my comments will address the requirements identified in this project regarding value set development and governance, so the requirements, the most urgent is definition of governance and roles of groups and stakeholders. Governance needs to include stewardship by content experts in each domain. Domain is identified here as quality, which includes measures, practice guidelines, clinical decision support rules. Research includes clinical effective research, pharmaceutical research, and public health.

The stewardship by the domains allows for rapid development in content areas by domain experts, avoid stifling domain needs, and provides for appropriate harmonization. The tools and infrastructures are other urgent needs. The vocabulary taskforce has talked about subsets and value sets. I will focus primarily on value sets here.

The infrastructure requirements include an authoring interface to allow appropriate selection of required values for the sets. It requires a clear understanding of the underlying terminology, which means that there needs to be involvement by terminology experts, not just those seeking concepts and looking for specific use cases, but also the terminology experts. There needs to be an ability to create a value set based on the concepts in more than one terminology, especially when looking for future guidance, and a crosswalk from one terminology to another to avoid excessive rework. An ability also to search and reuse existing value sets, recommend modifications where needed, and search or create new ones where existing value sets are insufficient.

There's also a required ability to version value sets. Taxonomies update at different times, some like RxNorm as frequently as weekly, and others less often. The complication is when to version the value sets for use in operations like quality measurement to frequent or to infrequent can be problematic, so the appropriate frequency by domain needs to be developed by that domain.

There's also a need to be able to take a group of value sets, subsets, or create a subset from them to enable implementation in EHRs and other settings. It's also the ability, as mentioned by Bron for CDISC to create a parsimonious set of value sets by domain that can be facilitated in cross-domain harmonization, so allow reuse from one domain to another. An ability also to request updates from underlying taxonomies. As the original taxonomy development was based on use case, the new use case needed for this particular measure, for an example, may find that there are elements in that branch of the terminology that don't apply, and so there needs to be feedback to the terminologies to help understand different use cases for their models.

What requirements are urgent is noted above: governance and access ability to value sets. The process should move at the appropriate pace for each domain, balancing speed against harmonization, but governance and ability to retrieve, especially for urgent processes like meaningful use is extremely important.

In some of your detailed questions, where are you using value sets? I mentioned the 802 for the 57 measures now done. If we would look at the 600 or so currently endorsed measures, it's averaging 16 value sets per measure, assuming about 30% reuse. We would be talking in the next year or two, which is the intent to have all measures retooled or new measures tooled. We're talking somewhere around 3,000 value sets in the near term to manage this process, so it is an urgent and large project, maybe not large by some folk's standards, but a large project.

In creating the value sets and updating, our findings have basically been that there are some challenges. Basically the challenges are presented in the paper, but will highlight the needs for collaboration among individuals, collaboration with the terminology experts to understand what's being chosen, so a finding or observation isn't used to indicate a condition and many other examples. There's some examples actually provided in the written testimony and also open community feedback, as well as feedback to the terminologies. Open community feedback is very helpful since no one isolated setting could possibly come up with a value set that might be perfect for everyone, so an open feedback capability is important. That's the majority of the scope of the testimony. There's more in writing. Thank you very much.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Now next we'll turn to Marjorie Rallins from the American Medical Association.

Marjorie Rallins – AMA – Director, Clinical Informatics

As many of you know, I'm Marjorie Rallins. I am the director of clinical informatics with the American Medical Association. I'm joined by my colleagues, Kendra Hanley and Delane Heldt, from the performance improvement division of the AMA. And, of course, we're very pleased to be here to provide our comments on the management and implementation of value sets. We feel this is an extremely important topic in advancing the integration of performance measures in the electronic health record.

To give you a bit of background on who we are and what we do, the AMA convenes the physician consortium for performance improvement also known as the PCPI, and it is staffed by the performance improvement division of the AMA. Together, the PCPI and the staff quite simply develop performance measures. The PCPI itself includes over 170 member organizations and, since its inception in 2000, have developed over 260 quality measures in 42 different clinical topics. Our measures are included in national programs including the CMS PQRI program, the CMS EHR certification program also known as the meaningful use regulation. Our measures are also used by payers in medical specialties in their certification process.

Now given the volume, scope, and adoption of measures developed to date, we have developed hundreds of value sets, and we are pleased to report to the taskforce that the PCPI's use and structure of value sets and subsets is consistent with the definitions that the vocabulary taskforces put together. As such, we offer the following comments and recommendations based on our experiences so far.

With respect to our internal processes and within the context of one-stop-shopping, we believe that the implementation of value sets requires a coordinated effort that spans a broad spectrum of expertise that includes, but is not necessarily limited to the following. The medical specialists and clinicians that are necessary to insure the clinical reference of the measure, the informaticist and the subject matter experts that are needed to provide the necessary HIT discipline, the IT and technical experts that are needed to implement requirements and produce deliverables and make things happen, and the very critical input of the skilled measure development professionals such as Kendra and Delane that serve as liaisons between the technical, clinical, and terminology experts.

Next, we recommend that the committee consider the value set endeavor from two perspectives, both infrastructure and content. Both perspectives are equally important, and we stress the importance of isolating the issues related to each because sometimes they can be confused. Next, we want to let you know that the PCPI value sets are a part of our quality measure specifications, and we are committed to insuring that the specifications and their relevant value sets are publicly available. We make them available by posting them to our Web site. And we are also committed to insuring that our specifications and value sets can be used electronically. In the context of infrastructure, we believe that value sets should reside in a registry provided via Web services, and that registry should be developed in close collaboration with value set developers themselves.

Now from a content perspective, we recommend the use of structurally defined value sets and subsets versus enumeration or cherry picking to identify members of those sets. For those of you with a technical background, and I don't purport to be a member of that group, we would describe this as the need for

intentional definitions of value sets. This recommendation is based on our lessons learned, as they relate to our requirements for effective change management.

When new versions of vocabularies and terminologies and code sets are released, it presents a considerable impact on our maintenance process. If we look at the SNOMED CT release as an example, we're pretty much capable of identifying revisions to SNOMED concepts that are already members of our value sets and subsets. But what's really difficult and what's more challenging is identifying those concepts that are new for that release of SNOMED that should also be members of our value sets and subsets. And it's a challenge because, historically, our work has been developed using enumeration. And, as we've moved through this retooling exercise, we've established a goal to incorporate structured rules and semantics into our workflow to facilitate effective change management.

We recommend to the committee that the value set infrastructure supports structured definitions as well, and we also recommend facilitating a change management report via a Web site that would also include a submission of feedback mechanism. In closing, we believe careful and comprehensive review of the issues related to value sets are essential for retooling performance measures for electronic systems—it's absolutely essential—and for the meaningful use of electronic health records. We appreciate the opportunity to contribute to the committee's deliberations on these issues. Thank you very much.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

I think, last now, we'll hear from Lisa Miller from X12. Lisa, thank you for joining us. I understand you were stuck in traffic, which can be a bear around here, so welcome, and we're pleased to hear from you.

Lisa Miller – X12 – WEDI Liaison

Thank you, Jamie. That's the challenge of being a local resident of the area. I'll just say that 3.5, let's hope value sets are a little bit easier than the traffic in D.C.

With that said, my name is Lisa Miller. I thank you for inviting X12 to be here and testify. A little bit about X12, we are an American national standards, accredited standards body. We have been around for 31 years, so we have a little bit of experience around creating value sets, subsets, and definitions.

We do appreciate the opportunity for this input. The theme of our comments, though, I'd like to give you three bulleted items that I know we've said this before, but they are very critical in the foundation, as you move forward. First, business case and use case must be the driver for what subset or value set is developed and maintained. The subset must or a value set must be implementable, and we ask that you don't reinvent the process to develop and maintain subsets or value sets used in health data when organizations and processes exist today.

With that said, moving on to our recommendations for the centralized location, we feel that that must be a neutral entity. It must contain a repository able to support all value sets, subsets, and vocabularies from the data content creation committees and standards organizations. It must contain the minimum metadata set, which is defined as the codified value and any associated definitions, versions, states of codes when added, modified, or deleted, status, and the organization responsible for maintenance. It must also support real time Web services, subscription, and publication and other means of computer-to-computer distribution. The centralized repository must provide the general public access to print downloadable, human readable formats, and electronic batch downloads for automatic consumption by systems.

All of the formats must contain version, dates of codes when added, modified, or deleted, status, which should be incorporated into the metadata for the subset or value set. The reason for the last comment, we are a slice in time. We have data that lives and spans multiple years, so they must have access to those versions.

The centralized repository must be easy to search and retrieve information with clear and concise information concerning the version and the organization responsible for the maintenance of the value sets. We must also have the ability for the system to record information requestors including contact

information, so the content owners and content creation committees are able to communicate. We must not disenfranchise the public via this repository from the actual content creation committees.

The system must provide a mechanism for the user to subscribe to the value set and provide the ability for the data content owners to be able to notify information requestors of those changes. Immediately, we understand and recognize that we must have this in place for meaningful use. Immediately, we need the search functionalities to find the value sets that would be the most useful right now for the implementers. If possible to have automatic links and downloads from the organizations of record would be desired, and the ability for the system to record information requestors, including that contact information that I mentioned earlier.

Moving on, X12 supports multiple industries, including healthcare. We were asked how many of these subsets and value sets we have. X12 is unique in that we have both value sets and subsets and then subsets again. And that's with our implementation and implementation guides, so we have the value set that we use for the standard, and then we actually create new value sets and subsets when we implement. So it would be absolutely very difficult for me to tell you how many of those X12 has at this time – thousands and thousands, as you look across all of our data content sets.

We do have extensive experience in creating and maintaining and disseminating value sets, subsets, and vocabularies. For value sets that change frequently, it's imperative that value sets not be tied to a specific version of the standard so that we can move forward very quickly and implement new value sets. For example, I would give you the ... codes used within our 835. The sit outside of our standard, yet we are involved in the content and maintenance of that, and that allows us four times a year to add things that the industry needs. There are, however, value sets and subsets, which do have to maintain internally to our standard and would require a change of the standard, and those we consider as structural and ones that we can't divorce from the standard, so we can do both external and internal code sets.

As far as who is to be involved in this, we can't say it hard enough, long enough, or loud enough. We need a varied cross section of resources to maintain and implement value sets. A team would include content experts representing all possible users of the value set, including resources such as clinicians, policymakers, informaticists, application IT personnel, and implementers including IT vendors. If any one group or domain dominates the creation of a particular value set, then the goal of the creating and implementable value set is compromised, and we cannot have that occur and have a meaningful value set populated in the repository.

Updates: We update three times a year, but that doesn't mean that that's the way the repositories, so you must give us all of the data content creation committees and organizations the ability to update on our schedules that we have today. X12 is working very diligently to make sure that those implementation documents that I spoke of are on a much quicker schedule so that we can incorporate new value sets. However, standards process development does take time, and it's one of our strengths.

With that, I don't believe I have any other recommendations other than we do thank you for inviting us to the table. We would like to be partners in this process and have you use our expertise, our longevity, and our historical ability to manage those value sets and disseminate them, as we have for over 31 years. Thank you.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Now we have about an hour for a discussion for the taskforce discussion with the panel on the set of questions and we have written testimony that I think everyone has read, except for a couple that I just saw this morning. Chris' card is up first, so please have at it.

Christopher Chute – Mayo Clinic – VC Data Gov. & Health IT Standards

I'm very impressed with the completeness and thoughtfulness of the testimony of all of you, and I suspect we all share a common goal. That being said, I want to raise the question of intellectual property and the issue of how you see, as a group of representatives of both standards development organizations and measure developers, the question of ownership, access, availability, and similar questions, as they

pertain to terminologies and, in particular, value sets. I can share my own bias, which is that having intellectual property or copyright or other types of restrictions on their use or their implementation, in my opinion, can be a significant impediment to the role of shared value sets ... worst case, lead end users and the community to make their own value sets, if you will, if only to avoid the intellectual property restrictions. Now having shared that bias or prejudice, as the case may be, I'd be interested in your views as to that issue.

Marjorie Rallins – AMA – Director, Clinical Informatics

I'll answer first because we knew that would probably be the first question. Let me preface my comments by saying that this project is extremely important to the AMA. The performance improvement division of the AMA works very closely with the intellectual property division of the AMA to insure that efforts and endeavors like this are addressed properly so that it minimizes the intellectual property issue. We are very aware of it, and we're very sensitive. We don't anticipate there being any barriers to use of our value sets with the proper licenses and intellectual property in place. I can say that.

Ted Klein – HL7 – Vocabulary Cochair

HL-7 has found that your phrase —significant impediment” is perhaps the politest way of putting the problem. The problem is compounded for HL-7 because it's an international organization, and our standards are distributed internationally. We've tried to do a workaround on the intellectual property again by not distributing terminology, by distributing only value set formalisms that point to terminology with descriptions that can be machine evaluated if the people doing the evaluation have intellectual property rights to the content. That's how HL-7 is solving the problem, which basically just dumps the problem into the laps of the people who actually have to use it. We see that any efforts to reduce the obstacle that intellectual property restrictions place on the use and distribution and maintenance of terminology is a very, very worthwhile thing to be pursued diligently.

Bron Kisler – CDISC – Director of Terminology & Strategic Alliance

CDISC's perspective on this is we're an global open data standards organization, so anything that we develop is free in the public domain. I think it ought to be the case for standard control terminology and value sets. So it needs to be in the public domain, open, and free of proprietary licensing restrictions. The way CDISC views it, even though we may have a CDISC tag on control terminology or value set, CDISC is about the community. It's our community that owns that standard. And because of the nature of the work we do with global clinical trials, all that content has to be open and free on a global basis, not just in the United States.

Clem McDonald – Regenstrief – Director & Research Scientist

I don't know whether you can hear the phone or I'm even ... ask a question.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Hang on just a moment, Clem. We have another panelist who is going to answer the question.

Sundak Ganesan – CDC- Lead Vocabulary Specialist

I just wanted to share some experience we had at CDC. I think that as far as the value sets development, that's exactly what CDISC is doing. We collaboratively work with stakeholders, as well as SDOs and various other folks who are going to implement those things, so all the value sets in CDC, vocabulary server or any of our implementation guides are free to use. But we also see in the context of the meaningful use, especially for one of them is the ELR to public health. We found a lot of issues people have been raising. It's because HL-7 has a copyrighted implementation guide, which is not free. So that's been brought up by various implementers as a major issue, so I understand there's a thin line between intellectual property and copyright and licensing issues. I think it will be useful to address those.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Thank you. Lisa?

Lisa Miller – X12 – WEDI Liaison

I'll be honest, I didn't come prepared to speak about IP issues, but I'll go ahead and do it anyway. I would like to actually echo a lot of what Ted had to say. X12 is certainly willing to come to the table and to collaborate. Where this project is concerned, we do, however, have an IP and copyright declaration. Our members do not freely get our standard once it's published. It is something that has a small nominal fee that is associated with it. As long as either we have an agreement with the entity that will maintain these or, again, as HL-7 purported that we would put it back on the owner. As long as they had the proper license to utilize the data, they could go ahead and use it out of the repository.

With that said, I do want to go back to the first one. As long as there's proper attribution, it does not impede on our IP and that it's been collaborated with, with X12 doesn't necessarily mean that those licenses would have to be there. So there is collaboration with the standards organizations to reach a way to make this as useful as possible, yet to maintain our IP and copyright to our standard.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Thank you, Lisa. Floyd?

Floyd Eisenberg – Siemens Medical Solutions – Physician Consultant

Just a comment from the NQF perspective. The measures that we endorse are publicly displayed for comment as part of the endorsement process, and we take the position of those measures being open for use, so if the measures are open for use, then the value sets that are incorporated in them, if they are to be shared and used in the measures, also need to be available, the value set content or the value sets themselves, not proprietary. That would be our view as well.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Thank you very much. I believe Clem McDonald on the line had another question.

Clem McDonald – Regenstrief – Director & Research Scientist

I had a question or a comment maybe. I think we need to distinguish between open and available and no copyright. I think some people maybe are mixing the words no copyright and public domain. But public domain, I don't think we do on public domain because if there's no copyright, that means they can change at will, willy-nilly everywhere. So I do believe that I'd like to hear a discussion on it. A copyright is essential to keep it standard because it will evolve, so it was the federal 1500 billing form of which there are 2,000 versions because it was not copyright. So maybe some discussion about the distinction between open and freely available, which is some other challenges still versus having a copyright that constrains changes to it freely by other users.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Any comments on that from the panel? Yes, Ted.

Ted Klein – HL7 – Vocabulary Cochair

The point Clem brings up is critical, and insuring copyright helps to control the content. The problems are restrictions on use. And even what many of us perceive as very, very low costs become prohibitive in many environments. I've worked in some public health departments of some of our smaller states in the country where they don't have \$50 to pay for a copy of some copyrighted standard. Fifty dollars does not exist in their budget anywhere to do that.

So any kind of impediment at even very, very low costs, impediments are not only monetary costs. You need to get approvals and all kinds of registrations and very, very complex set ups in order to get access to material also ends up being an impediment that is a problem for certain users that are less technically sophisticated with being able to go through forms and applications to get this stuff. Those are all impediments that we should seek to try to reduce.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Thank you very much. Yes, Bron?

Bron Kisler – CDISC – Director of Terminology & Strategic Alliance

Stan was first.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Are you still addressing the same question?

Bron Kisler – CDISC – Director of Terminology & Strategic Alliance

Yes. Just one clarification, so in the public domain and open, so that's for a large user community, you don't want there to be restrictions on the access of the content, but kind of getting to what Clem is talking about. You also need to have a facilitating or an owning organization that is responsible for the management of that content, and that's sort of the role CDISC plays. We represent that content on behalf of our user community, and we manage all the change requests and the versioning and everything coming in from our user community. But still, they have free access to use that content.

Clem McDonald – Regenstrief – Director & Research Scientist

Just a follow-on, public domain means you have no control, so I just want to make sure you intend public domain. I'm worried that you're using it as a synonym for free and open.

Bron Kisler – CDISC – Director of Terminology & Strategic Alliance

You're correct. I am. Sorry about that.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Thank you.

Clem McDonald – Regenstrief – Director & Research Scientist

...definitive meaning, which is not what you want, I don't think.

Bron Kisler – CDISC – Director of Terminology & Strategic Alliance

Thanks.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Sundak?

Sundak Ganesan – CDC- Lead Vocabulary Specialist

I wanted to share some real experience in the world with the public health where the client integrates the vocabulary server with the surveillance applications or any other applications. PHIN VADS, for example, they share the value sets, but at the same time the way we put the value set was underneath. It's really a pointer to the core system concepts, and value sets are free to use. But if you're trying to download from a Web site, it's easier. It's not a problem, but when you're trying to integrate, whether an application or a vendor application, so the whole thing has to go along with it, that's why the code systems are there.

And so now we have to really work with the licensing, and we're still working on that issue and work with the SDOs and let them know that we're really, the intellectual property is really the value set as far as the code systems and everything else. We put the metadata there, so you have to really follow the copyright and licensing issues as far as the SDOs. I think it's more with the new rules, we also have a lot of conference calls with the outside U.S. like WHO conference calls in various other countries, so we're kind of faced with the SNOMED issue, so we kind of say you need to follow the ... SDO guidelines on the memberships and the pricing and those kinds of things.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Thank you. Lisa, did you have a follow-on on this?

Lisa Miller – X12 – WEDI Liaison

Yes, I did. As one of the few SDOs here, we actually have experienced making our standard open. When I say open, I'm going to be very careful in my wording, where our standards were actually freely available for download. That did not negate, however, our copyright, and it did not negate our intellectual

property, but we did have an arrangement where our implementation guides for the first version of HIPAA were freely available and that anyone could go and download those.

That didn't take away our IP, but it put it into the space as freely available, and there is a big distinction there. I think you're going to have to do the same type of arrangements with the standards organization if you want this to be freely available. But you are going to have to contend with our copyrights and our IP because that is the strength of the standards body. We are authoritative. We are the system of record. We are the voice. We are the ones that bring the consistency to the table, and that has value.

The minute that's just put out willy-nilly, you lose the value of what we bring to the table. So there is going to have to be some collaboration. My suggestion would be that you have sitting at the table both HL-7 and X12. There is the standards collaboration organization. I'm probably saying that wrong, Ted, so you can correct me. But there is already a mechanism for you to speak to the standards collaboration.

Thank you. Collaborative organization, the SCO, and we did put that into our testimony and our response. That's the appropriate place to go to speak to the standards organization so that we have a mechanism to participate in this activity and bring really meaningful information and really be interictal in this where you still get the value of that copyright and that IP and what we bring to the table. I can't say it enough. It's the strength. You cannot diminish it.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Great. Thank you very much. Now I want to go on with our next question from Stan Huff.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer

It's actually a follow-on to this. I do have another question later. Just to express a further bias, basically, and to clarify the issue. I just want to second what many of the people have said. We have seen, in HL-7, and exposed that I'm a board member and a former co-chair with Ted on the vocabulary committee in HL-7. We've seen the delay probably at least five years in the adoption of terminology because of IP issues in HL-7, at least five years. It's really a nontrivial issue. It's a huge issue in terms of adoption and promulgation.

Just to put it in context, you have a situation then where you have a proprietary terminology that's licensed for a fee. Elements of that terminology become part of a value set. And then, through meaningful use and other standards that are stipulated by the government, that becomes a mandated value set for either incentive money or for conforming to standards that are specified by ONC. What you've essentially done is given a private organization a monopoly, and I just think that's bad public policy.

There are at least two ways that can be obviated. One is that we make a rule that we will never do that, which would be pretty harsh because there would be important terminologies that would be banned by that sanction. Or the alternative is that the U.S. government negotiates for use of those terminologies, and not just for national use, but for global use because that's been one of the huge stumbling blocks again with HL-7 is that, as an international organization, you'd say, well, this terminology is free for use in the U.S., and then there's huge outcry from Germany, Japan, other international participants who say that's not a solution for us. And so I think it's a really critical issue, and I'm glad Chris brought it up, and just express my own bias that this is one that is a real obstacle and that we need to solve it or it will be an impediment to the implementation.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Reactions, comments on that from panelists? Bron?

Bron Kisler – CDISC – Director of Terminology & Strategic Alliance

Yes. I echo what Stan said. That was actually a very nice summary. One of the things that CDISC has had to look with freely available—I won't use public domain anymore—but freely available standards is when we're binding a controlled terminology to the standards. We had to look at licensing and IP of the controlled terminology. We couldn't link in proprietary codes that had geographic problems with licensing.

What we had to do is if we were looking to harmonize with a particular organization is actually reach out to that terminology organization.

Just one example is Medra. Medra had system organ class terms and definitions that we wanted to use, we wanted to include in our terminology set, so we asked them if they would release those to us, release those to us to distribute to our user community. So it is a negotiation with those different organizations to make sure the IP barriers are removed.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Great. Thank you very much. Lisa, something else on the same topic?

Lisa Miller – X12 – WEDI Liaison

Yes. I just want to elaborate or maybe take it just a little bit further. I agree with you. We don't want to impede the use of standards or the use of the value sets and subsets. I do think the collaboration with the standards organizations and having them be part of this process will reduce that so that we do get to the end goal, which is that users have the ability to use the value sets and subsets. I think we need to better understand exactly how that will manifest itself, as it moves forward and matures.

There were very specific things in my testimony that when you have a value set and subset, that the organization is given that attribution. Well, normally attribution is given whenever there's a copyright or there's an IP issue, so we can't disenfranchise the value set and subset from that content creation organization. Sometimes when you get to freely available and you disconnect, then there are bad things that happen. So I agree with you, there is an impediment here. If we're not careful, it could be a huge one, but I do think, with open communication and collaboration with the content committees, with the standards organizations, that there is a path here where we can meet the common goal, which is that these are there to be used, and that we have won.

If we end up that you can't use it because you perceive an IP or a copyright issue, then somebody is going to make up a new one, and we know how difficult it is to move from one type of code set and value to another. All we have to do is look across the nation right now and look at ICD-9 to ICD-10, and you get kind of a good feel for what it means, especially if it's something that's widely used. Let's not just replace things. Let's find a way to work collaboratively on this issue. And I think there will be a way we can do it.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Now I have no doubt that we could spend a very long period of time on this topic, and I also have no doubt that it will come back up in our panel discussion. But I do want to switch gears and start on a different topic and allow for other things to come up as well. Now I'm going to use my own raised card to ask my own question now.

Several of you in written testimony, and a couple in verbal testimony referenced the importance of mapping and crosswalks for different purposes, and I want to start with Ted and Floyd, and address this to you because you mentioned this in your oral comments. How do you see the mapping and crosswalks being used in meaningful use, in particular, how do you see that versioning and distribution of the mapping, cross maps and crosswalks could be most effective in the context of meaningful use?

Ted Klein – HL7 – Vocabulary Cochair

I found that maps need to exist as separate entities that have their own versions and their own sets of annotative metadata. They are a bridge between terminologies, although how they actually function when people use them are a bridge typically between value sets where a value set in the general case includes coded concepts for more than one terminology very frequently. The versioning issue is important because, as maps change, and they change for all kinds of reasons. People identify errors. People improve accuracy of the map, or one or both of the terminologies on the source and the destination end of the map themselves change with a new release, necessitating a change to the map because there may have been a change in semantics of the codes being mapped, so you've got a lot of moving parts here.

The mappings are driven in large measure initially by the fact that everybody has existing systems in place. The vendor systems, sometimes the homegrown systems, they're operational, and now they have to essentially retrofit the meaningful use guidelines into their existing processes and systems. It's not possible to flip a switch at 2:00 in the morning everything is the old way, and at 2:01 a.m. everything has changed. That's not possible.

Systems tend to be upgraded piecemeal. They tend to be upgraded over a period of time. And once you have any system in a mix of systems that is using new terminology, new value sets, new codes, it still needs to talk to the other systems in the mix in the institution. So you find maps are ubiquitous. They often absorb even more resources to construct and maintain and keep operational than the underlying value sets and terminology that actually are required, and people are trying to enable than the map. So the mapping is a huge issue.

It's quite expensive. The same resources that you need in personnel to deal with authoring and maintenance of value sets, you need for the mapping. You need the clinical specialists so that they know that the content is sensible and makes correct clinical judgments. You need your informaticist to make sure that you're doing things at appropriate granularity with appropriate terminology practices, etc. You need the IT people involved because the maps are all implemented in certain technology. They have to bridge technologies, in addition to bridging the semantics.

Throughout the nation in public health, they do a great deal of work in public health, and so the mapping problem just exponentiates because now instead of just all of the different disparate departments and systems in a single institution, now you've got all of the institutions in the community, the communities in a local, all of the locals in a state, and then as that rolls up to the federal level, it becomes an enormous problem of mapping upon mapping upon mapping upon mapping. There's still a need, and there's some discussion underway in the HL-7 vocabulary committee on this topic. There is a need for some standardization for representation of maps and mappings so that they can become commoditized, to drop costs, to increase availability, to enable technology to be applied to them by the private marketplace.

Floyd Eisenberg – Siemens Medical Solutions – Physician Consultant

You asked for my response as well. I don't think I can say it as eloquently as Ted did, but what we experienced was a different use case than the user trying to take a given value set and a terminology and map to the local codes. Our use case was a measure developer thinking about what's there today and thinking of guidance to the future, wanting to provide multiple options. In doing so, had the right experts at the table, but needs the experts in the individual terminologies in order to make sure they select the right branch, and sometimes that branch has codes in it or concepts that don't apply to their need, and they have to be removed. That work from the measure development standpoint from what I've been hearing from many of the ones we've talked to, they're looking for a crosswalk to be able to say here's my concept. I know it in ICD-9. I need to be able to say what's that concept in other terminologies. I understand SNOMED maps down, not up, and that's part of the issue.

But we're also hearing, after the publication of the first 45 measures, from implementers who are saying, what do I do? Do I have to implement I-9 and 10 and SNOMED, and the answer is no. You can use those as guides, and depending on where you are in your implementation, that's why they're provided. But they also have the issue of, we have local codes. How do I know how to map those to what's now in this value set to make sure I'm getting the right data element to meet the denominator, the numerator exclusion criteria? That is complicated. Without crosswalks, implementers won't be able to do it. I'm sure you'll hear that from the HR group this afternoon that it's complicated.

We're also hearing others saying we want to employ parsing technology to do that for you. And without standards around that parsing technology, how can we be sure that the output that gets into the measure, that gets into the rule, is actually appropriate? I would agree, there needs to be standards around those mappings to be able to support this.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy Sundak?

Sundak Ganesan – CDC- Lead Vocabulary Specialist

I want to share some experience that we had with the public health, not only the creation, implementation, as well as also the programs dealing with these issues when they receive the data in the HL-7 message. One example I would use is really the body site and specimen site. I mean, we have issues with not only within the other standards, even within the HL-7 standard version 2X, 2.3.1 and 2.5.1, but there's big changes in there, so we need to have a mapping. We do understand it's not really going to be one-to-one. It's done in a different way.

But we also follow. We're trying to follow the ... recommendations very strictly. Like for example, we tried to use the SNOMED for body site and specimen things. But the challenges we face here is, first of all, HL-7 concepts are not there in SNOMED, or SNOMED allows you to do some sort of a post-coordination, which doesn't go along with the version 2X implementation guides. It may be suitable for CDA and version 3.0, so we're kind of facing issues. Even if you have the map, I mean, it's just not the map. It needs to be coordinated with the implementation issues.

The other issue that we also see is a lot of interface engine tools. They do some validation of these vocabularies when they are sending the data, as well as on the receiving end too. So I think it would be very useful to have these cross-maps so that it can be placed there, so that they can take advantage of those things and translate it to one way or the other, however the program needs.

So with the versioning, I want to mention one comment is CDC actually has several implementation guides, as I mentioned in the testimony. Each guide may not be using the latest version, so one program may be using the microorganism value set based on the July 2010 version, and the other program may be still using a January version. They have not moved over. So I think the versioning needs to be very coordinated with the implementation and also make sure the data analysis is done in a way that is useful for data analysis.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Great. Thank you very much. Bron?

Bron Kisler – CDISC – Director of Terminology & Strategic Alliance

You all are asking some very good questions. We prefer to do terminology mapping as a last resort, and I think the vocabulary taskforce should look at that as well. Otherwise, if you have terminology-mapping going on, it really makes it hard to achieve that one-stop-shopping environment. If you have mappings going out, it really changes the paradigm of one-stop-shopping.

Just to reiterate what we've done, again, is we chose to go with a collaborative framework that actually allows us to centrally share controlled terminology and terminology services. As part of the services, that organization works with the different controlled vocabulary organizations to see if they can get released particular codes and term sets that we need released. Anyway, we just think it's important to have a central repository and governance structure. I'm not talking about just a single controlled vocabulary within that structure, but I'm talking about central services in that structure.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Thank you very much. Marjorie?

Marjorie Rallins – AMA – Director, Clinical Informatics

I just wanted to build on some other comments in support of maps. I do believe maps are very important. One of the things I'd like to stress is that we've been coding our value sets in the various terminologies, and I think it's really important to stress that you code the value sets from the measure specifications and guidelines rather than there's a perception and notion that you start with the common vocabularies such as ICD-9 and then code from there. So we've gotten comments. I want ICD-10 codes. I want SNOMED codes based on these ICD-9 codes. And if you take that approach when your developing your code lists for your value sets, when you do apply the map, then your map will not work effectively, or you won't get the expectations, the things that you would expect to find.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Next, Betsy, you have additional questions.

Betsy Humphreys – National Library of Medicine – Deputy Director

Yes, my

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Sorry. Sundak, you have an additional comment.

Sundak Ganesan – CDC- Lead Vocabulary Specialist

I just wanted to give a little bit different dimension of the mapping. I'm not sure about what the question was. It was not really an equal and concept mapping in CDC or in public health. We do have a walk between different domains. One of them is a notifiable condition-mapping table, which is really a crosswalk between a nationally notifiable condition, which ... CDC code, and also you have a crosswalk to lab tests, which is really from LOINC. Then from LOINC, from lab tests, you're really doing a crosswalk to SNOMED results. So we're not only facing a challenge with the national instance of, this is the instance that we have at the CDC level, and every state actually has a slight modification of the mappings and different subsets of those things, and they may modify. And it's a big challenge, not only for the state, but even for the national labs to kind of go along with these things and do the crosswalks and do the decision support.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Thank you very much.

Betsy Humphreys – National Library of Medicine – Deputy Director

I have my other question, but I'll just follow on Sundak's comments that that is a similar approach to what's been done by the National Library of Medicine, in conjunction with CDC and a lot of other groups around newborn screening. It's the same kind of principle of connecting the standard that you would use for one thing to the standards you would use for the result and the condition you were looking for, and so forth, which I think puts together a nice package for people.

My question is entirely different. We want to get to one-stop-shopping, and it's clear, as I knew before and now know more from reading your testimony that we have at least a number of reasonably existing, robust distribution mechanisms for value sets, and that the value sets that are coming from these different groups, if I'm not mistaken, some of them are already necessary for meaningful use. I mean, I think that's definitely true in terms of HL-7 and CDC, and I'm sure it's true of other places as well. So we have to get from where we are to where we want to go.

We sort of ask this question, what's most important right now? We may have a lot of ideas about what would be the most desirable thing. But if tomorrow afternoon we said to those of you who are already offering up, make it easier between the two of you, or how would you say what would be needed so that whatever is needed for meaningful use that is already there in HL-7, anywhere else on the panel can speak, and whatever is already there that's directly relevant at CDC, what would we do immediately to make it easier for people to find those things and know that they were relevant to meaningful use? The fastest thing we could think of, cheapest, immediately?

M

I know what that could be.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

I think, Ted, yours was up first.

Ted Klein – HL7 – Vocabulary Cochair

If we wanted to do something quick and inexpensive and of immediate need, a very rapid decision of the value sets that were required and a decision of a primary housing location and a set of mirrors, and then

getting a one click, two clicks at the most away place from the meaningful use guidelines to get to the list of those, and each of those, one click to get to distribution with at least one, if not more than one mirror for when it's being updated or when it's not available for usual networking operational problems. I think the hardest part of that would actually be assigning the housing locations and making the decision because technically that would be very, very easy to put together. I mean, an IT geek could do that in a couple of hours. I mean, this is not a big deal technically. The problem is, we have to decide on the value sets because they're being developed in disparate places.

There has been, just in the last couple of days, as an example, there's been an active discussion on the HL-7 list that the old HITSP group published a recommendation for a set of SNOMED codes for marital status codes. Those are not accessible easily electronically from anywhere in particular. They've never been stuck into HL-7 for distribution. They are not in 100% alignment with the set that's been used in HL-7 for years. And all of a sudden there's great hue and cry. This is one collection of seven codes, nine codes. I mean this is not one of these complex, robust clinical things. This is about as trivial a set as you can imagine, and yet left hand, right hand not talking, and we can't get to these with one click. We should be able to solve this kind of thing easily.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Sundak, I believe yours was up next.

Sundak Ganesan – CDC- Lead Vocabulary Specialist

Yes. I think it'll be very useful to have some sort of a central registry where you can actually ... those things, any value sets or anything else, what you want, and then that registry would provide enough information so that it can transfer the request to the appropriate domain or appropriate organization or maybe a different vocabulary server. So the people can still go to the one place so that registry can take care of redirecting to the appropriate place. I also wanted to give an example where NLM has done a good job with the SNOMED. Apart from UMLS browser, they also have a list of other SNOMED browsers. People could use those things.

I mean, it's a lot easier for SNOMED, but in the context of value set having in one place, multiple sources could also cause versioning issues. One Web site, one distribution source may be having one version based on SNOMED July 2010, and the other one may be in a different place. So people, even though I may be in the metadata, but people may not look into the details when it comes to the implementation. So I think it needs to be very well coordinated and then just maintained with a central site. So that's my comment.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Floyd, I believe you were next.

Clem McDonald – Regenstrief – Director & Research Scientist

Jamie, could I put my card up? This is Clem.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Yes. I have your card is up, Clem, so hang on just a moment.

Floyd Eisenberg – Siemens Medical Solutions – Physician Consultant

One comment, first of all, to be very direct, to answer Betsy's question and, first of all, I want to follow on everything that Ted had said, which is true. But what would help, especially practically for retooling especially meaningful use is if you wanted to do something tomorrow to get one phone call where I could get somebody from two different repositories because they don't want to duplicate efforts. I have PHIN VADS. I have NCI. We could say this is what we need based on this measure. Can you tell me who already has something? Show it to the experts or the measure developer? Get the right one there. They can both share it and have it in their – the same one in both repositories, and then make that available. That would be simple.

What's not simple is how to get which of the current available repositories to work with. There are several government funded or proprietary or organizations that develop openly available value sets, but the measure developers themselves. So if there was an infrastructure, I could take advantage of it today.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Bron, I believe you were next.

Bron Kisler – CDISC – Director of Terminology & Strategic Alliance

Once again, I think it's important to look at existing content and infrastructures to look at existing standard content and standard value sets and try to point those, and also look at the federal funding. There are a couple of federal initiatives, NLM and the National Cancer Institute, that I think are very important to look at. You look at the content and the value sets already in production and, once again, Sundak was talking about the central repository and central mechanisms is important because, if for meaningful use of a ... taskforce says CDISC or HL-7, this electronic area has standard terminology and value sets we would like to use. If you have a central area to do that, you just want to be able to tag those terms and those value sets. You don't want to have to go recreate them in another space.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Clem, you had a comment on this?

Clem McDonald – Regenstrief – Director & Research Scientist

Yes, a couple of them. I mean, if I was hearing all this, if I was from Mars, and you've got 3,000 value sets. You've got mappings all over the place. You've got tools that haven't been built yet. I would question whether you could make this airplane fly that you're trying to build. That's just sort of a pessimistic comment. But maybe a more positive note, can't we make it simpler so that why do we have? I mean, I understand. Everybody is going to have to map from their local vocabulary to the standard vocabularies, but why don't we choose to have, in any given space or any given value set, do it with something.

You don't have to do mapping across as another step among standards. That's different than crosswalks, which are really interacting with standards. We keep making things better and have more and more need to do a crosswalk, and I'd actually ask CDISC, what are you going to do with these standards that have been chosen for clinical practice with the ones you've chosen in CDISC? I don't think they're all aligned, are they? Won't you have to map there?

Bron Kisler – CDISC – Director of Terminology & Strategic Alliance

There'd either be some mapping there, but what we're looking to do is with the new share repository is to look at ways to work with clinical care and public health and quality measures, so see if we can all work from the same common data elements and value sets centrally so we're all pulling from the same information. That's the idea of the shared environment and also the NCI semantic infrastructure.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

I think Nikolay Lipskiy had a comment on this as well.

Nikolay Lipskiy – CDC – Standards and Interoperability Lead

CDC is dealing with problems that we need a one-stop-shop maybe at least ten years. The problem is, if you have in a local department just one epidemiologist or you have in the state department just a couple people who need to implement something, they do not have any time or resources, etc. to make these mapping processes, to talk to HL-7, the ... already ... how to map this stuff, etc. A ... which we selected at CDC since probably 2003 We create our views, value sets views. By views, I mean sets of value sets. For example, if you have immunizations, and people need to implement all value sets related to immunizations, what is our responsibility at CDC?

We try to negotiate with all people ... while involved in this process. Versioning, etc., data elements, and then the represent set of sets for specific measures. The same way we're doing right now for meaningful use measures for ALR, for syndromic surveillance, for immunization, so what we try to do right now, we

want to tell our public health partners and clinical care partners. Listen, it will be our pain. We will deal with all the SDOs.

If you want to implement this measure today, take a look. This is a view of value sets with the appropriate version, etc. Take it and go with this combination of value sets, which are up to date. By the way, we have this mechanism at PHIN VADS to update it, to update and release a new version of value sets through these views. Thank you.

Betsy Humphreys – National Library of Medicine – Deputy Director

I just wanted to comment that I think that just the same way we saw it last time that many people who were saying one-stop-shopping, and we wanted to get behind that. What did you really mean by it? I think that clearly something analogous to what CDC is providing for a certain group of users, whether it's the public health or another group. I think, in the minds of some of these people, that's exactly what they mean.

On the other hand, if I'm developing software, or I'm involved across large whatever, I may have a view of one-stop-shopping, which is more analogous to what has been described by some of the SDOs because I have to deal with all of this, and I may have to support public health, as well as ABC, and I just want to know where everything is. So I do think that this is another area where the end goal or the most desirable set or place to end up is probably a large department store and a bunch of boutiques for people who need the boutiques, not one or the other.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

I do want to hear from Sundak, who had his card up, and then very quickly, I think, from Bron. I do want to draw this one to a close so that we can fit other topics into this panel.

Sundak Ganesan – CDC- Lead Vocabulary Specialist

Just one additional extension of the central registries: It should not be just dealing with the production version of the value sets, like people who are measure developers or value set creators who are in the process of creating the value sets. You should have a mechanism to kind of know who is developing what, so I think it really spends a lot time, and it also really reduces the duplication of creating these various versions of value sets while they are creating.

Bron Kisler – CDISC – Director of Terminology & Strategic Alliance

I like your example, of a department store with the different boutiques. I think one-stop-shopping is about the user experience. It's a primary entrance to that department store that they're coming in through. And they have to have a good shopping experience, so all these complexities that we're talking about, they cannot be exposed to the end user. As Ted was saying, you can't make it complicated for the end user. So you have to be able to, for them to go into the store and get what they need across these different infrastructures or different systems as quickly as possible and as intuitively as possible.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Great. Thank you. Very quickly, Ted.

Ted Klein – HL7 – Vocabulary Cochair

We already have an example in the world and on the Internet at large for a model that I think would be appropriate: Amazon. You buy things from Amazon, and then it has all these associated other specialty areas that you can get things from, and they manage all of the communications and making sure the right shipping addresses in billing and all that stuff. We need an Amazon for our terminology and HIT is what we need.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Great analogy. Thank you very much. Now I'm going to turn for our next question to Stan Huff, who wanted to bring up a different topic.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer

I think this is a smaller technical question. I wanted to second and agree with the need to support intentional definitions that Marjorie brought up. For those not familiar, that really means that you have a computable definition for the value set so that the value set can be derived automatically or computationally from the larger terminology, so you have a way of formally saying, for instance, this can be any primary drug or product, if you will, from RxNorm, or this can be that kind of definition, and I agree with that completely. The question I have, I guess, or clarification, my assumption is though that there's sometimes when that doesn't work, and so you still need to be able to do enumerated value sets as well, or were you asserting that you think you could do everything with intentional definitions?

Marjorie Rallins – AMA – Director, Clinical Informatics

I think, essentially, we'd like to do them with intentional definitions, and that's not my word. That's our technical consultant's word. I call them structured semantic definitions because we found, and there are pros and cons to both.

For consistency and nice facilitated change management, if you can say, okay, here's a new version of SNOMED. Here's everything that should be. Here's the definition of a value set. It's from this hierarchy and these particular attributes, then you can update it.

I think the only problem, this is where enumeration comes in is when there are quality issues related to the hierarchy. For example, we needed a hierarchy for – I think it was anemia. Correct, Floyd? We just took the list, and we reviewed it, but it also had some nonhuman things in there. Then when you send it over to the people that need to use it, those nonhuman things kind of scream at you. So I think, from a quality perspective, you will need enumeration.

Where does that fall? Does that fall in the terminology developer, the SNOMED people? Should they have marked that as a nonhuman thing, or does it fall with those of us that are developing the value sets? I think that's a very difficult question to answer, but I think that the intention definitions would work best for us.

Floyd Eisenberg – Siemens Medical Solutions – Physician Consultant

Let me just push on that a little. I agree, but I think it's domain dependent. I mean, it's hard for me, for instance, to see, for instance, where if you wanted to define the set of things that were allowed order statuses. I don't see a good structured definition that I could extract those from SNOMED very easily. There are just a lot of value sets where I think the only way you really get to what you need is enumeration. And, where intentional, where intentional is useful is where you're talking about large sets of things like medications or everything that would tell you this organism was present in a culture or where it's a combination of sort of everything that references that organism as an antibody or as an antigen.

Marjorie Rallins – AMA – Director, Clinical Informatics

Yes. I see what you're saying. Also, sometimes we have to cherry pick based on the intent of the measure.

Floyd Eisenberg – Siemens Medical Solutions – Physician Consultant

Exactly.

Marjorie Rallins – AMA – Director, Clinical Informatics

There isn't an attribute for everything that you need to represent. Sometimes you have to – and that's why Kendra keeps us very honest because there are times where we, as the informatics people, we think that we've cherry picked according to the measure, and there's always some flavor that we didn't catch. You don't know, but the measure says it can only be female and had children before the age of 35. How do you? You just can't capture that, so I think you're right. There needs to be a balance between intentional and enumeration.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Ted, you want to address this?

Ted Klein – HL7 – Vocabulary Cochair

Yes. On this, we've got – in Canada and the U.K., they've got tens of thousands of value sets using the HL-7 specifications ... and vocabulary model. They're using, especially in Canada Health ... it's been very broadly implemented. And one of the things that maybe I'm in a little disagreement with some of the taskforce, some of my co-panelists on is I think we have an artificial and unhelpful cognitive dichotomy between this intentional extensional thing.

What we're talking about in HL-7 is really there's a set of definitional formalisms that allow you to specify the content of the value set. The simplest and most straightforward formalism is a list of codes from a particular coding system with or without a particular version identifier. The computational operation to generate the resulting list is the identity operation. It's very simple to compute. You just copy it.

But the way that you curate and distribute and annotate this formalism of a list of codes is not terribly different from a formalism that might say the set that is the intersection between all LOINC codes with a system of blood and all LOINC codes with a property of finding, which is another, more complex formalism that takes quite a lot of computation to derive the collection of codes. But the way you annotate the formalism is the same as if you just list 50 codes or 100 codes.

And I also disagree a little bit with Stan about just saying it's a large collection. I mean, you may want to have this formal, nonspecific definition of the jurisdictions in which you're collecting information from in your locality, and maybe there are eight of them. But guess what, every election or every time they reorganize the public health department, they change, and just let the infrastructure deal with those changes. As soon as they enter the change in the jurisdictions, it kind of shows up in your value set. You don't have to deal with all of this manual maintenance business. So I think it's kind of artificial, this intentional extensional.

You define a value set. The simplest definition is a list of codes. And as the list becomes long and complex, or based upon things that change rapidly, then maintenance issues and considerations should come into effect if you decide you want to use a different formalism that simplifies and reduces the cost of the ongoing maintenance of the value set.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Other comments on intentional, where needed, and so forth? Okay. Great. We have just a few minutes left for this panel. Other questions? Have we explored what we wanted to here? Betsy is suggesting we give everybody a five-minute break. I think that's a great idea. I want to thank you very much for a great discussion here. Thank you.

(Break)

Judy Sparrow – Office of the National Coordinator – Executive Director

Everybody, if you could please take your seats. We're ready to begin. Let me just ask if there are any additional taskforce members on the line. I know Clem McDonald is on, and Doug Fridsma. Is anyone else on the line from the taskforce? Okay.

With that, I'll turn it over to Jamie Ferguson.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

I, in turn, am going to turn it back to Betsy Humphreys to introduce this panel.

Betsy Humphreys – National Library of Medicine – Deputy Director

This is a panel of end users, clinicians, hospitals, HIEs involving a variety of organizations. We have, as we did in the previous panel, have now moved some of our taskforce members from the taskforce member to the testifier table. And I think that we have a very nice set of organizations who know an awful lot about the subject that we're talking about.

I am going to allow each member of the panel to introduce themselves and make their initial comments, and then I thought the last panel worked extremely well where we heard very interesting brief presentations and then had a lot of time for questions and discussion, so we'll try to continue with that very valuable model. We will start with Moon-Hee Lee.

Moon-Hee Lee – Kaiser Permanente – Dir., Convergent Medical terminology

Let me start by thanking the taskforce for inviting me here today. This is a great opportunity to participate in this important discussion. My name is Moon-Hee Lee, and I am the director of convergent medical terminology team at Kaiser Permanente.

Just to introduce you briefly about Kaiser in general, Kaiser Permanente is an integrated delivery system of hospitals, health plans, and multispecialty medical groups. Our enterprise consists of eight different healthcare associations across various regions of the country. The electronic medical record applications across the care delivery system is known as KP Health Connect, and we have completed the implementation of KP Health Connect across eight regions, over 460 facilities supporting over 100,000 users and covering about 8 million members.

Next, I'll briefly describe how we maintain vocabulary sets and operationalize it within the KP Health Connect environment. Each of the regions within the KP enterprise have at least one instance of Epic, and Epic System is the basis for our KP Health Connection. In certain larger regions, we have multiple instances of Epic installations. These, additionally, at the national level, we also have an instance of Epic, and although it does not contain any patient transactional data, it is designated as a community lead or enterprise lead. These multiple instances or disparate instances of Epic is connected via something known as IntraConnect, which is also an Epic functionality.

The value sets or subsets within the Epic paradigm could be called master files and category lists. The master files and category lists have a special designation, whether it's a nationally built or a regionally built, depending on the needs whether the file needs to be standardized across all of the Kaiser or not. And these master files and problem lists support various functions within the KP Health Connect such as problem lists, order entry, medical history, charge capture, the family history, results review, as well as many other activities in the KP Health Connect.

Let me describe briefly about how we control the standardization and localization of these vocabulary sets. It is controlled by combining both policy, as well as the IntraConnect. The master files that require standardization across the enterprise is given a build level called National, and many of these national files are actually built and maintained by my team the convergent medical terminology team. Conversely, those files or vocabulary sets that do not require a high level of standardization is designated as a regional file, and that they are built and maintained locally by the regional teams.

Currently the convergent medical terminology team, we build and maintain these files in a staging database using several tools that is outside of the KP health connect, and these tools are some built in-house over the several years, and some we have bought from a vendor. However, we're in the process of migrating these toolsets to IHT SDOs workbench, so we build these vocabulary sets in the staging database, and then we extract the information necessary for the KP Health Connect. Then we convert that into a format that's consumable by Epic System. Then this information is imported into the instance called the community lead. Using the IntraConnect system, it is propagated and distributed across all of the KP enterprise.

This concludes my short comments, and I look forward to answering any of the questions that you may have. Thank you.

Betsy Humphreys – National Library of Medicine – Deputy Director

The next speaker is Stan Huff.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer

Thank you for this opportunity. I am really impressed with the level of knowledge and commitment of the people who are here, and so it's an honor for me to have a chance to speak briefly. I'm with Intermountain Healthcare, which is a not-for-profit healthcare organization in Utah and southern Idaho. We have 22 hospitals. We're probably about an eighth or a tenth the size of Kaiser Permanente. We have clinical data on about three million people, and we have 27,000 employees, 15,000 or so clinical users of our clinical information systems.

We use value sets in our electronic medical record system, in our clinical decision support system, in our quality assurance and quality improvement programs. We use the value sets extensively. We have about 3,700 value sets that we maintain. Those value sets are maintained by a staff of 14 full time FTEs that are a combination of technologists, nurses, physicians, and pharmacists that maintain the value sets and maintain our terminologies. If they're useful, by the way, we'd be glad to donate our 3,700 value sets as a starting point. We're not a standards group, so those wouldn't be authoritative, but they would be maybe a nice starting point for some value sets that need creation.

I briefly mentioned three subjects that I think have been mentioned or haven't been mentioned that I want to emphasize. The first is that I think it's very useful for value sets to have a human readable definition and intention. The sort of thing that would be very useful is to just say something that says this is the list of allowable order statuses, as used in electronic orders, or something like the set of allowed routes of administration in a medication order, or something like the list of substances that a person can be allergic too, which includes medications, foods, latex, and those things become grounding, and that doesn't substitute for the kind of computable or structured definition that we spoke about in the earlier session, but they're very grounding and very useful, as you maintain the value set over time because it indicates the intention and purpose for which something was created and becomes a grounding and a useful strategy.

The second thing that I would mention is the same thing that Lisa Miller emphasized, and I think Floyd said this as well. Each value set should have one and only one owner, and the way that integrates sort of with this maintenance process that we're hypothesizing is that you have a repository, and you have a set of people who are responsible for, if you will, sort of the mechanical and technical maintenance of the value set, but they're not the people who are determining the content. The owner of the value set, whether that's HL-7 or NCPDP or CDC or NQF, they're the people who are determining the content, and it needs to be maintained, and their decisions need to be reflected in the repository. But the person or organization that owns the value set is the one that ultimately determines the content. That goes back to the things that Lisa was saying.

If we've got a set of people in HL-7 that are figuring out what order statuses should be, that mechanism should stay in place, and that value set then becomes maintained and supported in a repository. So the people who hold the repository, if you will, don't own any of the content. They own the responsibility for maintaining and updating the content, as dictated by the true owner, which are organizations and users of the value sets.

The third thing that I would just mention briefly is my constant refrain, which is, the use of these value sets always requires context. So I need to know how this value set connects to the real world. Is it a field in a medication order? Is it part of a rule for a meaningful use measure? Is it some other thing? So I think there's a need for a file that's separate from the value set itself, but shows the association of the value set to its use, and so that's, I call that an associated file because that could change all the time.

In fact, where the value set is used and who uses it could change over time based on the organizations that are using the value set. But it would be the sort of thing that basically made the association to say this is the value set that can be used as order statuses in an HL-7 message, or this is the set of value sets that are used in the quality measure for medications used in geriatric patients or whatever the quality measure is. Or these are codes that count as codes that could be used as blood pressure measurements to determine hypertension, that kind of thing. And so I see that as a really important part of what we're doing is making the connection from the value sets to the context of use and doing that in a structured and computable way that helps guide people in the use of the value sets.

I'll stop there and, again, thank you for this opportunity.

Betsy Humphreys – National Library of Medicine – Deputy Director

Chris Chute?

Christopher Chute – Mayo Clinic – VC Data Gov. & Health IT Standards

Thank you, Betsy. My name is Chris Chute. I'm from the Mayo Clinic. I should disclose that Mayo Clinic has received substantial funding from the National Cancer Institute and presently also from NHGRI and NIGMS for related vocabulary services issues and is in a non-equity partnership collaboration with Intermountain Healthcare and GE associated with terminology services.

Mayo Clinic is also a nonprofit organization. We have a roughly eight-state footprint, employ roughly 60,000 people, and have patient record repositories on other eight million patients. We have a history of a century-long tradition of vocabulary development and use beginning in 1907 where we formally implemented structured vocabularies for patient data representation, albeit maintained on paper. And, for the past 20 years, have had a more formal representation of terminology management and terminology services, as characterized.

Integral to our organization is what I would characterize as data governance. I am vice chair of data governance in charge of standards, overseeing standards implementation, and we have recognized that while we have the century long tradition, the development of idiosyncratic local vocabularies is actually a significant disservice to our organizations, to our patients, and to our referring organizations. This is made obvious and manifest with meaningful use and the requirement for interoperable health information exchange, but nevertheless, the formal notion of data governance comprises three components in our organization.

One is the specification of data models. Very consistent, I might add, with what Intermountain Healthcare has been doing also for the past 40 years, I would imagine, tightly coupled with vocabulary value sets and infrastructures. The third leg of our stool is what we would characterize as metadata, which of course includes provenance. But again, analogous to Intermountain Healthcare, it's really the binding characteristics and where are these value sets used, and how are they used as a crucial component of the data governance operation that is employed enterprise wide throughout all of our clinical operations and related scopes.

On that point, the Mayo Clinic has advocated for the past many years the creation of a U.S. realm, which is analogous to what we are talking about with a one-stop vocabulary representation, the contents of which cannot and shouldn't be restricted to meaningful use value sets. I cannot say that strongly enough. It is terribly important that as we look at how we manage this approach to vocabulary utilization, we are Catholic and comprehensive in our representation of what should be in there. Obviously meaningful use and other clinical applications should be a component. But correspondingly, we embrace the requirement that research use cases, education use cases, other broad practice use cases, even if they are not incorporated within meaningful use, are crucial within the scope of how we address this problem holistically.

Toward that end, we have participated and partnered with many organizations, not the least of which is HL-7, and the specification of what we call terminology services and terminology infrastructure. Our experience, again, deriving from a century of activity and at least two decades of concerted effort on this problem, has shown that a well-specified model of how terminologies can and should be housed is again another crucial infrastructure that has to be shared. It does not do to receive a terminology from organization A or from organization B, and is left as an exercise to the user of how to decipher that and incorporate that into a shared space.

Furthermore, this shared space must have sufficient functionality in terms of well specified services and well specified interfaces that it can be used broadly throughout the enterprise, can be characterized in multiple use cases, and is not restricted to a particular boutique, profile, pattern, representation, or set of

services. I think this is most manifest when we look at the notion of scalability across the different use cases and was a topic, as we all know, of the value set summit that Intermountain Healthcare and Mayo jointly sponsored four or five years ago. Scary thought.

The existence of these services must also scale in a way that is not restricted to a single distribution point, either within an enterprise or, I would argue, nationally. As Ted Klein had characterized, mirror sites are one approach to this. We would argue that actually terminology services and terminology availability must be somewhat more sophisticated than that, and that they must approach the utility to have application programmer interfaces and other service resource interfaces be able to scale in, if you will, a cloud like formation across multiple machines, recruiting resource, recruiting availability, and recruiting scalability on a demand basis. This implies a more sophisticated infrastructure for terminology services than I think has been proposed in a number of situations. But, nevertheless, built on a shared model and built on a shared specification for interfaces, which I believe Mayo Clinic strongly endorses, would conform to the CTS2 specification as it is evolving and moving forward.

I would add that within our organization, we are implementing these, not just within a single vendor, as I alluded. We have a non-equity partnership development with Intermountain Healthcare and General Electric on specific implementation, but we are also a large Cerner organization and, hence, the generalizability for these services and resources to be vendor independent, to be implementation independent is quite central to our use cases and recognized implementations within Mayo.

We have deployed and experimented with these across multiple ..., as you know, both with the National Cancer Institute and the Lex EVS application, as well as the National Center for Biomedical Ontology and the ontology resource for the Pharmacogenomics Research Network, as well as our joint, non-equity implementation with General Electric, which now serves as our enterprise-wide vocabulary services for which we are actively creating content and hopefully working in partnership with a national consortium to create what we need for our use cases.

Betsy Humphreys – National Library of Medicine – Deputy Director

Thank you very much, Chris. Roberto?

Roberto Rocha – Partners Healthcare – Senior Corporate Manager

Good morning. My name is Roberto Rocha. I am a senior corporate manager at Partners Healthcare. The group that I work with is known as the clinical informatics research and development team at Partners. My responsibilities are basically related to development, implementation, and maintenance of what I would describe as enterprise knowledge assets, which do include the technology management activities, at least at an enterprise level.

Partners Healthcare is a large, healthcare provider in the Boston area. It's a nonprofit organization that includes two large academic medical centers affiliated with Harvard Medical School, as well as a series of medium-size and small size community hospitals. We also have a very large network of physician practices, some of which are closely affiliated with Partners, some of which are not. Partners has, particularly at the academic medical centers, a very long tradition of internally developed clinical systems that include not only advanced features, but a fair amount of clinical decision support capabilities. However, given the presence of community hospitals, our network also includes hospitals using commercial systems like many other places do.

At Partners, the enterprise efforts associated with terminology management are a relatively recent event if you take the history of clinical systems, particularly, again, at the academic medical centers. About four or five years ago, there was an initiative related to the development implementation of adoption, progressive adoption of a services oriented strategy for system integration and system evolution. A lot of the so-called enterprise wide terminology management activities were initiated at that particular point.

What I'm able to offer today is really sort of a partial view of all of what has happened within Partners in terms of terminology management. I'm going to speak specifically about these enterprise wide initiatives, which today are somewhat limited to data entry and decision support. We don't really have the groups

that are dealing with, for instance, data messaging and data reporting are not yet using the infrastructure that I'll talk about.

Turning to the questions that were suggested to us, I would like to basically walk through a few of the initial questions just to try to provide a more structured view on what we do and how we do things. Before we actually get to the actual Partners situation, I would like to speak about the first two questions, which are the so-called overall questions. So in terms of requirements for a centralized infrastructure to implement what we are calling this one-stop-shop place for value sets or sets of vocabularies, if we assume a nationwide common sharing portal, and we perhaps set aside the authoring activities and focus particularly on distribution activities. The types of functionalities that we would like to propose would include things most of which I think have been discussed today, so methods to browse, search and download vocabulary content and, by vocabulary content, we are including the value sets and subsets, but also, as has been discussed ... translations and other things.

Flexible tagging methods that would enable both the content sharers, as well as the consumers to identify and define items of relevance to them, the vocabulary content available using standard or at least widely used formats. And augmented with instructions and best practices for implementation and use, simple methods to upload vocabulary content, including proper management of versions and dependencies, again assuming this would be a place where organizations, perhaps like partners, could share value sets that we have developed internally. Simple methods to subscribe to content updates and extensions to this content, simple methods to request changes, report errors, and inconsistencies. And then methods to rate the content value and eventually, if the case may be, associated support services. The intent would that this place would offer the ability for a coexistence of open, as well as subscription based licensing models. And, as we will discuss this morning or in the previous panel, sorry, proper handling of real issues related to property liability and identification.

If we look now specifically at Partners, and there was a question about what are you using value sets, and what domains, and how many you have. Value sets and subsets derive from standard vocabularies, so I'm narrowing to the things that we try to align ourselves with external, standard vocabularies. As I said a minute ago, was used primarily for supporting data entry, particularly vocabulary terminology lookup, as well as concept classification for clinical decision support. And the two domains that we have spent the majority of time to date are vocabulary sets for problem lists and for medication related decision support and data entry. We currently manage close to 300 subsets for problem lists, all of which are derived from SNOMED, including a variety of subsets that are used to basically describe clinical states. These particular clarification subsets are used on a wide variety of clinical decision support rules that we have implemented in our systems.

The medication value sets, aside from the ones that we received directly from First Databank, which is the licensing, the vendor that we license our medication content from, we have extended that knowledge base, and created, to date, 23 medication related sets that we use, again, primary for decision support. And in terms of our experience of creating and disseminating value sets, the access to these value sets and subsets is to date primarily made via software services. The sets are created using custom developed editors, and the content review and vetting is assisted by clinicians, which we have subject matter expertise.

The areas that remain challenging for us in terms of these activities are basically the need to periodically review the sets when the reference sources in which they were based are updated, and the inevitable need to have local extensions to either accommodate things that Partners is doing that are not yet represented in those reference sets, or to accommodate the legacy term sets that we have created over the years because of our internal development. Again, I want to thank you for the opportunity, and I will look forward to the questions afterwards.

Betsy Humphreys – National Library of Medicine – Deputy Director

Thank you, Roberto. Adam?

Adam Wilcox – New York Presbyterian Hospital – Dir., Clinical Databases

Thank you very much also for this opportunity. My name is Adam Wilcox. I'm an assistant professor at Columbia University and the director of clinical databases at New York Presbyterian Hospital. Also thank you to George Hripcsak, David Baorto, and Gil Kuperman, who helped author some of the testimony, especially the written that I gave.

A little background in terms of terminology services at Columbia University and New York Presbyterian, we have employed a central terminology service there since 1989. We use a central knowledge based approach to organize the trends in the data systems of the medical center. The terms are organized into semantic network that was initially developed by Jim Semina that classifies items into useful groups and defines attributes for each term in relationships and among the terms. This knowledge is used to then define the terms, to map the terms from one system to another such as from the laboratory system to the clinical information system or to group terms so that when a clinician queries for blood potassium, all the data stored under the many laboratory codes for potassium can appear in the clinician display, and to manage terms such as when a new term is added, the system checks whether the similar term has been defined or not.

The system consists of a terminology structure, primary knowledge base with all of the terms, of which there are over 100,000, a set of tools to manage those terms, and a set of runtime routines that deliver definitions, print names, and traversal of the terminology hierarchy. And this is done within microsecond level response time. Our clinical applications can then query the terminology directory, or they can receive a code table that's automated generated by the knowledge base. The terms include local terms that were defined in the institution, and then appropriate subsets from national standard terminologies such as LOINC, ICD-9, SNOMED, and UMLS. Over the past two decades, we've swapped clinical information system applications, laboratory systems now twice, with completely different code sets, but without the clinical users ever noticing the change because of the terminology and mapping. When we reflect on the success of the infrastructure, that's been probably the greatest one is that we can shift out the backend without pain to the front.

Now I'm speaking in the experience of over the 15 years where I've been a user of these clinical vocabulary services either as a graduate student at Columbia University, where I used the Medical Entities Dictionary there, and the UMLS to assist in data mining in the clinical database, and building the vocabulary based data view, or as a system developer and project director at Intermountain Healthcare where I was responsible for creating clinical documentation templates and clinical reporting tools that used the health data dictionary, or now in my current role at New York Presbyterian Hospital where I'm responsible for extracting data out of our system for various regulatory reporting, decision support, clinical research, and quality improvement initiatives. From this experience in these multiple roles across these two institutions, both using robust, but different clinical vocabularies, I've come to appreciate, number one, the difficulty in controlling vocabularies as data are collected and tools are developed. Also, the value of the terminology in facilitating data retrieval, and finally, the frustration and regret when either data are not coded properly or when retrieval tools do not make use of the available terminologies.

Now, from this, there are really three large lessons that we have learned about this that would reflect on the requirements that were questioned in the written testimony. First of all, there is a need for defining common lists or common subsets based on the expected frequency of use. Developers are often not with sufficient clinical knowledge, as they build documentation templates in order to be steered towards the correct term, and especially when it relates to meaningful use. Most of the initial expected implementation of vocabulary around meaningful use would be around what is most common.

One of the examples is that a choice between should a developer in building a documentation template be choosing the concept of gender or the concept of sex in terms of defining the characteristics of the patient. Gender comes first alphabetically. Maybe that's going to be the first one chosen, so it can be often up to the arbitrary choice of the developer, or it may instead require developers with more advanced clinical knowledge, and so they can understand in clinical areas what may be most relevant. Or, even worse, developers, and we've seen this, will find ways around using the vocabulary and create their own internal terminology and certain just reference tables that they'll use instead.

Also in defining subsets that are based on expected frequency of use, we've found in our own experience that the large amount of data that are used are representing only a small subset of the total terminologies. For example, when I looked at just the lab panels or batteries in use at New York Presbyterian and Columbia University Medical Center, just over one week, 56 out of the 888 batteries represent 80% of the actual use, so that's only 6% of that total. Now that's the total that were actually used within a week, and less than half of these codes were used less than once per day. It seems for meaningful use to get there, it's not efficient to have developers navigating through 94% of data that is not likely to be providing the value.

Also, in terms of providing subsets based on expected frequency or actual use, the systems need a vocabulary small enough to fit within memory. Otherwise the translation queries that are used in the systems will affect performance, and I've seen this in both Intermountain Healthcare and Columbia University where we've had performance affected and then fixed when we could either use in memory vocabulary systems or caching of the most frequent terms.

The second less is the applications that consume the terminologies need to be protected against the semantic drift that occurs. There needs to be at least some level at which the terminology does not change. Now within the medical entities dictionary, we have the solution because the terms are organized into a hierarchy where the subclasses can then represent the increased precision. Often this increased precision is related to implementation issues, which tend to drive more semantically than other concepts. They change frequently, but the applications can avoid these maintenance challenges by using these higher classes, and that's been very valuable for us.

And, third, the vendors need to provide the initial mapping of terminologies, or it would at least be helpful if it was done. For example, lab systems, that should be the source of the LOINC coding rather than us, as we implement a new lab system, having to go through and do all of the mapping individually or a whole bunch of organizations having to do that a thousand times rather than it just being done once at the vendor level. Thank you again for the opportunity to speak today.

Betsy Humphreys – National Library of Medicine – Deputy Director

Thanks, Adam. Bonnie Westra?

Bonnie Westra – Alliance for Nursing Informatics – Chair

As chair of the Alliance for Nursing Informatics, I'm pleased to have a chance to provide testimony on nursing vocabularies. And I believe that patient centric interdisciplinary care is required to effectively improve healthcare quality, safety, and efficiency. Nurses are at the center of care coordination, and technology should be an enabler enhancing communication between healthcare providers and supporting care across the continuum. Nursing data overlaps with other care disciplines, but also has unique phenomena and, therefore, unique value sets. Therefore, nursing terminologies and data sets are essential to meaningful use of EHRs, not only to provide care, but also for reuse of the data for quality improvement research.

We have over three decades of experience in developing vocabularies. Now there's a shift from development to interoperability of data across the spectrum of healthcare settings. The supplemental materials provided describes a rich history of vocabulary development, as well as the ANA criteria for national recognition of vocabularies.

There are key lessons learned from our experiences that I want to share with you.

First: Nursing vocabularies do support codification of problems that represent human responses to health and illness, different than medical diagnoses and, therefore, these are essential and should be linked to the interventions provided and the outcomes to support meaningful use of EHRs.

Second: Multiple interface terminologies are useful in specific practices and settings and, therefore, these should be retained. But they do need to be mapped through reference terminologies for interoperability.

Third: Recognition of vocabularies using ISO standards insures reliability, validity, and usefulness of terminologies and also supports appropriate, ongoing maintenance.

Fourth: Conceptual mapping is the first step towards interoperability. All of the nursing terminologies that are currently mapped through SNOMED or we have an agreement for the last one to harmonize ICNP into SNOMED. However, conceptual mapping is the first step towards semantic interoperability, and we need to continue our work of mapping at value sets.

Nursing has successfully employed or is developing methods to improve process interoperability that can represent some good best practices, and we want to share just some examples of those with the taskforce. One of the best practices that's been developed by the AORM, the operator room nurses organization, is they've taken their perioperative nursing data set, and now have moved into the development of software that provides consistency in the process for using the perioperative nursing data set to improve process interoperability.

Another example is the Omaha System Partnership for Knowledge Discovery and Healthcare Quality. What we've done there is we've been using a lot of training and sharing of guidelines, beset practices, and interpretation in the use of terminologies on an open source Web site so that all public health nurses, for instance, will use the Omaha system in a very consistent way, so we can reuse the data, then again for quality improvement and research.

Another one is the ICNP, International Classification of Nursing Practice, has developed a process for how to create subsets so that there's a consistent way of being able to create subsets of the terminology to make them much more useful in practice. Fourth, IHE has developed the e-nursing summary profile, and what they've done is looked at the mapping of nursing terminologies into continuity of care or transitional care summaries to provide consistent care across settings. Fifth, nursing vocabularies, through research, we've been able to demonstrate that we are able to reuse the data for quality improvement and, therefore, could be useful for developing quality metrics.

Some of the key lessons that we've learned from this is that nursing vocabularies are useful to translate evidence based practice guidelines for documentation of care. Consistency in documentation can be simplified using subsets of terms and vocabularies and that software alone cannot assure interoperability. That training on consistent use of terminologies and information systems is required, and that there is a cost associated with training that absolutely cannot be ignored. And then, fourth, a variety of multidisciplinary experts are needed to implement and manage value sets, subsets, and entire vocabularies, as listed in the supplemental materials.

For immediate recommendations, we have four. One is that all vocabularies to support meaningful use of EHRs should meet criteria similar to table one in the supplemental material in order to assure reliable, valid, and usefulness of appropriate terminologies and their ongoing maintenance. Two, nursing terminology should be incorporated into continuity of care records, including the data elements and the value sets for using nursing diagnosis, interventions, and outcomes to assure semantic interoperability. Three, that all stakeholders must be included in the design, implementation, and meaningful use of vocabularies in the EHR to insure semantic and process interoperability. Fourth, terminologies can be used for quality metrics and should not be replaced by additional documentation requirements.

Our long-term recommendations include two. One, improve process interoperability by requiring software vendors to integrate the recognized terminologies to support both semantic and process interoperability. We would recommend that this requirement be included in certification criteria for achieving meaningful use. And, two, a well-funded, central source is needed to support the ongoing growth, development, and proper use of nursing terminologies that need to continue to be incorporated into SNOMED. We would recommend that the National Library of Medicine, for instance, might be a good neutral organization that already has the foundation, the experience, and tools to serve this purpose.

In summary, nursing vocabularies complement data from other healthcare disciplines and provide more complete details of the patient care experiences and context that can be used to better describe safety, quality metrics, and outcomes linked with diagnosis and interventions. Nursing has a long history of vocabulary development and experience in semantic and process interoperability that might be of value for the taskforce to rapidly implement methods of meaningful use in EHRs. Thank you very much.

Betsy Humphreys – National Library of Medicine – Deputy Director

I appreciate the interesting presentations, which obviously represent a wealth of experience on matters directly related to our questions. So I'd like to open this up for questions from members of the taskforce. Stuart Nelson?

Stuart Nelson – NLM – Head, Medical Subject Headings Section

I really appreciate all of this testimony. It's very, very interesting. I have a question that kind of relates to something that Chris said, but I think Adam can comment on it and Stan and Moon-Hee. It relates to this. It's very hard, from my experience, to put up multiple vocabularies in a way that it's easy to adopt their use to a specific institution, which I think Chris called for us to do, and for the central source to provide a simple interface into this. My question is really about the various data models that are used.

Now I understand that Stan and Chris both said that they have a central team that is really controls the data model. I think Moon-Hee and Adam, you basically use a vendor's data models to do this. I wonder if you can talk about what are the foundations of making something simple for use in multiple systems with multiple data models?

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer

I can take a shot at that. There's hope for doing this, mostly because they're all drawn from the same reality. Drug orders that have a drug that's ordered. You need to say a route. You need to say a dose, so there's a lot of commonality.

Where you get into differences, you might choose to pre or post coordinate to a greater or lesser degree in different institutions. So I think there are two principles. I think another axis of where things change is because people have use cases that collect the data at different levels of specificity. For one use case, they just want a blood pressure. They don't care where it was measured, how it was measured, any of that information. Somebody else, for instance in a clinical trial, might have a lot of detail about exactly how they want the blood pressure measured and to collect that information as part of the data set.

One part of the diversity, if you will, is sort of covered by having it possible for models to be simple and then grow in complexity as the sophistication grows, but those become optional elements in the model. Then the other underlying technology basically is to say recognize that the degree to which people separate things out into separate fields or clump them into one field is something actually a computer can do. I can translate from that representation from a post coordinator representation to a pre-coordinated representation. So a lot of the diversity is handled by those two mechanisms, and I think it's an important question, but at a national level, I think what we're trying to do is in fact engage people and have a public dialog about this because, without getting to the root of this, you don't actually get the interoperability.

Then there's a third level of this that modeling doesn't solve. It clarifies the discussion, but it doesn't solve, and that's when people are just doing different things. So you can collect data about smoking, and there's just no way to get from average smoker. If that's all you're collecting, did you ever smoke, you can't get from that to pack years. So there's a level of inconsistency in how we do data representation and how we ask for it that's not solved by modeling. It clarifies the issue because you've got these two models, and you say, they talk about the same subject, but I can't use the data from these two questions in any way in the same kind of analysis or quality improvement or other things. So that's a political and a business issue, not an issue of modeling, per se.

Betsy Humphreys – National Library of Medicine – Deputy Director

Chris?

Christopher Chute – Mayo Clinic – VC Data Gov. & Health IT Standards

I think many of us came to the conclusion a long time ago that at the heart of understanding whether we're helping or hurting in healthcare is having data that's fundamentally comparable and consistent. Early in my career, personally, I thought that meant vocabularies, and it was with great horror that I discovered that was not sufficient. Vocabularies, sadly, have context, and context is, to put it formally, a model. There are reasonable and appropriate ways to approach the same ground truth reality with differing models where varying amounts of the semantics, if you will, are incorporated into the model versus into the vocabulary. This is the whole interoperability or inter-convertibility problem between formal structured models and compositional terminologies. They are, as ... Bachman said to a terminologist, the world is a blank sheet of paper, and to a formal model or vocabulary, it's just what you fill into the slot. Both are true.

As a consequence, It is not going to be successful for the country to have only value sets as a semantic representation context and expect reasonable interoperability or reasonable comparability and consistency to do all the good things that we want to do ranging from quality improvement to outcomes effectiveness research to translational research. Ultimately, it becomes incumbent to bind those to a representation. Of course, the master is sitting next to me, and I learned everything at his knee. I'm referring to Stan Huff, for those of you who can't see him.

But it's important to recognize that while it is true in the practical world that differing models do exist in the universe, and we are striving, in the context of meaningful use, to bring practical starting point value sets to improve the problem, it will become inevitably a continuum of continuous improvement because it's crucially important to understand that value sets by themselves will not solve the problem, and the trivial example I will leave you with is if we have a clinical problem in a box and the label on top of that box, which constitutes a model, is family history. The inferences that we can make about whether or not heart disease is in that box relative to a particular patient in front of us are going to be profoundly changed by the fact that the context of that vocabulary element is family history assertion rather than a patient history assertion.

Betsy Humphreys – National Library of Medicine – Deputy Director

Adam, do you have a comment?

Adam Wilcox – New York Presbyterian Hospital – Dir., Clinical Databases

We've found the struggle and actually where the battle is usually lost is on the data collection tools in terms of when you have the multiple vocabularies. An example is, as we've implemented the Eclipsys System, both in the inpatient and outpatient setting in New York Presbyterian Hospital where we have also had the medical entities dictionary, that is the place where we have a local vocabulary, but we also have a vendor vocabulary that we're kind of not battling with, but trying to advocate the use of terms in different ways. And so, as the developers are building the documentation templates, we'll make strong advocacy statements about why, if they use the med, it will be a benefit to them. They've got their own pressures and their own timelines that they need to meet.

Every time that we want to meet and discuss things, it slows them down. So often the battle is lost on the data collection tools. And I understand why that is. In many cases it doesn't affect us so much until we try and then make use of the data later on, and so the challenge gets exposed then when the data has to be analyzed.

The benefit, thought, there's a silver lining there because when we've approached it post implementation, at least we've been able to see the use of the terms. By looking at, mapping the existence of the data in the databases, we've been able to give some indication of where the mappings might, and also to prioritize around where to do the mapping, and we've then now coded the Eclipsys code sets into ... so we can do the translations across there. It's difficult to do all at once. Fortunately, we've been able to use the database and indications in terms of frequency of use to prioritize around that.

The problem, though, is that this really isn't, this brute force approach, I don't think, is very scalable to the rest of the nation. We happen to have some good resources and have the flexible vocabulary that we can use, and that was mainly why that first point that I made in my testimony is that it needs to be easier for whoever is developing these tools to have some general list of common terms that most likely to use because often when we say use the med and don't have a good tool to browse through it, and there's 100,000 terms there, it's a nonstarter for the discussion. If we had some common lists, these are the ones that you're most likely to use. That may be seen as a helpful tool rather than something that adds burden and will slow the developers down.

Clem McDonald – Regenstrief – Director & Research Scientist

Betsy, can I put my card up?

Betsy Humphreys – National Library of Medicine – Deputy Director

Yes. You've got your card up. You're in a queue here, Clem.

Clem McDonald – Regenstrief – Director & Research Scientist

I understand.

Betsy Humphreys – National Library of Medicine – Deputy Director

Moon-Hee ...?

Moon-Hee Lee – Kaiser Permanente – Dir., Convergent Medical terminology

Yes. I'd like to also address that question as well. A couple of comments: One is, I do want to make a correction. We do use Epic System, but we do not use the vocabulary that comes from the vendor. We actually have our own terminology team, and we create our own terminology. One of the reasons is because we believe the controlled medical vocabulary is a very—I mean, it's crucial to the quality of data captured within any electronic medical record. And, unfortunately, the Epic, the vendor that we use does not come with a good set of tools that are designed for maintaining a large-scale vocabulary. Kaiser actually—we developed our own set of tools. However, we're in the process of migrating to the IHTSDO workbench.

The second point I do want to make is even though the data model from various vendors may be different, I think sort of a core requirement is that we do need some sort of terminology toolset that helps the local institutions take the existing standard vocabularies and extend it to meet their local needs in as much consistent manner as possible. So I think the collaborative framework or the open source terminology tool is one of the requirements that can bridge the gap between different taxonomies and different terminologies and so on.

Betsy Humphreys – National Library of Medicine – Deputy Director

Clem, are you commenting on this thing, or were you putting up your hand for a question?

Clem McDonald – Regenstrief – Director & Research Scientist

Well, it goes way back to the discussions.

Betsy Humphreys – National Library of Medicine – Deputy Director

Go ahead then.

Clem McDonald – Regenstrief – Director & Research Scientist

There were three things. I wanted to sort of reecho or emphasize what Stan said about the specifics about how we do some of this, this is close to the ground and just hope everybody heard that and reiterate it. Adam Wilcox's actual data is, I think, really, really revealing, and I hope that the people who are figuring out how do to this, listen to that and look at it. If it's 98%, it's a 2:98 ratio; we really should be doing this not so extensively and make it more practical. Floyd, that might be ammunition for any discussion you might be having about it. But we're going to kill ourselves doing thousands and thousands of things that will never have an impact on the statistics of things.

Then finally, there's another difference in how different practices work that Ken Wausau, when he collected the seven different coding of problem lists, and there are sort of differences in style or intention of what people will want to do with the utterances physicians make, and it looks like some places kind of commit to representing almost any utterance that they would put on their problem list as a coded thing, and that some of the statistics of that are also disadvantageous because there are so many one-timers, and whether one can ever use that for any practical purpose if it only happens once. So some others seem to be a little more restrictive in at least the discussion of how intense one should try to replicate the utterances of physician problems versus being a little bit more high up the chain, how much good it does to do the detailed utterance recording.

Betsy Humphreys – National Library of Medicine – Deputy Director

Thank you, Clem. Floyd?

Floyd Eisenberg – Siemens Medical Solutions – Physician Consultant

Actually, I think Clem actually addressed part of what my question was going to be, but in some of the discussion, I think that I heard, especially from Stan and Chris, is about the pre- and post-coordination and dealing with the model. In our experience in retooling, we understood that the value set itself was not going to get us where we need to go for an element and a measure. What we've done is applied what the national quality forum, also quality data set as the model to apply context. What that meant was, in developing the value sets, we couldn't really use an pre-coordinated terms because the pre-coordination applies to context.

But one of the questions I have is based on Stan's comment about the additional data. You didn't call it metadata, but associated data about the use of the value sets. How would you propose that in a value set registry that would be maintained? My concern is if this value set is used in various ways one thing I could see a user saying, if it has been used there, it has value to me. Also, it's been used in another concept text. How do we know if it's appropriate?

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer

The thought I had there is that the organization that owns the context, if you will, would maintain that. So if we're talking about HL-7 messages and knowing the value sets that are used in HL-7 messages, it would actually be HL-7 that would populate that table so that I could look up for any HL-7 message and know here's where order status is used. Here's where a list of medications is used. For NQF, it would be the same way. You would say, here's a measure, and to the extent I'm not sure exactly how you're doing context, but I think the kind of things that are going on is if you see this on the problem list, or if you see this as a reason for whatever the context is, it would be NQF, and the context of that measure, and the raw data that is used to compute the measure, that that would be NQF's responsibility to make those associations and show that and keep them updated, NCPDCP, the same, etc. That's the thought that I had.

Betsy Humphreys – National Library of Medicine – Deputy Director

I think I got a little bit in your question that we might also want sort of a crowd sourcing approach to people being able to provide potentially useful comments on off label use of the value set that, in a sense would not be the official definition, but would be associated things. We used it for this, in this context, and this is what we found out so that if there wasn't one for that context that was coming out of an authoritative source, some poor soul who had a need would be able to potentially say, well, you can take it. Is that what you were thinking?

Floyd Eisenberg – Siemens Medical Solutions – Physician Consultant

That is what I was addressing, right.

Betsy Humphreys – National Library of Medicine – Deputy Director

Right. It certainly seems to me that both things are very useful, but the original measure developer should be able to have bound to that, I mean, that value set, what it was intended for. And my own experience would show that that will not absolve them for criticism when somebody attempts to apply it to a totally different thing and finds it failing in some way. But it still would be good.

Do you have an additional comment, Floyd?

Floyd Eisenberg – Siemens Medical Solutions – Physician Consultant

No. I agree, and I think that that was my concern is I like the term “off label use”. What are others using it for? And it’s true. It’s easy to have ... place, where that was not my intent for using it.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

I’m going to switch gears a bit here. Nothing is forever, so choices that we make as care providers, choices that we make of EMR systems and vendors are not forever. Choices that we make as a country of what taxonomies to use for what purposes are not forever. Regulations are not forever, etc. The measures that are in place for meaningful use are not forever, for example.

So thinking about this as implementers and users of vocabularies in hospital and clinical practice, and for all the other purposes that we have, what I want to ask is what are the most critical functions or services or qualities of a centralized vocabulary infrastructure to make change possible? In other words, how can a one-stop-shop best facilitate change?

Bonnie Westra – Alliance for Nursing Informatics – Chair

I have one comment I’d like to add to that, and that is, there had been a lot of good comments about what a one-stop-shop could serve for us. The one comment I’ve not heard at this point is the assumption is that if we build it, they will use it, and they’ll use it right. I think it’s a bad assumption. I come out of a background of having helped develop vocabularies, done NIH funded studies. I’ve implemented information system, designed it, and now I’m doing research on reuse of electronic health record data looking at the effective use of standardized terminologies. We’ve used both quantitative and qualitative methods.

Natural language processing is one of the newer ones we’re working with right now. It’s real obvious to me that even with good processes in place, you get inconsistent use of the data no matter what. So it’s really critical, one, that we actually fund science to look at whether or not what we’re doing makes any difference at all and whether we’re using it in a very consistent sort of way.

Secondly, I think we really need to take a look at that we can’t assume that all of life can be represented by value sets and that we always have to have linked with it unstructured data so that we can really understand the context of use in a much more effective way because unless we really look at what we’ve accomplished and not just what we’re trying to build, it really won’t matter in the long-run. So we need to take a look at looking at it from the backend of really examining the effects of our decisions and not just building systems consistently.

Right now I think there’s not enough support financially to do that kind of science. Genevieve Melton-Meaux, for instance, who comes out of Columbia University, does some wonderful natural language processing. Mayo supported a lot of natural language processing. And I think that’s a really useful way when we can link our unstructured data to our structured data to look at effective use and to try to understand what should be structured and what really does not have to be structured. Let’s just tell the story.

M

Here, here.

Betsy Humphreys – National Library of Medicine – Deputy Director

Here, here. Yes. I think there would be a lot of agreement for those comments. I certainly, myself, have always believed that having structured for data for some things would be very valuable. It would not be all of them. And I agree with you that we need more analysis to prove where it is, what it costs to get it. But since we do believe it’s valuable somewhere, we have these issues that we’ve just been discussing.

Chris, did you want to respond to Jamie’s question?

Christopher Chute – Mayo Clinic – VC Data Gov. & Health IT Standards

Yes, and it has to do, I think, with the whole notion of what we would characterize as data governance. It's one-stop-shopping, while desirable, is not really sufficient because it has to do with how these things are implemented. By the way, who decides what's in the store given that it's a single store?

In our organization, we've recognized that to have comparable and consistent usage, which is the bottom line across departments, across enterprises, across campuses, we need to have commonality of definition and specification. For that, we generate, in a consensus process, what we want to use within our organization and define a one-stop-shop to service it. Again, seeking not to be idiosyncratic as an organization, we would welcome the creation or evolution of a national forum or, frankly, wearing my ISO 2ce215 hat, we would recognize an international forum where these similar types of activities go forward.

With respect to structured or unstructured, as many of you know, I'm a great fan of natural language processing, and we've been responsible for the proliferation of many open source, natural language processing tools that I think are becoming widely adopted nationally. However, one of their purposes at the end of the day is to make unstructured information into semistructured information that has an underpinning commonality and similarity of semantic specification to ... vocabulary or value set because it's really hard to take a stack of clinical dictations and put them into a logistic regression or any other kind of inferencing infrastructure absent this binning, as the statistician would call it, but reduction into a comparable and consistent representation, which is, at the end of the day, vocabulary.

Betsy Humphreys – National Library of Medicine – Deputy Director

Moon-Hee?

Moon-Hee Lee – Kaiser Permanente – Dir., Convergent Medical terminology

I do believe in the sort of central location or the one-stop-shop. But I'm not sure if that's the end of the story. I think, potentially, it can serve as a single point where we could get at least the common concepts that are members of certain value sets of subsets. However, is that going to be useful for everyone?

At Kaiser Permanente, we spend a lot of time and effort in insuring the usability of the end user terminology. I think it's going to vary, and I do not if there is a one-stop-shop for the end user terms. This is because although the concepts can be standard and common, the end user terminology is going to be very specific to the electronic medical record, their design, their data model, the local community behaviors, their local preferences and so on, as well as their own business requirements for the specific enterprise. I guess it's a question on my mind. Is it possible also to create the end user terminology or one stop shop for that as well?

Betsy Humphreys – National Library of Medicine – Deputy Director

Well, I think it's very interesting. Obviously I think there will be good reasons for local or for local developments, additions, and so forth. But all the organizations sitting across here have the resources to do that. Obviously when we're talking about implementing EHRs across the country, we're dealing in a lot of environments where they just never will have a central terminology services of the degree of sophistication of the organizations that are represented here. That's another place where one size doesn't fit all. Adam?

Adam Wilcox – New York Presbyterian Hospital – Dir., Clinical Databases

I think, in order to affect change, one thing is to understand and show how the change actually happens. Bonnie and Chris have both mentioned natural language processing. I remember in my own experiences of working with it and watching how things start as free text and eventually, over time, they will make it into some structured form, or there'll be some structured coding. Then eventually that might get used. But what I found is that the actual use of structured data sometimes lags the reporting of it.

The tools that you will use that are—because you're using structured data that provides some benefit have to be there in place in order for the users to start using the structured data. We found this at Intermountain Healthcare specifically with the diabetes face sheet that after it was implemented, there

was a spike in or not a spike. There was a jump in the use of diabetes on the structured problem list. That structure and those vocabulary concepts existed for a long time. They just weren't used until the clinicians could find some benefit of it.

Now the more that we have clear examples of where it's worked, where we've evolved from a concept that was recorded in free text in some places, then documented consistently, and then finally became part of a quality initiative, we can then look at those and give an example to those who may be following behind what can be leapfrogged. They may not need to start with natural language processing. They may have learned that, to use Stan Huff's example about smoking, maybe people will never document packs per day. They're just happy that they'll document whether someone is a smoker currently or has been just one of three issues: currently, has been, or never. If we can have more examples of how things have evolved and to a point where they've worked, I think the places that don't have the resources in order to go through the experiment on every issue may be able to leapfrog some of the learning and be effective.

Betsy Humphreys – National Library of Medicine – Deputy Director

Excellent points. Does anyone else, Stan, sorry?

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer

I agree with all of the discussion about Simple as I am, I interpreted your question, Jamie, more simply. In terms of sort of the technical structure of the repository to allow change, an essential part of that is a versioning infrastructure. So, I have to absolutely know when NQF approved a new addition to a value set that has to be absolutely known to me. In my own environment, that has to be that kind of infrastructure has to actually be part of my institution because it's also a very different thing now to say when did I put that new value set into service in my own institution. And so there's a central obligation to know exactly when things were updated and who updated them and potentially a reason for that update.

I have the same responsibility in my own institution to know when I made that change to the value set that I'm using locally. I don't see any way that nationally you can manage that local thing. The local thing has to happen. I have to have that, and it's not just for decision support. For medical legal reasons, I need to know, essentially, on September 21st, what could the physician see in this value set? It could become a medial legal issue in some liability case or a malpractice case. My answer would be the technical capabilities that you need to allow change have to do with metadata related to really good documentation and time stamping of versions of these items.

Betsy Humphreys – National Library of Medicine – Deputy Director

That gets at one of our questions about sort of what's the irreducible minimum that has to happen in a local site, and certainly the irreducible minimum is when did we implement what. I mean, even if it's not stored in a terribly sophisticated way, it needs to be there at the local site, or there isn't a way of interpreting data over time, and there isn't a way to deal with potential legal or other issues that are around the data.

I just would be interested to know. I know some of you are service providers, as well as users, but from the point of view of the users of external resources vocabularies, value sets, or whatever, more than the provider of them, is there something you do now that you could easily see you wouldn't do if the thing, the central provider or the central services, came with additional functionality?

Moon-Hee Lee – Kaiser Permanente – Dir., Convergent Medical terminology

Maybe I can take that question as well, but I did have a comment to the earlier question. Let me start with a comment to the earlier question. Going back to Jamie's question real quick, the central sort of a one-stop-shop for the content itself is important—the value sets and member sets. But I keep going back to the need to have a sort of consistent toolset for the organizations that may not be like Kaiser Permanente who doesn't have the resource to create their own toolsets because there's always going to be the need to extend the value sets or subsets at the local levels to meet their own enterprise needs. Let me end there. Thank you.

Betsy Humphreys – National Library of Medicine – Deputy Director

Thank you. Nobody has thought of anything.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer

I don't know that it takes a whole step away, but it's a huge difference. Again, just putting this into— We have 3,700 or so value sets that we've created. Our normal process for creating those is we go read what we can find from HL-7, from NCPDP, from other people to understand the semantic context, and then we look at SNOMED. We look at LOINC depending on the context. And so we spend a lot of work.

I think, even with the national value sets available, we're going to review those. But we would have a library, if you will, a reliable library as a starting point as opposed to going out and doing all of that base research for each one of those things ourselves. That's just a huge, that's a huge benefit.

Then others have mentioned, and I would just second that you don't do it, and it's done. All you've done is created a burden that you're now going to carry forever with you the rest of your life. So when you get into the maintenance phase of these, that's huge that if you know that there's a national organization that's watching and says, when this new drug comes out, it's important that we now include that as one of the indications or contraindications or whatever it is, and to have that maintenance go on at a more general level as opposed to every institution worrying about that kind of maintenance of the value set forever more because it truly is every step. Every value set you make is something that you're now going to carry forever.

Betsy Humphreys – National Library of Medicine – Deputy Director

To hark back, certainly ready access to the ones that already exist and being able to understand where they come from and so forth does seem to me to be a huge benefit, and harking back to what Ted was saying earlier this morning, I think we need to think about this one in an international context. I mean, if there are hundreds, if not thousands of value sets in use in Canada, U.K., and other places in the world that I am a firm believer that that's better than starting with a blank page in the United States because we're different or something. We need to get that integrated too.

As we are right at the witching hour here, I want to thank you all for what was a very interesting set of presentations and another very interesting conversation and discussion following. We are adjourning now for one hour for lunch, and we will reconvene at 1:30.

(Break for Lunch)

Judy Sparrow – Office of the National Coordinator – Executive Director

Excuse me, everybody. If you could please take your seats, we're ready to begin. Operator, if you could open the public line please. Thank you very much. All right. We're back from lunch, and we're ready to begin again, and I'll turn it over to Jamie Ferguson and Betsy Humphreys.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Great. Thank you very much, Judy. We've had a great morning here with our first two panels, and now we're going to hear more from the EHR perspective. We have representatives of the EHR association representing different perspectives of the vendor community, and we also have on the phone Dennis Giokas from Canada Health Infoway. Actually, Dennis, if you can hear us and are prepared, I'd like to start with you giving oral comments on the phone, if you don't mind.

Dennis Giokas – Canada Health Infoway – Chief Technology Officer

Sure. Hello, everyone. This is Dennis Giokas speaking. I didn't have any written commentary. I was on a vacation. I don't know if it was well deserved or not, but was on vacation when the invite to contribute to this hearing was presented, so I haven't had a chance to prepare anything.

There are a few areas where I just want to kind of give you our perspective. First of all, let me tell you who we are, what I do, because we're not an EHR vendor, but having said that, we're an independent,

not-for-profit corporation. We've been created by the 14 deputy ministers of health here in Canada to invest in electronic health records in the broadest sense, and our definition of that is a bit different than what you would experience in the U.S. As I told Judy, we're kind of a blend between ONC, HITSP, CCHIT, and leverage our role to lead the EHR agenda from a strategy, investment, architecture, standards, benefits realization, and adoption perspective. In my role, I head up the business and technical architecture of the EHR and the standards agenda and the IT privacy and security agenda.

The topic of vocabularies is very near and dear to our hearts. Just to bring up a few salient points for you is we are a central point of contact for everything that's standards related with respect to health IT. Prior to 2006, all of the domestic SDO representation was done by independent organizations, so for example, there was an HL-7 Canada. If organizations wanted SNOMED CT or LOINC, they'd go to the respective organization and go and get that. At the time, it was KEP and, of course, Regenstrief for things like LOINC. Or if they needed an HL-7 value set, they'd go to the HL-7 international organization or HL-7 Canada and get that value set.

What we did in 2006 is we brought in all the domestic responsibilities with respect to SDOs. So far, it includes IHT SDO, HL-7, ISO, the relationship with Regenstrief, and the relationship with IEEE and DICOM. And we're soon to bring in IHE Canada into the family where we provide all of the access to the IP. All the rights and distribution are managed by us when there's IP rights associated with access to the standards. We provide the formal liaisons to those SDOs, representation in the context of work we do, secretariat support where we have delegates outside of Canada Health Infoway participations. And, very importantly, think of us as the national release center for those artifacts as well, including vocabularies.

So we're a central point of contact for that release and distribution and rights management of those vocabularies, but we also play a role in training and education, maintenance where the vocabularies need maintenance or realm localization. In other words, let's say it's a Canadian specific concept that has to be added to the value set or terminology.

In our context, we're dealing with two official languages, French and English, so we take on a responsibility of doing the translation where it's needed and appropriate, and distributing that as well. And then requests for enhancement or maintenance, we're the central point of contact for that as well where maintenance requests come in, and we schedule those and fund those maintenance requests. And sometimes we'll do what we call a full maintenance release, and that'll happen roughly every two years.

Then we have delta releases that we release periodically if there are some significant changes that benefit the whole country. Then we have hot fixes, so if a value set is missing an important concept, we can quickly add that and make that available to the stakeholders that need that particular concept in the context of the work that they're doing. The other thing we do, it's not in my group, but we do provide a service around certification, and that is a fee for service offering where you get some benefit from the Infoway brand, but we are starting to embark on a role where we're certifying solutions on functionality, privacy and security, and interoperability, and that interoperability aspect of certification will cover obviously information that's being exchanged, including the vocabularies.

Then the final point I wanted to bring up is around our adoption of vocabularies. We have this philosophy. We want to adopt international standards where we can. Probably SNOMED CT is a very great example, especially the English version of that that we don't really have the need or expertise to do a lot of customization around localization of SNOMED CT.

Right now, the English version, we distribute as we get it from the IHT SDO. We can't adopt. Our philosophy is to adapt, and that implies things like realm localization or, in the case of LOINC or SNOMED CT, adapting it is translating it into French. And in other contexts, we develop standards as well, typically under the auspices of an SDO's framework. So we've done a lot of message development under HL-7 V2 and V3, for those kinds of frameworks, but develop messages specific to our needs and specific to our requirements. In the case of vocabularies, we would consider doing development as well where we've found needs that could not be fulfilled by the various SDOs.

That's a bit of a high level view on what we do, and some of our philosophy on the vocabulary. I think, Jamie, if I'm not mistaken, had about five minutes. I may have consumed that and a bit more, but I'd be happy to take questions or elaborate on any of those points.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

No, that's great. Thank you very much, and look forward to you participating in our panel discussion. Next I'd like to turn to Lawrence McKnight to start off our presentations in the room here.

Lawrence McKnight – Siemens – Physician Consultant

Thank you very much. My name is Larry McKnight. I'm a physician. I work as a hospitalist and also work for Siemens and a member of the EHRA, so testifying on that behalf.

I'd just like to applaud this effort in general. I think it's a fantastic thing. At one level, I think both Jacob and I were talking over lunch that we're both humbled, and it's somewhat hard to say something that Stan Huff or Clem McDonald hasn't heard 100 times already or hasn't experienced. Nonetheless, I'll try to just highlight a couple points that maybe I heard this morning or maybe thought needed to be emphasized.

The first is that when talking about value sets, I often hear the discussion as if it's one thing, and my experience is that in fact the value sets have different flavors to them, so when you're handling medications, the types of things that you can say and do with medications act and behave pretty differently than what you would do with problems, for example. I didn't hear that. Some things are clearly the same. They have the same kinds of versioning issues and same kinds of maintenance issues. Nonetheless, the timing is going to be very different.

Even the structuring and the amount of variability that you're going to find in the very different products are going to behave differently. I think, in the development of a one-stop-shop, there does need to be some kind of discussion about what is the type of content that you're really looking at and what are the things that are appropriate for that. And there may be different answers for content that's related to, say, medications as opposed to a structural type of value set that is appropriate for a particular HL-7 message.

The second point is just about the issue of integration and quality, and we heard a lot about that this morning, and I'd really like to emphasize that point and maybe bring up as an example one of the things that I see going on in our customer base is around order sets. Order sets is a type of value set, I suppose. You could consider it a subset or a value set. But early on when order sets were developed, I think there was a push for a lot of content rapidly, and like other terminologies, quality went out the window.

In order to maintain that in our customer base, we often see that policies and procedures are set up around those order sets at the local sites for periodic review, and the order sets essentially expire. I think that's an important concept to consider almost with respect to any value set. The timing may be different on when expiration occurs, but at some point the information needs to be reviewed again, and it doesn't mean that the value set completely goes out of existence. It just needs to have that human review in order to establish that the content is still clinically valid and appropriate for the use case, so that may be something that you can take from the customer sites that has benefit.

The process of review, I think, is also an important consideration because in the reviewing of that, they don't typically structure the reviews as being, there is an owners, but it's not a single person that is doing it. It's like a quality checkpoints where if there is a team that is responsible for a particular order set, they will draft, if you will, a particular set, and then it goes through a series of quality checkpoints to make sure that other perspectives have been reviewed. I think that's another consideration that might be valuable in trying to align the various different needs. If quality is a stakeholder interest in a particular value set, they may be the owner of that value set and draft the responsibilities for it.

But there are other perspectives that probably need to be considered. And by having a review process where you can tag the value set as needing review and sign off from a various different perspective, it

might be that there is a clinician review. It might be from a usability perspective. It might be strictly from a content completeness perspective. I think that could be an important addition to the discussion this morning.

Just in terms of the idea of content completeness, one of the things that I think is important from a vendor's perspective that sometimes gets overlooked is that when a value set is distributed, it needs to be shoehorned into the existing software, both for legacy reasons and for practical reasons. In that process, we often need to do a number of different things, but there may be some value in being able to share some of those things that we're probably doing in common and don't really need to compete on, don't want to compete on.

For example, they need to have shorter names that fit on a PDA or a 32-character name as opposed to SNOMED delivers with a 256-character name. Or it might be synonyms or ways to look up the particular type of concept. It might be the maps that can be shared. I think all of those things, when I think about any particular value set, any value within that value set needs to have a completeness around it in order to make sure that it works in an actual product. And there probably is at least some sharing, not normative sharing, but sharing that can occur between the vendors and the providers on that space.

Just two more very quick points: Number one is just echoing the licensing issue and the importance of that from a vendor's perspective, the capability to separate out. What license content needs to be not delivered to a particular customer can be very challenge and, to the extent that that doesn't happen, it blocks us, and there will be other solutions found.

Then, finally, I'd like to bring up the point of durability of the maintenance. We've seen this already in the content, as it's been established over time where organizations like HITSP come, and then are replaced and the content basically becomes orphaned. Whatever process goes forward, I think the durability of that maintenance needs to persist because it leaves both vendors and the providers in an uncomfortable situation where there may be changes that need to occur in order to implement, and we have nowhere where we can feed that back. Thank you again for the chance to testify.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

I'll turn next to Jacob Reider.

Jacob Reider – Allscripts – Chief Medical Informatics Officer

As Larry said, we've had a lot of extraordinary testimony, so I'm the dumb kid who went last or the one who will try and look smart and add some value to what's already been a pretty extraordinary set of valuable comments that have been made before.

Adding a little bit of value, I think I'll tell a little bit of a story and provide a little bit of context for that story. I'm a family doctor. I work rarely now, as my partner reminds me frequently, but I work in a two-physician practice. The company that I work for, of course, has many customers who are very small practices. We also have some large practices. But I think that's a voice that I haven't heard yet today. So I'd like to represent that perspective, so I'll put on my two-doctor family practice hat for a moment, and try and paint the picture of what the needs are of that environment.

In that environment, there is no IT infrastructure. There is no team of people who will review vocabularies. There is none of the stuff that we heard from KP and Mayo and Intermountain Health.

What is the one-stop-shop that the two-doc family medicine practice needs? It's very different from what Kaiser Permanente needs. I can tell you that for sure. And so, as I interact with docs in this setting, both myself some days, and many of our customers, what I hear is that they don't know or care or want to know about vocabularies and subsets or anything. They want simplicity. And I was reminded, as I was taking notes, so I have this thing, and I won't, for those on the phone, I'm holding up my iPad. This is simplicity. There's a box that's drawn around it, around what functionality it's capable of. It's not capable of all the things that the laptop is capable of.

What I heard this morning was not unlike what happens when software vendors go to clients and say, what do you need from your system? We have requirements that span the spectrum. There are all kinds of complex requirements, and especially when we have people who have been studying this stuff, like some of the people in the room who I deeply respect, who get this code, and they get all of the complexities. And yet, if we are thoughtful about each of the details of those complexities, we create a set of requirements for a system that's far greater in size than we can implement, especially for the small practices.

As I think about the vocabularies and the one-stop-shop for what we need, and you can see in my testimony. I tried to focus on some of the things that were mentioned this morning. As an EHR vendor, I want to be a broker. As Larry said, I don't want to compete with other vendors for this content. We want to compete on the creativity of the systems and the user experience and really good stuff like that. In general, we don't want to compete on content. So I want to subscribe to content. I want the licensing stuff to be worked out for me, as the vendor, and as the end user because if every end user in the country needs to license this stuff, shouldn't it just be licensed by the public for the public? I rhetorically ask once again.

What do I want as a vendor so that I can broker that stuff for my end users? I do want a one-stop-shop. I want it to be authoritative. I want it to be updated frequently so that I can know that it's authoritative. I want a lot of the detailed pieces worked out for me so that I don't have to worry about them. Now I'll put on the hat of the small vendor. So as the EHR vendor ... it's not the vendors association. Our marketing department changed that. The electronic health records association, 53 vendors, many of them small, most of those folks couldn't send somebody like me or Larry here today because they're too busy back in the shop building software and getting ready for certification.

Those folks don't have the infrastructure that larger vendors like we have. They need all this stuff worked out as a public service so that they can then innovate on the fun stuff that they want to innovate on. So if they could subscribe to services that are going to give them updates of what the NQF, CMS value sets are, and if we can focus in on just that to start, and this is where I know, Betsy, you were trying to drive to, right?

What's the bear minimum? What do we need to provide that's really going to be an accelerant for the community so that we can get this stuff off the runway? I think that's focusing on the content that we already know. For stage one, we know what that is. We have an Excel spreadsheet from CMS that's barely useful. Let's take that Excel spreadsheet—sorry Floyd—turn it into something more useful so that we can subscribe to that thing so that our systems, when we talk about diabetes, we're talking about the same thing.

When we're talking about an A1c, we're talking about the same thing – very simple concepts that then we can—so I'm arguing that we don't want to try and solve all the complex problems the first path because small vendors won't be able to handle them, and the majority of healthcare, as you all know, happens in small practices, and they won't be able to consume them either. I think the lessons learned in the larger institutions are very informative, so I'm not saying we don't pay attention to that. I am saying that we need to think small, as the Hanukkah story that we used to read to our children always preached just enough is plenty, and I think that's where I'll end. Thank you.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Now we'll turn to questions from the committee members. I'll start with Betsy.

Betsy Humphreys – National Library of Medicine – Deputy Director

Dennis, we all know that the United States is not Canada, and Canada is not the United States, but I wondered if you had any lessons learned from your approach to in essence, herding cats to get everything together. I'm not saying that the model that you're following is necessarily one that would be followed here, but I just wondered where there were any lessons of what worked and didn't work, as you were attempting to bring that together. Maybe what works is that you had the checkbook.

Dennis Giokas – Canada Health Infoway – Chief Technology Officer

Sure. For those who don't know, I'm an American and still have residence and been working here in Canada for nine years, so I'm familiar with both systems and both cultures, and I'll start by sharing a couple pseudo jokes here. In Canada, why does the chicken cross the road? Well, it's to get to the middle. To be quite honest, we have to do a lot of consensus building, and we have to do a lot of collaboration to get there, to get people to some kind of middle ground.

Having said that, given our role, and given the fact that we have \$1.2 billion to move this agenda forward, it's not a magic wand. It's not a magic bullet. The adoption of standards in particular is impacted by a number of things. One is, is there a business need or requirement to make changes to systems? Is there an opportunity to change that system?

We're dealing with a lot of legacy systems, and we're not – we often compare ourselves to England. We're not England in doing a rip and replace. We are embracing legacy systems while deploying new systems where there's been a dearth of health IT solutions in place.

One great example, they're in GP offices. Canada is much like the U.S. with respect to the penetration of GP based systems or community physician based systems. So that's somewhat Greenfield for us, and there's an opportunity there to get those systems enhanced and upgraded before deploying them, and we're trying to do that. But in hospitals, it's a matter of embracing the legacy systems and trying to get those upgraded and enhanced at the appropriate time when there's a business need to do that, so that's a big challenge for us.

Unlike the U.S., we don't have a legislative framework to mandate the deployment of health IT or the adoption of standards in the broadest sense. So you can write regulation or write law that ... publicly paid or federally paid dollars mandate certain things, we do not have that capability here in Canada to do that. The delivery of healthcare is the responsibility of the 14 jurisdictions, the federal government being one of them for certain populations.

The provinces, territories are very independent, just as independent as some of the states in the U.S., and do not like federal meddling in healthcare. They welcome their dollars, especially when there's no strings attached, but they don't want to be told what to do with those dollars. And, certainly, in my area of health IT and standards in particular, our dollars come with the requirement to use standards, but we have to be flexible on that point, but the federal dollars can only encourage the uptake of standards. I hope that addresses your comment, Betsy. If not, I can elaborate.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Other questions?

Clem McDonald – Regenstrief – Director & Research Scientist

Could I put my card up? Just tell me. I can't see.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Clem?

Clem McDonald – Regenstrief – Director & Research Scientist

I can't be up now. I just put my card up.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Well, you're up.

Clem McDonald – Regenstrief – Director & Research Scientist

I wanted to engage the question about the small practices and getting stuff into the small practices. I agree fully that it's a whole different problem and a big problem. I think what I heard the proposal was to make it simpler. But I'd like to point out a reality that maybe we can't make simpler, and so I hear this from other practice centers. They just want to have a hemoglobin A1c be a hemoglobin A1c, but what if

it's ...? That is, that may not be a good example, but there are tests that you can say in the same way, but there are really two different versions.

The labs can't ignore that because the numbers are quite different in meaning. A good one is D ... which has two different ways they do it, and one gives you the threshold for treatment is 400, and the other one you get a threshold for treatment of 250. I guess I add a pleas for those who might represent them to keep remembering, there are cases when it can't just be the simple words they use in their handwritten notes because there are distinctions that have to be made. That's all really just a comment, I guess, or maybe a question of whether that's recognized in the small practices.

Jacob Reider – Allscripts – Chief Medical Informatics Officer

I'll respond. This is Jacob Reider. Absolutely, and it's sometimes recognized in small practices. Of course, the vendor is often the one that does that education when the small practice doesn't recognize. The examples you gave might be in an order set or orderables or something like that.

Clem McDonald – Regenstrief – Director & Research Scientist

The order set is probably, I don't care, as the clinician. When it comes back, if I don't know that these things have really a quite different – makes different numbers, and I might mistreat the patient because I'm not paying attention to the normal range That's ... so there are some distinctions. It's a little more complicated than you can think it when you're just planning, thinking about making it work. And the other side of it is almost all the major lab vendor providers, I mean, say Quest and LabCorp and ARUP and Mayo, they all are now able, and I don't know how often they do it, to send LOINC codes so the little guy doesn't have to worry about it if the receiving vendor could file them right.

Jacob Reider – Allscripts – Chief Medical Informatics Officer

In general, I would agree, although I would say we still have some trouble getting LOINC codes when we want them.

Clem McDonald – Regenstrief – Director & Research Scientist

I'm not surprised. I'm not surprised. We should talk offline whether I can do something to make them say the same thing in two different places.

Jacob Reider – Allscripts – Chief Medical Informatics Officer

Agreed.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

I will put my own card up. I want to ask a little bit about versioning. I think, Larry, you talked about the fact that there are different update frequencies and different needs for different sets that are used for different purposes. Jake, you talked, I think, about the need to make it simple for the little guy, which means just give me a subscription with one frequency on a certain day of the month or whatever it is that I can just consume.

What I wanted to ask you was what's the range or the minimum set actually of different kinds of capabilities that a one-stop-shop would have to have in terms of meeting that range of needs for distribution capabilities given that variation and the needs for version control and management. I'm assuming, I think, Jake, that the actual update frequency in the small office systems is going to be infrequent, right? And so how does that square with the set of needs?

Jacob Reider – Allscripts – Chief Medical Informatics Officer

I think, A, the update frequency will be a product of the connectivity of the practice, so a practice that's got a T1 line or they're Road Runner cable modem is going to be able to update every night, if they'd like to. And the practice that's rural that has to get the CD-ROM mailed to them is going to update less frequently. I think versioning, as in the iPad, it's the magic that's inside. I would expect a system to include versioning, and that's something that we, the vendor community, will know how to handle for the small practices. And I would even say that small vendors could handle the technical needs or requirements of a versioning system because I think that's essential. If that's the question

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

But something that's automated basically.

Jacob Reider – Allscripts – Chief Medical Informatics Officer

Yes. Automated versioning so that when I get an update ... version.

Betsy Humphreys – National Library of Medicine – Deputy Director

I do think the versioning issue being under the hood and not known to people who are dealing with data creation and also with access to their patients one at a time, you're absolutely right. But I do think is probably very important to remind people about versioning when they start doing longitudinal inquiries across their data.

Jacob Reider – Allscripts – Chief Medical Informatics Officer

To some extent, I agree that this is a manageable issue. But one of the things that greatly affects it is the structuring of the data to begin with. If you start out with a fixed model, if you will, then versioning against that model is going to be relatively more straightforward. If your model is changing underneath you, then versioning is going to be quite difficult. I think, to Stan's point, we're probably in a much better position today than we were 15 or 20 years ago even with respect to understanding what are the standard types of content and what kinds of things.

There's certainly what I would consider a low hanging fruit that has not been widely done yet or widely implemented yet with respect to the types of content and value sets that are necessary in order to get a pretty big bang for your buck. To the extent that physician documentation is much more highly variable than something like the labs that you might use in LOINC, I would probably start at that. If we can get the labs, the meds, the problems, and start there, then we're probably going to be in much better shape.

There are still major sets that are necessary, even to get some of those things. Things like frequency schemas are not widely adopted in any standardized form. So I would maybe start with those low hanging fruits. Then by the time we get to the versioning of clinical documentation and what are the implications around that, where it's going to be much more challenging, I think we have a little bit of time.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Great. Thank you very much. Stan?

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer

A question for you, Lawrence. You mentioned, and we've had a little bit of followup already that, in your mind, and I intuitively agree that there are differences between the issues you might get with lists of drugs versus a problem list versus other kinds of things. Are those differences things that you think we need to account for other than, say, timing and process. Are there differences in metadata or structures of the repository you think we need to be aware of to account for those differences?

Lawrence McKnight – Siemens – Physician Consultant

I think it's more a matter of the way we think about the problem, for example, when a lot of the discussions around the complexity of how pre- and post-coordination works. Those are very applicable in the problem domain space. They're not terribly important if you're trying to do even something that I would consider like order set status or a small smoking cessation set.

I think that's more in when we talked about the enumeration phase. I think that there's a lot of stuff that you can just simply enumerate at the 90% level, leave the rest to free text, and be done with it, and those sets are not going to be 5,000 or 70,000 terms. That's really where the distinction for me lies. There's a type of simple value set, and without being overly simplistic, the HL-7 value sets that you see, the X12 value sets, I think when we're talking in that domain, those are kind of a fundamentally different beast than when you're talking about what you need in order to manage a problem list.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Jacob, did you want to address that as well or no?

Jacob Reider – Allscripts – Chief Medical Informatics Officer

No, I had other random thoughts that, if somebody gives me the opportunity, I'll throw them out there. Go ahead, Floyd.

Floyd Eisenberg – Siemens Medical Solutions – Physician Consultant

Just a question for Larry, in one of your comments about the difference in, if you would look at, say, a problem versus a med. If you were to separate the context, I mean, context of use is clearly important, and I think that's what you're trying to talk about, if there are values that could be applied to different contexts. It's the context that would, in a sense, might carry the attributes with it that would be different. Is that what you're trying to refer to?

Lawrence McKnight – Siemens – Physician Consultant

Perhaps, but I think it's actually a little bit different. It's more a structural thing when you're trying to communicate, some things fall into patterns, which are, just as an example, if you were to try to post-coordinate all substances in the world. HL-7 has, in the clinical statement model you have the substance box. You've got to put a code in the substance box, and you're going to do either pre-code or post-code thing. And you're going to try to enumerate all of the different substances in the world. What are you going to use in order to break down what Lisinopril is, or do you just list Lisinopril?

On the other hand, if you're trying to look at acute myocardial infarction versus rheumatoid arthritis versus SLE, and assign whether or not that can be acute or chronic, the meanings of the chronicity is something that potentially can be broken down, but that's a lot more variable, and it becomes a lot fuzzier on how you're going to break down problems, and so problems is just inherently a much more complicated domain than something like routes of administration, I would say, even. Maybe that's over simplistic, but I think most docs when they think of the routes of administration maybe don't go to the endless details.

But at the other end, we already talked about the fact that at some level you can stop. You don't need to enumerate all possible things. You need to have an exception that says if you're doing injection into the paramecium as a route of injection, that probably can be an exceptional value, and it doesn't need to be represented the same way that oral does.

Clem McDonald – Regenstrief – Director & Research Scientist

Could I comment on that ... reinforce?

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Yes.

Lawrence McKnight – Siemens – Physician Consultant

Yes.

Clem McDonald – Regenstrief – Director & Research Scientist

This gets back to the statistics from this morning. For completeness sake, we may be quadrupling the effort for one percent value. I think that's a really good thing to think about is where can we stop coding just say text.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

I'd like to ask a different sort of question, and this is for Dennis on the phone. I heard you mention in your remarks some aspect of managing intellectual property issues that's a function of Canada Health Infoway. I'm wondering what the approach is that you have and that you take to overcoming hurdles to the distribution of value sets that may have restrictions on intellectual property.

Dennis Giokas – Canada Health Infoway – Chief Technology Officer

Sure. I'd be happy to. Our model is quite simple, actually. We, I don't know if you want to call it this, negotiate licenses with the respective owners of that IP so we can distribute that across Canada for pretty

much any use. In very simple terms, we're a member of the IHT SDO and it affords us that right. We are the affiliate holder to HL-7, and so that allows us to distribute those HL-7 IP artifacts throughout Canada as well for use in Canada. The way we do that internally on a domestic basis is we have a membership model. The department under me is called the standards collaborative and, for a very nominal fee, students, individuals, corporations, NGOs, departments and ministries of health, hospitals can all become members of that organization, and that gives them access to download centers or national release centers that we provide so they can freely have access and use of those IP.

Betsy Humphreys – National Library of Medicine – Deputy Director

Am I assuming correctly that your membership model is not designed to recover the costs of whatever license fees you may pay, but in fact is designed to define the universe for you so that you can deal with the fact that you have a Canada wide license, but it isn't an international license, so you have to not put things up freely up on the Internet because then India could use them, or the U.S., as well as Canada? Is that right?

Dennis Giokas – Canada Health Infoway – Chief Technology Officer

Right. You're absolutely right. The fees probably do not even cover administrative costs. It's more of a contract between us and the individual that's obviously sealed by some kind of payment. But having said that, it does afford you other benefits as well, so when we put out thing to public comment, when we're looking for volunteers to chair committees or working groups, those rights are only given to members, discounts to educational sessions or semiannual domestic standards in architecture conference are also discounted for members. So there are other benefits of membership as well, in addition to access to the IP.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Great. Thank you very much.

Dennis Giokas – Canada Health Infoway – Chief Technology Officer

Could I just comment on free text versus value sets?

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Please.

Dennis Giokas – Canada Health Infoway – Chief Technology Officer

One of the things, I've been at this, and Canada has been at this actually since 2002, so we've been at it for a long time. And I've always said when I embarked on this initiative, we'll be at it until 2020 because it's a very, very, very long journey, especially when you want to continue to get benefit from the install base of clinical systems.

One of the things that we established or I established fairly early on is a lot of rigor with respect to the information exchange between systems and very rigorous with respect to messaging. We selected HL-7 V3 in part for that reason many, many years ago. And we've begun. We established a lot of optionality when it came to value sets in our messaging in that we allowed for free text, but we encouraged the use of SNOMED CT. As I said earlier, the use and skill base with respect to SNOMED CT in Canada is, I would say, very low, especially in comparison to maybe the U.S. and certainly the U.K.

But at this point, we are really starting to push more and more coded data for a number of reasons, some that you will clearly resonate with this audience. We need good, structured, discrete data that's coded for things like clinical decision support. It could be something as simple as an alert or a reminder, or it could be something as complex as detecting an adverse drug event on e-prescribing.

The other thing that we started embarking on just about 18 months ago is secondary uses of this health information. In order to get good quality data that can be analyzed for managing the health system, for looking at quality or safety or research or surveillance, we need this good quality data. The more effort you could put now into using these value sets and getting good quality coded data, the more payback you're going to see down the road. You're going to have to be patient on that because the payback could

be years out. But doing it now, I think, will save you an enormous amount of pain, but expensive long-term if you can bite the bullet now, even though the benefit may be two, three, five years out.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Let me ask a followup question on that—particularly for those of you here in the room, Jacob and Larry—there's been previous discussion in this taskforce about the ability to perform real time lookups essentially for terms or concepts that aren't implemented in the system that the end user is using. So as opposed to just saying, well, then that's just a free text entry, what alternatives do you think might be provided out of a one-stop-shopping infrastructure or is that the appropriate place to provide look up capabilities for the variety of different kinds of end users that you have?

Lawrence McKnight – Siemens – Physician Consultant

It may be that this is an example of where the type of content that you're looking at really makes a difference. But I get a sense that there are solutions in particular domains that could be applicable. For example, BID and ACNHS are two different concepts, but they're related. One is a restriction of the other.

There are many use cases where there can be a parent term, which is of a sufficient level of granularity, and other things can be mapped into it for localized use cases. ACNHS might be different at each site even. So there is one potential solution in trying to map from progressively granular terms into standardized codes at a higher level. Even there, though, I think the utility of trying to go beyond a certain threshold limit, there are diminishing returns. This really gets more at the problem domain space where I've looked at things like ICD-9 codes and the frequency of use over time.

The question that I would have there is if something is occurring at a level, one in every 100,000 patients, is it really ever going to be important for quality, for decision support? It might be important to identify that that's something else that you've got to deal with and have somebody have an exception routine around that, but when I see particular terminologies that go beyond 5,000 or 6,000 terms, in some cases it's important to classify that. In some cases, it's not.

In the case of medications, I think it is important to have an explicit understanding of what the medication is. And even though a medication might be infrequent, that falls into that category of you just need to know that that is a distinct thing. In other cases, I'm not convinced that that rule holds, and so the answer that I would have might depend on the particular use case and the particular data types of content.

The other thing that I would say with respect to that is it's probably important to understand or at least some inkling of an understanding of how the information is intended to be used downstream and how it's intended to be entered. And if you have a clear understanding of both of those, how the data is going to be entered and how it's going to be used in decision support, how it's going to be used in quality reporting, how it might be used for patient empowerment or the other users that might view that data, that is then going to feed back as part of your requirements now. You have a clear understanding of what that threshold limit needs to look like. Again, the answer may be different depending on what type of data you're looking at.

Betsy Humphreys – National Library of Medicine – Deputy Director

I'm a believer, as we heard Clem and others this morning are in terms of this frequency issue. I would believe, however, depending on who your client base is, that the issue really becomes what's the frequency there because obviously when my colleague, Kim Wafung and others helped on the problem list, they were trying to take a very wide swath. For a lot of people who are doing care, this is probably a nice place to start, but not if you are in the X specialty, or you're running a special clinic for whatever. So I guess something I think we all need to avoid, and I suspect the vendors who deal with smaller, but very specialized practices, need help with to avoid is, well, we started with this problem list, but it didn't have the main things that we wanted, so we just added those. And, of course, these concepts could be things like MS or whatever.

It could be something that's very well specified in the controlled vocabularies, but just has a cross of wide swath. It doesn't rise to the top 5,000. In this practice, it's what they deal with. So I mean, that's one of the things that I have a little worry about, even when we produce these general purpose subsets, which I think are wonderful, like the most frequently ordered tests and stuff for reported results, but maybe not for the XYZ clinic that specializes in this, and so I guess we should all do what we can in our own fears to not have that be the silly way that things happen. While I got the general subset, it didn't have half the diseases we see every day, so we just made up names for those.

Lawrence McKnight – Siemens – Physician Consultant

Right. Actually, to Clem's point about labs, I think that's a particular risk that if you have to be able to clearly distinguish what kind of result you're coming back, and the reference ranges are dependent on that, and you need to clearly distinguish that, then you need to clearly distinguish it, period. I mean, you don't. That is not an appropriate use to try to dumb down. On the other hand, some things I think you could.

The other thing that I think may help with the issue of adding the user that adds a free text as an easier way is to make sure that if you're providing the content that it really is easier for the user to use that content, which means that it is appropriately indexed and that it has the appropriate label, so that they can find the content. And, in that case, the threshold of, is it more pain to enter it free text, or is it easier to pick it because it's already there? The threshold will be there automatically that they'll pick what's there because it's just easier.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Jacob?

Jacob Reider – Allscripts – Chief Medical Informatics Officer

I was going to start where Larry was just finishing which is, I heard your original question, Jamie, as one of user experience. I am the physician using a system, and I think I heard your question as how can this service, this one-stop-shop, help with that experience because

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Or should it?

Jacob Reider – Allscripts – Chief Medical Informatics Officer

Or should it, so my answer is yes, it should. But not as much as perhaps you would expect me to say, and here's why. If the end user is – so if we go back and we say to the doc, well, why did you enter m-u-l-t-i-p-l-e-s-c-l-e-r-o-s-i-s? Why did you type that in? Why didn't you just search for it and click here and click there and click there and click there and then find it? Right?

We would ask this, and no kidding. I've seen these conversations happen. And the doc looks funny and says, well, what do you mean? I'm just typing a couple letters, and I'm done, or I type MS, right, because that's what I use, and I'm a neurologist, and I type that all the time, so it's two letters, and it's easier for me than pointing and clicking. So some of this is a problem that we, as an industry, and I don't know if anybody else was here, but NIST had a great conference on usability about a month ago. And we, as an industry, get it that we're behind Apple, Google, and everybody else. But we're getting there, and we understand that that's an opportunity for us to significantly improve.

Now the stuff that we need to make the user experience great is content, right? So when I'm at home and I type in pizza into Google, and it tells me that pizza place near my house, right, or I use my cell phone, and I do the same thing, right, because Google knows what I'm going to be looking for because they know who I am. They know my zip code, and they know that other thing about me. I would actually argue that we're not looking for the subsets in general because we'd much rather solve those problems ourselves than have, and I think, Betsy, you made a great point. If we rely too much on subsets, we're going to miss stuff. And we are going to assume that we know what the user will need when in fact the data of the user's activity is going to be much more valuable. Google has demonstrated this well. The

data of that activity will be much more valuable than a bunch of smart people in a room predicting what those folks are going to need.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Chris, did you have something?

Christopher Chute – Mayo Clinic – VC Data Gov. & Health IT Standards

I think the point has been made.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Other questions for this panel?

Betsy Humphreys – National Library of Medicine – Deputy Director

I have ... I feel that I divide—you know, I think we have sort of three levels of, at least three levels of problems if we use the old alligator and swamp analogy where we have to drain the swamp. Some of the longer-term issues that we need to solve, as somebody who has been laboring in this swamp, I'm afraid that I do have to put fixing all licensing issues in the draining the swamp category. 2011 meaningful use is coming up pretty soon, right? I have devoted a long time to that, and I unfortunately will devote more, but I'm not really expecting to solve all those problems or have anybody do it by January of 2011.

Then I think we have the alligators. I mean, they are actually about to grab the baby. We need to kill that alligator. Then we have in between. Let's get the alligators back into their corner of the swamp at least.

One of the draining the swamp issues, which I really do hope we'll be able to as a country in this domain is this issue about the very critical terminology and classifications in code sets, very important for a health system, that are all coming out at different times in uncoordinated things, and everybody has to deal with them. Now I'm sitting next to the guy who issues RxNorm once a week, but I really do think that when new drugs are approved, we have to have a record for them. So I also think that if we invent a new test, and people start ordering it, we need to have it. So I think this addition business is one thing.

Then we have the code sets that have to be implemented at a specific time. We have one law for CPT. We have a different law for ICD-9, CM, or whatever. But what I've never really gotten a clear sense on from—I ask this question. No one ever tells me. If you could have what you wanted, what would it be? If we were trying to move toward a consolidated scheduling and figure out at least some of these players we could probably move more easily than passing new law. What would it be? Do you have any sense of that? What would be the great schedule in the sky that we should all be herding toward?

Jacob Reider – Allscripts – Chief Medical Informatics Officer

I think you asked us that question in February, and I guess I'm hearing we didn't answer adequately.

Betsy Humphreys – National Library of Medicine – Deputy Director

No.

Jacob Reider – Allscripts – Chief Medical Informatics Officer

My sense is that you actually just started to answer it yourself. For some things, especially medications, that frequency is going to be much more critical to be a short frequency.

Betsy Humphreys – National Library of Medicine – Deputy Director

For those that you would be offended if it came out once a week or once a month, and you really would be very happy if it didn't happen more than twice a year, once a year, would there be a preferred schedule at all?

Jacob Reider – Allscripts – Chief Medical Informatics Officer

I'll take a shot, and then I'll ask Larry to do the same thing. Quarterly or biannually for the

Betsy Humphreys – National Library of Medicine – Deputy Director

Would it please be that everyone's quarter and biannual would hit the same month, or would that in fact be awful?

Jacob Reider – Allscripts – Chief Medical Informatics Officer

If it was together, it would be ideal because we don't want to do seven different because otherwise we're doing updates every month with a different thing. If I have my one-stop-shop, I don't know

Lawrence McKnight – Siemens – Physician Consultant

To some extent, I mean, clearly some content gets released more frequently than others. I think it's also important to understand that there is a step in between so that even if you were to release codes every week, we would not release those to our customers every week. There is a synch point that needs to happen, even internally within our products, to make sure that our content is lined, that we've done all our work, so to some extent you can update it as long, as frequently as you would like in between there, and we're going to collect those up, all those change requests, and then probably release it at a particular point in time. It's appropriate for that type of content.

Betsy Humphreys – National Library of Medicine – Deputy Director

But if we're doing a lot of this to enable interoperability in exchange, I would think that an absolute minimum national requirement is that anybody receiving a message, which is in a standard format that has a standard code in it, could in fact find out what that code meant irrespective of whether their vendor system had been updated yet or in fact they ever thought they would need or see this thing. But now it's come in the record of another patient that they're having to do something with. I mean, I guess I think that's a minimum requirement that whatever is a valid code, you can look it up.

Lawrence McKnight – Siemens – Physician Consultant

Yes. And that's actually, I think that's a great point on the messaging side, especially some of those value sets. Those value sets, by the way, tend to be more static than things like medications. However, the

Betsy Humphreys – National Library of Medicine – Deputy Director

I think the medication list is going to be part of ... standard messages

Lawrence McKnight – Siemens – Physician Consultant

Well, it can be. But even within the product, I think the important thing there is to identify that there is some capability to handle exceptions. I don't understand this particular type of content. What can I do about that?

For interoperability that's across enterprises, I believe that for a reasonable time to come, there will be a period where there will always need to be human review in between for a lot of these things like medication reconciliation or allergy reconciliation or problem reconciliation, and that's, to a large extent, because of those types of problems. When you're messaging things in a very tight, completely automated fashion, then things need to be much more controlled. If there is a human review in between, then I think the important step is that you start being able to produce it first, and that the other side can at least read it and accept it and not reject it, and that some human can make some sense of it and potentially help them to get to the right value and code it appropriately in their system.

If it's completely automated, then that sequence may be different where the syncing needs to occur much more tightly, and I would suspect that the capability to do that across any enterprise anywhere in the world and have it automatically work without any exceptions is probably not going to happen within my lifetime. As far as could we get there close, I think we can make significant strides. To a large extent, even if it was something like, say, a LOINC coded lab on an HL-7 message, and there's a new lab that comes out, it's going to be an infrequent occurrence initially. So within the first couple months of that LOINC being there, the frequency is probably going to be low. And so it probably, even if it was rejected in an interface engine, as long as the end customer has that capability to identify that and map it, it's probably going to be a rare occurrence.

Jacob Reider – Allscripts – Chief Medical Informatics Officer

I would ask rhetorically, and being the simpleton of the two of us, I would say why wouldn't this work like the DNS system works in the Internet? If I type in www.lawrencemcknight.com into my computer, and the local DNS server has never seen lawrencemcknight.com, it goes upstream and asks until it gets an answer that there is no such Web site or that there's an answer. And so if my system digests something from some source that says new drug 12345, why wouldn't I have a very similar system that would go ask your one-stop-shop and say, I've never seen this before. Do you know what it is? Thank you. It seems technically rather straightforward. I would see that if such a service ... this is a built it, they will come, kind of question. But if such a service existed, and if it was simple, I think that vendors would embrace it.

Lawrence McKnight – Siemens – Physician Consultant

I would add that that is philosophically what the Lex Grid philosophy has been precisely that, a networked, integrated suite where you have local caches that know so much. And if they don't know something, they go to the next layer.

Dennis Giokas – Canada Health Infoway – Chief Technology Officer

I think that largely works. The difference is probably going to be in dealing with the legacy or the fact that your system can't accept it for other reasons, and that's making sure that the content can be done completely through a Web service because all of the other data that goes along with it is also provided, things like all the maps, all of the encodings are matched and things like that. Yes.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Thank you. I'm going to go back to my own card being turned up, at least in my own mind, and I'm going to switch gears again. I want to go back to intellectual property issues because you both, in your comments here, addressed both the fact that IP is a hurdle and a desire from the small practice perspective to just solve it for me.

Now in testimony earlier today, we heard the same issue addressed, specifically with regard to IP restrictions on content of value sets that are being used in meaningful use, and two alternatives were proposed. One is to essentially make it illegal or prohibited to have, to grant monopolies to make it required for the end user to go out and seek an IP license on their own. And the other alternative is to have nationwide licensing made available for anything that's included in the meaningful use program.

I'd like to suggest there may be other alternatives that could include different schemes of a system, not perhaps unlike models behind Apple or Amazon's management of digital content that requires licensing where it's aware of different jurisdictional and time limit expiration date kind of requirements, redistribution capabilities and things of that nature. I'm wondering, from your respective perspectives of both with your vendor hat on, but also with your customer end user hat on, what works best and how would you address that question?

Jacob Reider – Allscripts – Chief Medical Informatics Officer

Larry is looking my direction, so I guess that means I'll start. I have concerns about the overhead, so I'll be a vendor for a moment. I have concerns about the overhead of the Amazon or rights management model because I could see that becoming very complex and hard for us as a vendor community to maintain. Lots of checking to make sure that so-and-so has the rights to use such-and-such. And what do I do when their rights expire or they forgot to pay a bill or something like that, and then the systems needs to fail gracefully. I can imagine lots of scenarios where that would be painful.

As the end user, I guess I'll be redundant. Just tell me where to send the check. Don't make it to be too much, and I'm in. And I'm okay with sending the checks. When we heard from Dr. Giokas about what happens up north, I thought, yes, that probably would be okay. I'll pay a nominal fee. Every practice pays a nominal fee. Practices are accustomed to paying nominal fees, right? We pay for our medical licenses. We pay to organizations that make sure that we're not going to hurt people, whether it's joint commission or others. So we're accustomed to these things in the provider community, but ideally it's not pay this one and this one and this one and this one. If we could aggregate that, that would be optimal.

Dennis Giokas – Canada Health Infoway – Chief Technology Officer

I think I would mostly agree with that. The other consideration that we have is that we do need to support international customers, and usually they problems that I've seen are not as problematic at the U.S. level. It really comes where you need to separate out particular types of content at the international level. It gets much harrier. One thing that perhaps could help in the negotiations with the problematic standards is if the licensing could occur at different levels.

In other words, if you have a customer that is, say, Sweden or Switzerland, and Switzerland doesn't want to pay SNOMED because they feel like they have a very high cost and a lower rate of return than another customer, then all the customers of Sweden need to agree together and/or provide some kind of solution that is more difficult to manage than if it were licensed even at the individual site, as Jacob mentioned. Part of it is just working out the distribution of the licenses as much as it is the actual, I don't want to pay for this because I don't see value, and the disagreements that occur there. But if we are going to provide content, it needs to not break, and to the extent that you have one customer that can't take that content, and you have to provide other solutions, that drives you in a domain or in a direction to use something that doesn't have that license.

Clem McDonald – Regenstrief – Director & Research Scientist

Jamie, could I put my card up? This is Clem.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Yes. Please do, Clem.

Clem McDonald – Regenstrief – Director & Research Scientist

It's up. Tell me when it's my turn.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Go ahead. It's your turn.

Clem McDonald – Regenstrief – Director & Research Scientist

Well, some other thoughts on this, the licensing, again, the licensing complex. There are a set of items that could be made simpler, maybe. LOINC has a license, but there are other free things that have licenses, but they're different probably. I mean, I haven't looked at that. Shouldn't we may be think about a sort of common license for medical vocabulary among the places that don't ordinarily have a money requirement? That'd be one thing. Maybe it's easy enough already with those, so it doesn't matter.

The second one is there are a couple of edge situations that might be dealt with, with some government support here or there, and one of them might be HL-7. I heard the complaint about the \$50 for buying a license, and I actually can't believe any place in this country doesn't have \$50, but besides that, it is causing irritation, and whether there couldn't be, say, for public health at least in the U.S., CDC bellies up and buys 100 licenses. There are only 50 states, or for whatever it is, \$500 a year, and settle that.

And maybe if there are other issues in HL-7 with the vocabulary licensing that someone could do a deal. I'm thinking government someone could do a deal. Maybe that's not a problem, but if we could kind of rustle up, get a list of all the vocabularies that are involved, a lot of them, I think CDC are free, LOINC is free, ICD, I guess, I think is free, at least 9. So a lot of them really don't have a big problem. But we could figure out the ones. And there are some bigger ones that are different, and they'll have to be dealt with, with this licensing fee business like you just described, but it might reduce the total problem if we spent some time on that.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Now I just want to ask the taskforce members if they have other questions or comments you want to address with this panel, otherwise we're about five minutes before the end of time, and I think that's it for us for now. So thank you very, very much for participating here today. I greatly appreciate you coming in and spending your time with us today. Thank you very much.

I just want to reflect a little bit on a few of the themes that we've heard through our panels today, and see if taskforce members want to have any discussion at this point. I think one point that came across loud and clear in all the discussions was the absolute criticality of versioning in managing distribution and also the idea of expiration dates on sets. And another theme really was the idea of cross-functional stakeholder involvement, both in the development and review and validation quality assurance of value sets and subsets.

Another thing that I think came across in each one of the panels was the importance of the context of the sets being described and managed appropriately and describing and establishing a particular suitability for purpose. And then, related to that, we had a number of examples of problems with what was referred to as the off label use of value sets, and I like that way of constructing it. Then, finally, I think the other thing that was to the point of the last question that I asked in this panel is we also heard, I think, as a persistent theme throughout the day, intellectual property issues as a very significant barrier to the adoption and use of vocabularies and value sets for meaningful use, and we heard some different approaches discussed there.

Does that sound like an appropriate set of themes that we heard here today? Are there other things that folks would like to add to that or expand or discuss on those themes?

Betsy Humphreys – National Library of Medicine – Deputy Director

I think that we heard from a variety of perspectives the issue of having to have clear ownership of value sets and also, in terms of various parts of infrastructure or responsibility and so forth for the development of new value sets, particularly those that are already designed for meaningful use, that we need to get a clear understanding, or if it requires an assignment of responsibility in certain places, and that then we need to not— I think we also heard some strong statements about not undoing ownership or responsibility that already exists in terms of obviously the various message standards development organizations that have fairly robust things in place and have been developing value sets for their messages, and talking about the fact that whatever one-stop-shopping approach that is implemented. In my own view, I can't imagine this not happening in other than a phased approach. But with some initial capabilities that would help everybody who is scrambling, and 2011 is coming up quickly. And other things that would be wonderful to migrate to over a longer period, that we keep in mind a distinction between the assigned responsibility and ownership of the content, that is who is determining what the content is of a value set, and the responsibility for infrastructure dealing with those groups to be sure that we have an efficient mechanism of distribution or at least ready access to wherever it's already being distributed or should be distributed.

Jacob Reider – Allscripts – Chief Medical Informatics Officer

I'd add, I think we also heard a plea for simplicity and just enough complexity to serve the use case. However, that was balanced with graceful recovery in the event that we're dealing with uncommon or unexpected issues that we not have localized reinvention of concepts to augment such simplified terms. I think there was this implication of broad spectrum of use cases, including research, I will choose to add, while at the same time having simple interfaces that implicitly requires that whatever we implement have the model for that type of graceful recovery between the two extremes.

Betsy Humphreys – National Library of Medicine – Deputy Director

I also think that we heard some good examples of things that exist already and so forth of the fact that what constitutes simple, one-stop-shop packaging may vary by the specific group. We, therefore, may regard it as a feature. I would, myself, that there be potentially a place where you can get everything if you need it all, and maybe some places that were designed around a particular group. And obviously the services that CDC is currently providing offers us an example of something that gets built around that principle and is useful.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Right. I would just jump in on that and say we heard the analogy of a department store with a number of boutiques inside that would meet Yes, please.

W

Can I just summarize? Back to the sort of responsibility, simplicity, but I would also add harmony because we don't want multiple things being developed that's already there.

Clem McDonald – Regenstrief – Director & Research Scientist

I think Betsy would agree with that.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Other comments on the day from the taskforce members? If not, then, Judy, I think we're ready for the public comments today.

Judy Sparrow – Office of the National Coordinator – Executive Director

That's right. Yes. This is the public comment portion of the meeting. If anybody in the room cares to make a comment, please go to the microphone. You need to state your name, your organization, and there is a three-minute time limit.

While we're waiting to see if anybody has a comment, just a reminder that we start tomorrow morning at 8:30.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Yes. Thank you. Starting at 8:30 tomorrow morning, and tomorrow we will have one panel in the morning, an extended panel with terminology developers and providers of terminology services and vendors of those services as well tomorrow. We do have a public comment in the room.

Judy Sparrow – Office of the National Coordinator – Executive Director

Good. Please.

Debra Konicek – CAP STS – Dir., Clinical Informatics Consulting & Mapping

Hello. I'm Debra Konicek from CAP STS in Chicago, and we actively help folks with a variety of mapping initiatives, either legacy data to SNOMED, ICD-to-ICD, just all kinds of different things, and we've been involved in a variety of government related mapping exercises. We helped with some of the HITSP mapping of the quality measures, and it became very evident to me, as part of that process, that there are a lot of different ways that people map the same thing on a Tuesday versus a Thursday. So if we have a designer mall with a bunch of different boutiques,

I'd like to hear the panel's thoughts about how we get down to that level of quality. If I'm in the boutique on level A, and I think that asthma maps to these five things, how do I know that up on level C the designer for the day who may or may not have as much mapping expertise thinks it maps to only two. So I really want to talk or have you talk, I guess, about mapping quality and how we maintain that across all these value sets from all these different places.

Betsy Humphreys – National Library of Medicine – Deputy Director

With great difficulty.

M

I'd make a crack at that. I guess I've felt for a long time that while ONC is coordinating both value sets and vocabularies, maps have to be on the list. The notion of canonical mapping, I mean, the poster child is going to be SNOMED and ICD, clearly. It will not do to have everybody go out and make their own map. You'll get into concerns about fraud and abuse, not to mention incomparable and inconsistent data. So I think ultimately a responsibility for having— Oh, dear. We've started a stampede. I'll stop.

Debra Konicek – CAP STS – Dir., Clinical Informatics Consulting & Mapping

No, I was surprised that the question didn't come up earlier, so to see all the cards come up now, it makes me feel better. I mean, just watching how people were hungry for that core problem list in the NLM with the SNOMED codes attached to it, it was like a gift. Then right away, where are the ICDs, and

I'll put my own on there, thank you very much. And if everybody is putting their own on there in the same county at eight different places, yikes.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

I think, in discussion on that point, we have Floyd and then Sam.

Floyd Eisenberg – Siemens Medical Solutions – Physician Consultant

I think one thing I heard pretty clearly in a number of presenters today was harmonization is important, parsimony, and that the originator of the value set is the owner. I think, the way I would take those comments that I heard through the presenters was, if there's an owner, and there's a method for harmonization, that's how you would solve boutique on floor one and on floor two. Floor one owns it.

Debra Konicek – CAP STS – Dir., Clinical Informatics Consulting & Mapping

Right, but then who would be the person that makes that decision. If the two owners have a difference of opinion in the correct map—

M

(Inaudible.)

Debra Konicek – CAP STS – Dir., Clinical Informatics Consulting & Mapping

I think that's probably Betsy on Friday afternoon.

Betsy Humphreys – National Library of Medicine – Deputy Director

As far as I'm concerned, I think that I would agree that we have to have the agreed upon canonical map, and then I think, in essence, the use of the map is then driven in some sense the way the use of certain standards is being driven or assisted by certification criteria in the sense that you can create your own map, but guess what? When you send a standard message according to whatever, if there is a standard map, then that's the one you're supporting in your product, or you're not going to be a certified product. I think once we have something that we believe in that much and is acceptable in terms of what it's doing for Medicare billing and everything else, then I think it's going to have to be, in some sense, part of a certification criteria that you're supporting it or updating to and so forth.

Clem McDonald – Regenstrief – Director & Research Scientist

Yes. Could I comment or put my card up?

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

You're in the queue, Clem. I think Stan was next.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer

Yes. I would just expand a little bit on what Floyd said. The saying that comes to mind is HEDIT has, it's the golden rule. HEDIT has the gold rules. If this mapping is for purposes of going from SNOMED to ICD-10 for purposes of reimbursement, it's CMS. They're the ones paying for that. They're the authority. If the mapping is for a different purpose, if it's for a research purpose, it's the research group that has the final authority that says what is the mapping. I think, in every case where we care about interoperable use, there is somebody who's paying, somebody who has authority to make a decision about the mapping, and that's who you go to. It's not us terminology geeks out there sort of theoretically deciding what maps to what.

Debra Konicek – CAP STS – Dir., Clinical Informatics Consulting & Mapping

I absolutely agree. I'm just saying, what would be the process for someone to look across eight maps from authoritative sources like CMS and NCI, etc. to make sure that that coding for the exact same data element is correct, or not even correct, is consistent.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Sorry. I'm going to cut this off. I think this is a great topic for future followup. We do have other public comments we want to get to both in the room and, I think, on the phone.

Betsy Humphreys – National Library of Medicine – Deputy Director

Yes. Dr. McKnight.

Lawrence McKnight – Siemens – Physician Consultant

Yes. Just a followup actually on the last question, more of a comment that it's important also to remember that the maps go one way, and that the existing maps that are included in SNOMED have implications, even though they're theoretically written as bidirectional or one-to-one that simply do not hold true. So in the identification of the authority, I think it is important. The authority for which map and there may be two maps or multiple maps, which are going multiple directions, and that's where a lot of the confusion often arises.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Do we have comments on the phone?

Judy Sparrow – Office of the National Coordinator – Executive Director

Thank you. We do not.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

We do have one more comment here in the room.

M

Just my question is regarding the timeliness of getting the concepts. I want to expand a little bit more. I didn't have time earlier. I'm specifically referring to SNOMED. If I submit a concept on September 23rd, I have to wait until July 31st or August 1st to get a concept, so that's the status we are in. So I wanted to know if this committee or group actually was working on a SNOMED extension for the U.S. level or maybe try to work like with LOINC actually when you submit a concept, it's a reasonable timeframe like three or four months, or three or four weeks. You may get a concept before the actual release date.

Betsy Humphreys – National Library of Medicine – Deputy Director

There certainly are discussions about moving to a U.S. extension to SNOMED in order to address that issue specifically.

Judy Sparrow – Office of the National Coordinator – Executive Director

Last comment.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

I think that's it for today.

Clem McDonald – Regenstrief – Director & Research Scientist

Wait a minute. You said my card was up.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Clem, okay. Clem, yes.

Clem McDonald – Regenstrief – Director & Research Scientist

Yes. It's about the mapping question. I think there are two potential confusions. A place with native data is going to have to map to the standard, period, and that's going to be universal mapping. Everybody understands that, I'm assuming, because we kind of cross those two different lines. I'm assuming the CAP is mostly helping local mappers map to the universal, so that's one thing.

The second is mapping among standards, and that I think we ought to be careful about not having it be too ... because that's where the problems will occur. And we ought to really try to enumerate where it's necessary and if it's necessary and other ways to deal with it because what we'll have is we'll have no end of new standards that will have mappings if there isn't some intension to sort of keep it simple.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Great. Thank you very much. I think that's it for today then, and see you back here at 8:30 tomorrow morning for our final panel on this subject. Thank you.

Public Comment Received During the Meeting

1. Value sets are only constructed and used within a context: lab, cancer, measures, etc. You cannot talk about value sets without also discussing that context such as a message profile or other data exchange specification. The one-stop-shop must include those contexts, even allowing that to be the entry point to obtaining the value sets.