



Transcript

HEALTH INFORMATION TECHNOLOGY ADVISORY COMMITTEE (HITAC) INTEROPERABILITY STANDARDS PRIORITIES TASK FORCE 2021 MEETING

June 17, 2021, 2:00 p.m. – 3:30 p.m. ET

VIRTUAL



Speakers

Name	Organization	Role
Arien Malec	Change Healthcare	Co-Chair
David McCallie	Individual	Co-Chair
Ricky Bloomfield	Apple	Member
Cynthia Fisher	PatientRightsAdvocate.org	Member
Valerie Grey	New York eHealth Collaborative	Member
Jim Jirjis	HCA Healthcare	Member
Edward Juhn	Inland Empire Health Plan	Member
Ken Kawamoto	University of Utah Health	Member
Victor Lee	Clinical Architecture	Member
Leslie Lenert	Medical University of South Carolina	Member
Ming Jack Po	Ansible Health	Member
Raj Ratwani	MedStar Health	Member
Ram Sriram	National Institute of Standards and Technology	Member
Sasha TerMaat	Epic	Member
Andrew Truscott	Accenture	Member
Michael Berry	Office of the National Coordinator for Health Information Technology	Designated Federal Officer
Wanda Govan-Jenkins	Office of the National Coordinator for Health Information Technology	Staff Lead
Denise Joseph	Office of the National Coordinator for Health Information Technology	Staff Lead
Peter Hollmann	Brown Medicine	Presenter
Nancy Spector	AMA	Presenter
Matt Reid	AMA	Presenter
Richard Landen	NCVHS	Presenter
Robert Wah	Individual	Presenter





Call to Order/Roll Call (00:00:00)

Operator

All lines are now bridged.

Michael Berry

Great. Thank you very much and welcome, everybody, to the interoperability standards priorities task force. I'm Mike Berry with ONC. We're really happy to have you joining us today. And I just want to thank Arien and David and all of the task force members for a great presentation last week at our HITAC meeting. We did transmit six of the seven recommendations to Micky Tripathi on Monday of this week. And so, those will be processed and posted on our website after this review. So, thanks, again, for all of the hard work. I know we have some special guests today that have joined us. And Arien and David will introduce them shortly. But I'm going to open up things first with roll call. We do have several task force members that are joining us as I speak so if I miss you, I will capture your name in the attendance as we go. Let's start with Arien Malec.

Arien Malec

I'm here.

Michael Berry

David McCallie.

David McCallie

Hello, everyone.

Michael Berry

Ricky Bloomfield. Cynthia Fisher. Valerie Grey. Jim Jirjis. Edward Juhn. Ken Kawamoto.

Ken Kawamoto

Good morning. I'll be on the first hour.

Michael Berry

Victor Lee.

Victor Lee

Present. And I'll also be on just for the first hour.

Michael Berry

Great. Thank you. Leslie Lenert. Clem McDonald. Jack Po. Raj Ratwani. Ram Sriram. Sasha TerMaat. And Andy Truscott. Okay. As I said, I proved my point. The task force members are dialing in a little late today. So, I'll turn it over to our co-chairs, Arien and David, to get us started.

Introductions (00:01:50)

Arien Malec





Let me get the mute button. All right. So, as Mike noted, we approved in the HITAC meeting almost all of the recommendations. And there were a couple of concerns raised about the vocabulary recommendations, in particular, a concern raised by Robert Wah that we hadn't listened to AMA's public testimony in addition to the public comment that AMA helpfully submitted. And then, by one of our task members, Clem McDonald who had some additional wordsmithing that he wanted to do on the vocabulary recommendations. And so, we convened this session to hear from our esteemed presenter from AMA. And then, could we go up to the previous slide? And then, we're also going to hear from Rich Landen from NCVHS. And so, there is a previous agenda that was a little more detailed. There we go. Thank you. I need my cheat sheet. So, what we're going to do is really turn it over to Dr. Hollmann from AMA on procedural terminology, a helpful presentation to give context on the role of CPT relative to international standards as well as the curation role for CPT.

Rich Landen who is on NCVHS and with whom I worked on the ICAD task force is going to give an overview of parallel NCVHS recommendations on terminology and terminology systems that I think align with the recommendations out of the ISP task force. And then, we're going to have a little bit of discussion on some proposed revisions that Clem has made as a task force member. I'm not sure if Clem is able to attend to be able to propose those recommendations. So, we can have a conversation as a task force about any proposed changes to recommendations. And then, hopefully, we'll get to clear consensus and wrap up. We do have some potential additional testimony that some other folks would like to give. So, if we fail to reach consensus and get to a set of terminology recommendations, we may get at it for one more task force meeting, which I proposed potentially here to get some additional hearings and get finalized comments back to the full HITAC.

So, with that, Mike, I'd like to turn it over to you to tee up our next speaker. Or if not, I can just tee it up for Dr. Hollmann who is going to talk to us from an AMA perspective on procedural terminology. So, David and I will go off of webcam and Dr. Hollmann, we'll turn it over to you.

AMA Presentation on Procedural Terminology (00:05:22)

Dr. Peter Hollmann

Thanks. Can you all hear me all right?

Arien Malec

Got you.

Dr. Peter Hollmann

Great. I very much appreciate the opportunity that you have given us, myself as a practicing physician and volunteer for some of the AMA things such as the CPT. Next slide please. As I said, I'm practicing in geriatrics and I work in a medical administrative role for the Department of Medicine at Brown University. I also am a medical director for our Medicare Share Savings Program ACO in our community and have been the past chair of the CPT [inaudible] [00:06:01] panel, worked with the RBRVS update committee and spent about 20 years also working as a part time medical director for Blue Cross and Blue Shield. And in the community, I spent a lot of time on our quality measurement in our Office of the Health Insurance Commissioner's programs and rules for quality and performance measurement that is the basis of contractual agreements between the health plans and the physician and other provider groups. With me





from the AMA are Matt Reid, senior health IT consultant and Nancy Spector, coding and HIT advocacy director. Next slide please.

So, of course, for procedural terminology, it is important that it be designed to reduce clinical and administrative workflow burdens. For the past 2.5 years, I've been the co-chair of the evaluation of management work group. And we have revised the offices of codes, which account for something like 20% of the physician fee schedule spend and made modifications to them precisely over a very lengthy process with getting in lots of input from people precisely to reduce the burden of them. And Medicare estimated that we saved 2.3 million hours of physician and other healthcare provider work in those changes. So, we're very proud of that. The terminology needs to be flexible and agile to meet industry's ever changing needs. I think we've done that. When I first started out in CPT, Medicare was beginning its first value based payment programs, the pay for performance programs. We quickly jumped in and created all of the Category 2 codes that made performance measurement reporting more simple.

Digital medicine is, certainly, rising and I was the founding co-chair of the digital medicine payment advisory group that the AMA founded. And the AMA has jumped forward at times of crisis such as coming up with COVID vaccine and vaccine administration coding. And we did the same for H1N1 before. The system needs to be trusted and evidence based. I think the AMA has key criteria that these are services performed, that they are part of accepted medical practice, which is really important. They're not just theoretical things that can be coded but they're, actually, things that are performed and performed prominently. That creates a considerable amount of validity to the process. But very important is also the process by which codes are created and that we have participation by all stakeholders and input is very seriously used. The ANM work group was a process where I learned a great deal about the viewpoints of many different practices and physicians and non-physician professionals across the country.

And we really tried to do a lot of work to make it a better product with better guidelines and better code structure. It needs to fit the purpose. As I said, I think CPT has to be clinically relevant. And it's not just for billing. The PNCPT is not for being practical but that is, in fact, what it is. It's not just about procedures. A lot of the things that we're talking about are high volume. They're not necessarily high pay. So, it's not the same as the DOG where you might be talking about having coders spend a lot of time on something that's going to pay \$10,000.00. We're talking about high volume services. And there is probably no one terminology system that's going to meet every single need from payment to clinical care to quality improvement to research. But I think this is a very effective one. It's one that's been used for a long time and is well established and is well known to everybody. One of the big issues that even when you make a modest change that we, certainly, are confronted with in changes in the evaluation and management codes is not just creating a coding system.

You have to teach people to use it and to use it well or all of the information that comes from it is really not going to be particularly useful. So, for example, when ICD-9 went to ICD-10, it wasn't quite as much a crisis for a lot of the practicing clinicians because they could get close enough. But in the procedure codes, it really needs to be very accurate so that we don't have problems with fraud and other things. Can I have the next slide please? So, I have been teaching the coding course for the American Geriatric Society for something like 20 years. And this is one of my very first slides. I try to remind everybody that coding is not just about payment. It's all about quality measurement as well and that's why we have the Category 2 codes. NCQA has embedded all of the codes into their value sets. And we use them, certainly, in our





committees in Rhode Island and the data and evaluation committee that I co-chair. It changes with need that any services in terms of tracking quality trends, etc., would be somewhat disrupted.

So, I think it's a valuable thing to maintain as it is. In public health, the patterns and analysis are already established. It's probably already being embedded into augmented or artificial intelligence programming. And looking at historical data sets, it's important but yet, it's still responsive and meets public health needs such as COVID and also promoting public health through things such as creating codes for self-reported blood pressure monitoring and encouraging physicians and other healthcare professionals to engage their patients in taking care of their own health. It's been responsive to technology. And I think technology is one that I don't always teach in the coding course because it's a little less relevant to geriatrics. But, certainly, we are having more and more of the digital medicine and how important that is. And the AMA has taken a serious partnership with industry experts in this area and innovators in the field so that we can make sure that the coding meets the needs of the world.

And, of course, researchers use it as well. Two bullets that I didn't put in but I think are very important to consider, one is finance. The Medicare fee schedule is designed that when there are changes in it, there are changes in the conversion factor or in the payment rate per relative value unit so that Medicare doesn't spend a lot more in a given year in an unintended manner. If they create a new benefit, that's one thing. But when it's just coding changes, that's a problem. And there would be significant financial implications and work that would need to be done, crosswalks and estimations that could potentially be somewhat treacherous in changes. So, I think that's something to consider. I've been talking to people in Canada about adopting CPT and this is the kind of concern that they have as well. It also needs to be efficient. And I think that CPT is efficient today because it's in use and is well understood by the folks that use it. Next slide please.

As I mentioned, it's important that the code development process be trusted and evidence based. And CPT is a public transparent process. Actually, anybody can submit a proposal for a code change. And, actually, I had a friend of mine that was not a physician, not worried about billing but wanted to improve the quality improvement measurement codes. And she submitted one and revised and did that. She had a little help from me but really, she did all of the work on her own and I wasn't on the panel at the time. So, I was really just a public citizen helping her. We really try to make sure that we engage everybody. That includes, of course, the clinicians and the folks that are performing the services. But there is also public and private payers, advice manufacturers, laboratories, entrepreneurs. And it's a system that is, as I said, flexible and agile and can respond to the needs of the moment. The codes really need to be multipurpose. It's not just about administrative or billing things. They also are embedded in clinical workflows such as in electronic health records, in planning for things.

And the CPT panel and the AMA worked very closely with Medicare and CDC in this most recent public health emergency to help design things that would better track what's happening in the public health front as we work to put an end to the pandemic. Next slide. As I mentioned, CPT is not just about administrative processes. It goes well beyond that. It really is in the workflow of treating patients. And it helps us create more order sets, treatment plans, provide for care coordination. One of the things that I don't have as a bullet in this slide but I think is important to note is that it, actually, has transformative potential. I had been on the CPT editorial panel for a few years when Dr. Burlock, of course, a person who has dedicated his professional career to quality improvement and performance improvement, became the CMS administrator.





I'm not sure of the title he had. I know he was never confirmed by the senate. But he was very knowledgeable about a patient centered medical home being involved in practice transformation and quality improvement and being a pediatrician himself.

And he, essentially, wanted us to take the office visit codes and to put them through the RBRVS, the evaluation recommendation process that the AMA engages all of the specialty societies and others in. And we spoke to him saying that really that wouldn't change much because we had just gone through that process a few years earlier but that we definitely understood the need to address better the work and efforts of care coordination and things that were really taken, especially by primary care but also by many specialty practices that do a lot of care coordination such as oncology, people that have heart failure management programs, and lung disease management programs and even for pediatricians as well. So, we worked with Medicare and got a sense of what they thought was acceptable. We worked with all of the professional societies and got a sense of what they thought would be helpful. And, eventually, we came up with two key concepts that we thought could at least get us a start in addressing some of the care coordination and the practice transformation activities that were taking place.

And one was a transitional care management code. It was a payment that was in addition to the office visit and it was bundled in with the office visit for 30 days of care of managing a patient who has just been discharged from hospital or who has come back into the community from a skilled nursing facility visit. The other thing that was created was chronic care management. So, people with serious illnesses to more chronic conditions that really put their health and functional status at risk. And you would be able to have nurse care managers work with you and manage them for a 30 day period or a calendar month is, actually, the way it's structured. So, those are two codes that were created. They went through the CPT process, described them. Chronic care management as a little more complicated because it, actually, went through a couple years of work with the Office of Planning and evaluation under the assistant secretary of DHHS and also through CMS. But both of those coding systems were put into place. And evaluations by Mathematica and the GAO has come to the conclusion that they have, in fact, been very effective.

There is decreased readmissions. There are decrease costs. There were two different studies, one for the chronic care management one for the transitional care management. And the goal was not just to describe the service but was, actually, to help transform the healthcare delivery system. So, it's important to be responsive to the needs of our country as we make healthcare more high quality, better care coordination, more effective, and meets all of those standards of quality that we all expect. So, I think, actually, it sounds a little bit bold. I sometimes say that CPT, actually, can affect the health of the patient. But I think this is an example where it truly did. And I don't think it's, actually, boasting. I think it's really an important part of what was done. The system is well understood, as I mentioned. And one of the concerns that I have as a practicing clinician having been through small coding changes and bigger coding changes of ICD-9 and ICD-10 is that the substantial changes in the system really can become both costly but they become more directly a distraction to clinicians while they have the patient in front of them believe it or not.

I saw patients today and it's always a challenge wrestling with the electronic health record. So, distractions, eventually, detract from care of the patient. Next slide please. Now, some folks participating in today's meeting and, certainly, the folks from the AMA are probably better experts on international work than myself. I was kidding to the AMA that when I was editorial chair of panel, I was really upset that I didn't get to go to any glitzy international travel so I could talk about CPT to other groups. But CPT, in fact, is well used in





some form in some 40 countries across the world. It's adopted by a national standard by four non-United States governments. And, actually, even more interestingly to clinicians and folks like myself, they're very interested in quality improvement. And the American College of Surgeons and National Surgical Quality Improvement Program, which I think is an extraordinary database allowing people to work together to improve care of patients is based upon CPT code set and has global participation in that set.

Next slide. So, what we've learned in CPT and I'm sure everybody in this group is very well aware is that it's very important to engage people with expertise and users of the systems in which we're designing and all of the work as you proceed. You really need to look at what is needed and then, strive to meet that need. And policy decisions really, ultimately, require input from many stakeholders. All of the entities from researchers to every day clinicians and all of the private stakeholders, payers alike, sometimes those interest me. Some would be conflicting but it's important to hear all of them and make your best efforts to align them as much as possible. The system really needs to align with other interoperative and regulatory assessments and requirements as well. It also needs to fit into the system that we have in our country. So, for example, all of the Medicare payment system would be impacted by any changes in coding and all the RBRVS recommendations. Even the capitation systems and Medicare Insured Savings programs and quality measurements are based upon having the current coding structure that we have today.

So, they would all be effected. You want a system that really is able to be used both in valued payment and creates value for the healthcare system, not just administrative burden. It should be consumer friendly. We have consumer descriptors for all of the CPT codes and, of course, having worked with Blue Cross in Rhode Island, I know there was a lot of effort to try and be able to tell people how much a CAT scan might cost. So, they had to be based upon our fee schedule system there. And finally, as I started out as a practicing physician, I'm going to have that bias because I want it to be usable for me and not disrupt my practice and not disrupt my ability to provide the best care that I can for my patients. So, I really thank you very much for the opportunity to speak to you. I know you have some period where you have public comment and potential questions. But I would like to, of course, return back to the chairs so that they can manage the meeting from this point on.

Arien Malec

Thank you very much. And maybe we can open it up to the task force. Initially, Dr. Hollmann, we invited AMA to look at the recommendations that we put out and whether there was any commentary that AMA had about any particulars in the Section 3 language that AMA was reacting to or was suggesting any changes to. Dr. Hollmann, it looks like you're on mute.

Dr. Peter Hollmann

Am I off mute now?

Arien Malec

You're good now. Thank you.

Dr. Peter Hollmann

I should be good. Right. Sorry. When you switched me off, it shut off my computer. And then, when I turned it back on, the speakers were going. I apologize for the feedback during your questions. So, you had some





comments about the comments that the AMA had responses to the comments that were made in the process. And I think probably Nancy Spector would be the best person to answer that if that would be okay.

Arien Malec

Sure. Nancy, if you're on, if we can enable her line and if AMA has any comment related to the set of initial recommendations.

Nancy Spector

Sure. Can you hear me okay?

Arien Malec

We got you. Thank you.

Nancy Spector

Okay. My understanding is that you are going to be walking through these recommendations a little later in the meeting. And I also know that Dr. Wah is on the phone. So, I don't know if we want to hold that discussion and if there is anything more specific that you have for Dr. Hollmann.

Arien Malec

Are you saying that Dr. Wah's comments are also inclusive of AMA's comments as recommendations for the vocabulary recommendations?

Nancy Spector

Yes.

Arien Malec

Okay. Thank you. Let's turn it over to David. Do you have any questions? Otherwise, we'll turn it over to the task force?

David McCallie

I do have one question and maybe Nancy is a better person to address this. One of the issues of concern in the language of the recommendation that we'll be debating later is around funding and licensing issues. Since not everyone may be familiar with what the current licensing strategy is or the current requirements, I should say, for licensing of CPT, I wonder if it would be worth it to summarize that for the group. Nancy, you may be the best person to do that.

Nancy Spector

Sure. Although, I guess I wasn't thinking that we were going to get into some of the details around the licensing other than yes, there is a licensing model in place. And then, I can just broadly speak to the fact that we do hear from the AMA. We hear concerns from the industry around some of the friction that there is with the licensing. And there are efforts that we have been doing over the last couple of years to make that process as smooth and easy as possible for the end users. And within our licensing model, it is fair, transparent, consistent. And it's something that is applied uniformly, nondiscriminatory. So, that's just some broad points that I can make about licensing.





David McCallie

I appreciate that and I'm not trying to surprise you with a hard question and your answer addressed much of what I wanted to hear. But could you clarify who is required to license the CPT codes? I think that's been a point of contention as well. And perhaps it's changed in the couple of years since I left Cerner where I was involved in working on that. But who is obligated to license it?

Nancy Spector

For the most part, I'll say end users. But there are some pieces that go around that. For example, we do work with CMS and they do have a royalty free license to use CPT within specified files of theirs and applications. We do have agreements and we've done some recent amendments within our agreement to provide greater, more efficient access to the information. And we do have, again, royalty free models that do support our price transparency efforts, for example.

David McCallie

But if a portal wants to show what happened to a patient in terms of the procedures they received, etc., the patient would be obligated to have their license covered to view that CPT code text?

Nancy Spector

No. By end user in that situation, we would be talking about the app developer. We do not license individuals, certainly, not patients.

Arien Malec

I'll follow up on that one. I apologize. This is not meant to be a detailed deep dive into AMA licensing. But just to follow up on that, I have been involved in the past and maybe AMA licensure for CPT has changed where there was an obligation by the app developer to license on behalf of the patient users who were accessing. I don't think David was suggesting that individual patients would be click charged. But that the app developer or the portal developer had to license on behalf of all of the patients who were accessing. I've also come across situations where there was a request to, prior to interoperability, validate that all of the downstream users of the data also be **[inaudible] [00:28:43]** in licensure for CPT.

Nancy Spector

It's my understanding that that's not involving patients. So, we don't have patients or licensing of patients as part of any of our models.

Arien Malec

Okay. Thank you. Let's open it up maybe to the task force if there are any additional comments. All right. Well, hearing no comments, Dr. Hollmann and Nancy Spector, thank you very much for your input here. We're going to move over to Rich Landen from NCVHS to do a presentation on the parallel recommendations that NCVHS provided to HHS relative to vocabulary standards. And Rich, a pleasure to turn this meeting over to you. And thanks for your ability to jump in and provide testimony.

NCVHS Presentation on Terminology & Vocabulary Standards (00:29:55)

Rich Landen

Thanks, Arien. It's my pleasure to be here. Let me start just by giving who NCVHS is. I presume most everybody knows that but in case there are some that don't. The National Committee on Vital Health





Statistics is a federal advisory committee or FACA. It's been around about 60 years and it works in the general area of health data. It makes recommendations to the secretary of the Department of Health and Human Services. And it has some specific obligations laid on it under the HIPAA legislation and some legislation since then to look into standards, which include code sets, terminologies, and vocabularies. So, what I'm talking about today is a set of recommendations that NCVHS made to the secretary of the HHS. The letter was dated February of 2019. So, in terms of health information technology, in some senses, that's recent. In other senses, it's progress and evolution of HIT is ancient. So, just keep that in the back of your mind. The body of work that went into the development of the recommendations from February 2019 happened in 2017/2018.

There were two significant documents associated with that work. One was an environmental scan, which I'll get to in just a few minutes. The other was an expert panel roundtable. Both of those were dated in September of 2018. The recommendations themselves consisted of just two recommendations. The first was revisions to the criteria for Health and Human Services adoption of terminologies and vocabularies. This was an update of I think it was a document from around the year 2000. And, essentially, what that is is what is it that HHS should consider when evaluating terminologies and vocabularies for adoption, whether that adoption be by regulation such as HIPAA or by Medicare or any of the HHS programs. The second recommendation was a set of new guidelines for those organizations who are the curators or updaters of already adopted or already in place terminology and vocabulary standards.

And those guidelines talk about what the infrastructure and the processes of the organization who develop and maintain terminologies and vocabularies should have, what the developers, maintainers/curators should have in place to ensure quality, sustainability, and interoperability. So, that's the big overview. All three of these documents that I'm referring to, the letter itself, which embeds two attachments and then, the environmental scan and the report of the expert roundtable are all available on the NCVHS website if any of the members want to review those in more detail. So, the environmental scan report, again, dated September 2018, I'll just note that that's pre-COVID because there's a lot of stuff that we've learned since 2018. The report sets the context on terminologies and vocabularies, includes some definitions, a thumbnail of the history. It talks about current terminology and vocabulary standards, processes, and the status of those standards.

It address governance and coordination for the standards. And it talks about maintenance and dissemination and the adoption and life cycle. The companion document, the report from the expert roundtable, again September 2018, just captures the discussion of NCVHS, including invited industry experts that took off from the review of the environmental scan and then, talked through the issues and formed the substance of what NCVHS, ultimately, then put into the recommendations and the letter to the secretary. So, NCVHS reviewed adopted terminology and vocabulary standards after two decades of experience with the HIPAA adopted standards. It looked into uniform data standards, what is the necessary infrastructure for effective and efficient exchange of data both at the individual level and at the population health level and not just the physician and hospital data but also wellness. The recommendations then looked at the validity and reliability to ensure that there is usability across a wide range of purposes.

And that includes both different users and different use cases among the users. The conclusions that the committee reached are in the two attachments to the letter. In Attachment A, if we talk about the criteria for adoption and implementation of terminology and vocabulary standards and that's an updated assessment





criteria for HHS to use when considering updates and addition of new terminologies or vocabularies. And as I mentioned before, that replaces previous guidance that the NCVHS have gotten in about 2000. The second attachment, Attachment B, talks about guidelines for what we call curation and dissemination. That document, essentially, was an attempt to raise the bar for development and curation of terminology and vocabularies and code sets that were both named as standards by regulation or not named or not adopted by regulatory but were in use within the general aspects of healthcare and wellness.

So, Attachment B then, was an attempt to set a national bar or a baseline for the development process, which would include transparency, good documentation, data quality, compatibility with other terminologies and vocabularies, ongoing maintenance, and a number of other critical issues to ensure that the terminologies and vocabularies were reliable and dependable. It also addressed support of distribution and implementation at a national scale. And we'll talk about that a little bit later. But not all of the terminologies and vocabularies that were included in the landscape were, actually, designed or intended for something other than a very self-contained and relatively small user community. So, again, you can look at those documents, some of which have been sent to you. The others are available on the NCVHS website. NCVHS did this work in 2017 and 2018 culminating in the recommendations in early 2019. For many aspects that was pre-pandemic and long ago. So, things have changed and have evolved since then.

But I think the fundamentals of what we looked at and the recommendations we made are still valid because like most things NCVHS, it tends to be high level at a policy and focus on what needs to be accomplished without getting down into the who should do it or how it should be accomplished. We just recommend the targets to the secretary. So, we recognize the need to increase the scope of those terminologies and vocabularies that need to be brought into the expanding world of interoperability. As I mentioned before, some of the terminologies and vocabularies that we looked at were intended for very narrow purposes. If you want to use the analogy of the silos, that's exactly what we are looking at. The HIPAA legislation addressed, specifically, a number of what it called medical code sets to work with the HIPAA administrative transactions claims, eligibility, prior authorization, payments. And those transactions flowed only bilaterally that is between the providers and the payers.

NCVHS recognized the national need for a more multilateral data flow and the need to begin the task of aligning the large number of terminologies, vocabularies, and code sets whether or not they had been regulatorily adopted that are used in individual and population health and wellness, including social determinants of health, public health reporting, vital statistics, mental health, and a number of the other aspects of the national health and wellness system. The recommendations from the NCVHS continue to rely on the same developing and curating organizations as has been doing them, have developed, and initially have been maintaining them. But we propose principles for what might be termed a floor for organizational processes if you think of ISO or ANSI accreditation, which include opportunity for external input into those organizational processes. Also, things that would be built into the process, the development maintenance process, which would be technology or vendor neutrality, quality control of both the development and the dissemination of the code sets.

NCVHS was encouraging a shift from terminologies, vocabularies, and code sets that were designed to serve a unique community with unique use cases to an outside the box look at how those narrow terminologies and vocabularies could and should be incorporated into the larger health information technology community, for example, ensuring non-conflict with other terminologies and vocabularies and,





importantly, a relatively good capability for cross mapping and interoperability. The recommendations touch on the need to address getting terminologies and vocabularies into the hands of end users in a way that minimizes cost, licensing, and other barriers to implementation. The discussion that we had, although it's not explicit in the report, implicit in there is the NCVHS did and does recognize the intellectual property and the necessity of maintaining organizations to recoup their cost to develop, maintain, and disseminate. But we call on HHS and the larger community, in general, to figure out a way how to do both.

That's to ensure the fiscal viability of developers and ensuring a simple and affordable access to the terminologies and vocabularies by the end users. That's it in a nutshell. I didn't want to go deep into the specifics. Those are available if you want to look at them in detail and if that detail is pertinent to the work you're doing. But I think the larger picture is what is important in that NCVHS and this report two years ago is very clearly on a parallel path with what the task force is recommending in its current work. Although, the task force gets a lot more into the details **[inaudible] [00:43:30]** and gets into some of the how's and the who's that the NCVHS work didn't. But, again, just in a nutshell, it was the intent of the NCVHS to take the existing series of terminologies and vocabularies and raise the floor to ensure that all of those disparate vocabularies can work together on a national scale to achieve the purposes that are important to so many of us at the time and that is interoperability with an eye on burden reduction to all concerned.

That's the end of what I had prepared to say. I'd be happy to respond to questions.

Arien Malec

Excellent. Thank you so much, Rich. And just to summarize, when you look at the recommendation in our Section 3 and you look at the recommendations in the NCVHS appendix, they're pretty confident in your opinion.

Rich Landen

Yes. I see them as very, very parallel. The difference is in the detail and the difference is in the charge between NCVHS's work and the charge for the task force.

Arien Malec

Okay. Let me invite task force members who have questions for Rich. Clem, I see your hand is up. Sorry, David, your hand is up. You get co-chair privilege.

David McCallie

Thanks. Rich, thank you for the detailed and dense presentation. There was a lot of facts in that. I'm going to have to listen twice to get it all. But one question. We mentioned OMB Circular A119 on voluntary consensus standards in our recommendation. Did NCVHS see their work as supplementing that, replacing that, being in contradiction to that in some way? And I guess my question is really should we be referencing your document, your work instead of A119?

Rich Landen

David, I reviewed A119. Unfortunately, I'm not the expert that I might be. I was kind of the generalist on the work so I can't give you a definitive answer. Normally, what NCVHS does is it tries to leverage existing work so there was nothing in our recommendations that, I think, conflicted with 119. But 119 was considered in the environmental scan and the **[inaudible] [00:46:26]**.





Arien Malec

It might be helpful to cross reference, in addition to 119, to also cross reference in a bullet the NCVHS recommendations. Okay. Maybe we can open it up for task force members. I see, Clem, you've got your hand up.

Clem McDonald

So, that was one thing [audio interference]. There was a lot of discussion about [audio interference].

Arien Malec

Clem, I don't know if it's just me but I'm having trouble hearing you. I don't know if your connection is gone.

David McCallie

Yeah. Speak slower.

Clem McDonald

Do you have anything you might say about the discuss of ICD-11 during NCVHS meetings?

Rich Landen

Clem, let me just probe there. Are you talking about as part and parcel of the terminology in vocabulary work two years ago or are you talking more recent?

Clem McDonald

Well, up to whatever you know. I thought it was still active from Bill Steads' comments.

Rich Landen

NCVHS has been working on ICD in two respects. The first being as part of the terminologies and vocabularies and ICD, irrespective of whether it's 10, 11, or any potential subsequent version, would all be subject to the same recommendations as for any other terminologies and vocabularies. And in addition going back two years ago, there were some separate recommendations that talked about adoption of ICD as specifically referencing the HIPAA specified medical code set adoption process and clearly delineating the difference between ICD-10, ICD-11 from the US clinical modification, which is something quite different. So, that's the historic relative to the letter of recommendation. Since then, we and NCVHS have had a separate process. And about a year and a half ago prior to the pandemic, we did another recommendation to the secretary of HHS calling for a study of, at that time, the newly approved by World Health Assembly ICD-11.

And we didn't call it a research agenda but it, essentially, was a research agenda. And things that we thought needed to be looked at before the US made the determination on adopting ICD-11 for morbidity. Mortality was a different issue. Mortality is governed by international treaty. The mortality aspect of ICD-11 is not a HIPAA medical code set. And along with them, the research that we were recommending. We also then looked closely at the process in this country under which ICD-10 was adopted just a few years ago and made some recommendations that HHS develop a communications plan that would educate the user community about what's in ICD-11 and, hopefully, established a more evidence based approach to the decision on whether to adopt or not to adopt ICD-11 with or without a clinical modification and the timing of





any adoption. So, I hope that answers your question, Clem. We are currently revisiting those recommendations even as we speak because the pandemic, essentially, derailed HHS resources. And only a small look at some of the research has been completed.

So, we're in the process of updating and we're considering a timeframe of our September meeting for maybe sending an updated letter and recommendations to the secretary on ICD-11. And one other aspect. Again, with the principles of the burden reduction for the approval and adoption of updates, ICD-11 is included in that in a general recommendation that the updates to the HIPAA medical code sets happen at a more predictable pace at a level that meets industry needs and the industry is capable of adopting in bite sized pieces rather than massive updates to HIPAA once every decade or two. That's a whole different topic though.

Arien Malec

Thank you. Do any other task force members have questions for Rich? All right. Thank you, Rich. That was fantastic. And as I said, I think it might be worthwhile as we contemplate any potential modifications to our recommendations to put a cross reference to the NCVHS parallel recommendations here. Clem, maybe I want to turn the floor over to you in that you had a set of potential wording changes to our recommendations that you wanted to propose back to the task force.

Discussion of Updating Recommendation #3 (00:53:19)

Clem McDonald

So, Robert Wah and I [audio interference] joint work. And I thought he was going to send you that joint work.

Arien Malec

He did. And I think we could display it. I would just be interested in having you, since you're the task force member, walk through the proposal for the recommendation changes.

Clem McDonald

Okay. Is Robert on the call? Because I don't want to be solo.

Robert Wah

Clem, I'm here.

Arien Malec

Yeah. Just from a process perspective though, Robert, I think Clem is the task force member --

Robert Wah

Right. I just want to let him know I'm on.

Arien Malec

Got you. Thank you.

Clem McDonald

Well, [audio interference].





Arien Malec

And, Clem, since you're having trouble with your phone and connectivity and since you're on the phone, I'll just read over some of the recommendations. So, in current language 3A, you recommend adding in terminology curators, ONC worked with federal stakeholders and terminology curators to establish policy. I think that's reasonable.

Clem McDonald

That's a term that was used in the original content. And I personally didn't mean for it to mean anything different. I was just trying to be consistent with what they called it, what we called it. And Robert, does that align with it? That's, I think, where it came from just to be consistent with a name for –

[Crosstalk]

Robert Wah

I know you want this just to come from the task force member. I'm happy to chime in where I can help because Clem and I did work on these recommendations together. So, I don't know what your preference is.

Arien Malec

If he's got an alternative perspective to Clem's, again, I don't think this is terribly different from anything else the task force has previously contemplated or agreed on. So, things like that are fairly –

[Crosstalk]

Robert Wah

On this particular point, I think we're just trying to use the terminology that was in the document. But the concept is that including people that are working on terminologies and code sets be included in the discussion is all we're just trying to say there.

Clem McDonald

So, (ii) is probably the biggest difference. And I think the key difference is we soften the word from open to facile.

Arien Malec

We also inserted adhering to licensing components of the 21st Century Cures, interoperability, information blocking, yada, yada, yada. So, when you're talking about that, Clem, are you referring to 302 or 303?

Clem McDonald

Robert, you better help me here.

Robert Wah

I don't have the specific numbers in front of me. We just thought that would be a better reference.

Arien Malec





Just to be clear, are you proposing a –

[Crosstalk]

Robert Wah

Just to be clear, I don't know if the distinction between those two makes a difference here.

Arien Malec

I'll help you with this one. So, the distinction between this one is 302 really calls for a cost plus basis for interoperability. And 303 is an IT licensing basis for interoperability components. And it's sort of ambiguous to me as to whether you're proposing that the focus be on, effectively, FRAND licensing or with respect to a cost plus structure for terminology developers because I'm going to react somewhat differently. And I assume other task force members will as well depending on how we frame that term just for context. Again, this is not to call out any particular terminology developer. It's been a consistent theme of the standards committee and then, the HITAC that interoperability, and this is really consonant with what Rich mentioned with respect to NCVHS and their no or low cost framework for licensing maps and terminology.

The framework here is that if we're promoting interoperability then, putting barriers to interoperability that are licensure barriers is problematic and that, to the extent that we can get to a world where standards developers and terminology developers have a cost basis for doing the important maintenance that they do that that's a really helpful framework and that's not an impossible activity that HL7 has really navigate to that for HL7 FHIR. That's been the model that one could use, the model that **[inaudible] [00:58:31]** has used in terms of the US's position on **[inaudible] [00:58:33]**, etc., our position with WHO, yada, yada, yada. So, it's a little ambiguous to me what we're calling for here as we're thinking about this language. I might counter propose that we just align with the NCVHS no or low cost language as an alternative way of framing this recommendation if open and as ambiguous. I think we've got already approved recommendations to the secretary on terminology from NCVHS that already contemplate no or low cost.

Robert Wah

What I thought I heard Rich say is that they continue to wrestle with that balance. And those recommendations were made in, I think, 2019. I thought the more recent document was the one that was cited here.

Arien Malec

That's right. That's the language that uses no and low cost. Rich, I don't know if you're still on if you can comment. Rich may have dropped off.

Rich Landen

I was just on mute. As I mentioned, we were looking at this very high level. So, our goals as stated is that it's essential that the intellectual property and the financial viability of those organizations who develop and maintain terminologies and vocabularies be, I don't know what the right words is, protected or maintained or ensured. The counterbalance being that when you look at all of the standards, all of the terminologies and vocabularies that entities within the health data arena need to have, it becomes a huge burden. So, our recommendation was simply to acknowledge that a balance needs to be struck. And we left the actual





solution to others. It was important to us that barriers to obtaining terminologies and vocabularies be minimized. And by minimized, we mean well within the capability of small practices, patients, if that's the case, consumers, similar to patients. But it is also protection to ensure that the work continues.

And I guess the case in point today being CPT, whether it's CPT, which is, of course, American Medical Association, or if it's the International Classification of Diseases, the World Health Organization, which US supports by tax dollars. NCVHS did not identify a solution, only that we need a balanced solution.

Arien Malec

Rich, just to clarify what we're talking about, if you look at Attachment B, which is Guidelines for Curation of Dissemination of Terminologies, Vocabularies, and Standards, Sub Bullet 8 is no or low cost ways to obtain standards, implementation guides, and maps and other resources. And Sub Bullet 9 is use of electronic resources, dissemination methods that minimize cost and licensing barriers. And then, if you look at Attachment A under the Bullets 1 through 8, there is also the note implementation of adopted standards should be supported by or **[inaudible] [01:02:08]** available. 2.) No or low cost ways of attaining standards, implementation guides, and maps, documented lines of responsibility and plans across future implementation specific to standards yada, yada, yada. So, that no or low cost rubric is one that I'm just pulling directly, Rich, out of the NCVHS transmittal to the secretary. Is that a fair summary of at least that portion of that? That's the policy framework that you're calling out just like we are.

You're not calling out a specific way of addressing it. As you note, there are multiple models for whether it's US participation in WHO, granting to **[inaudible] [01:03:00]** relative to LOINC, etc. There are multiple ways of achieving that outcome. That's really the outcome that the recommendation transmittal is looking towards. Is that a fair summary?

Rich Landen

That's a very fair summary. Yes. We're aware of the models, the World Health Organization. The NLM, I believe, was licensing of SNOMED, HL7's models, LOINC. There are a number of different approaches. But, again, the principles here are we want something that will not be a barrier to the use of these terminologies and vocabularies and yet will provide to the maintainer the fiscal resources that are necessary for them to continue to do their job.

Arien Malec

Absolutely. Perfect. Thank you.

Clem McDonald

If I could chime in, Arien. I didn't, actually, dig into it. I just thought it was **[inaudible] [01:03:56]** of 21st Century Act. So, I'm glad you knew the details there.

Arien Malec

Got you. Thank you. Thanks, Clem. Okay. And then, we've got a couple of additions for purpose. Ensure the clinical administrative workflows are minimally impacted, etc. I, actually, think for this one, NCVHS did a really nice job of articulating many of these care abouts. And I wonder whether it might be appropriate just to replace this with a call out to the NCVHS requirements here.





Clem McDonald

Go ahead, Robert.

Robert Wah

No, Clem. I'll let you go. But I was just going to say I didn't have that when we were looking at this. So, I wasn't contemplating what Arien is proposing. And I don't have it right in front of me now. So, it's hard for me to compare and contrast what we're talking about. Obviously, a lot of work has been done on the NCVHS work and well respected and well prepared. So, on the surface, I would be hesitant to say it's a problem. But at the same time without knowing the details, I'd just be hesitant also to concur with it without seeing it. So, I'm sorry.

Arien Malec

No problem. And we distributed it to the full task force. Robert, I'm happy to send you a copy or give you a link to the reference. It's a public transmittal. Let's go into the next section.

Robert Wah

I thought the 21st Century Cure language was useful in this regard and that's why I referenced it. And it was more recent than the NCVHS document to the secretary in 2019.

Arien Malec

Got you.

Robert Wah

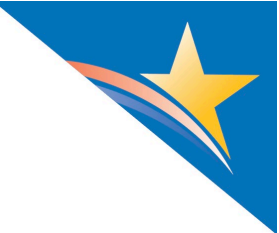
And particularly to the comment that you made about, I guess, you were citing the low cost, what I heard Rich say was low cost so long as it doesn't impact the financial structure of the people that are spending the time to create, maintain, and disseminate the code set. I think that has to be in there as well just because we have to have viable systems to maintain this. To Rich's point about making sure there is less friction in the system due to the code sets, I think everyone agrees to that. We're not looking for code sets to increase the friction of the workflow across the healthcare ecosystem.

Arien Malec

Yeah. And, again, just the policy point here is that I think everyone agrees that terminology and standards curation takes effort and work and that we need an appropriate financial model that allows on a cost basis that work to get done. But we want to make sure that we're not inadvertently creating a model where the licensing to achieve interoperability is a burden or barrier to interoperability itself. So, I think that's the balance. I agree with you. That's the balance that needs to be struck. And, again, I think using the NCVHS call out is probably the right way of framing this. They spent a lot of effort in putting together that balanced language. Thank you. And then, I think on Sub B, there is a lot of very helpful language that clarifies the language. David, I don't see this as something where I look at it and think it materially alters the language that the task force already agreed to. I leave that to task force members to see if there is any perspective on this language.

David McCallie





My take on B is consistent with that. I think the terminology curator language is a positive addition. The correction of our inadvertently omitted not is a necessary correction. The rest of it, I don't think it's material one way or the other.

Arien Malec

As we do transitions from Vocabulary Version A to Vocabulary Version B or Vocabulary 1 to Vocabulary 2, as we will from time to time as a health system that there is necessary transition. I don't think anybody thought that the ICD-9 to ICD-10 transition was fun. And yet, I think it's an appropriate impact so I don't know if nimble or appropriate. We can wordsmith that one. That might be the only thing. We don't want to create language that inadvertently causes us to stall out as a system because we can't upgrade things. Let's go onto the next one, which, again, I think is just helpful corrective.

Clem McDonald

Yes. That I can be blamed for or given credit for because I think it was kind of messy. And it wasn't developed. The problem is the word laboratory results sometimes is a very confused word to start with. Does it mean the whole thing or does it mean just the value? So, that's where I got stuck on that word. And then, the other one I reorchestrated. The way I think that ONC says there are really two parts to the results and one part is supposed to be what you might call the question and then, the other part, if it's a number, it's got to have a unit that's standardized to UCUM. And the other part, if it's a coded name with a code then, it's got to be SNOMED CT.

Arien Malec

Yeah. This was super helpful. I read this and I learned something. This was a really helpful framing. I don't know, David, if you have any comments here and if task force members have any comments here.

David McCallie

Well, maybe my take is that this is the kind of detail that ought to be in an implementation guide that's use case dependent and not a high level recommendation. I'm reasonably confident that in most cases, this is going to be accurate but I wouldn't say that in 100% of uses of either SNOMED or LOINC or UCUM that this exactly captures what should be done. So, to me, this is unnecessary and belongs in an IG somewhere. But I'm not going to fight hard about it.

Clem McDonald

It's what we say in other places and I think it is accurate.

Arien Malec

Yeah. I think it is, generally, in alignment with, for example, standards committee questions, LOINC answer or SNOMED or UCUM is a useful way of framing it up. I think this is one where it's useful, clarifies the language, unless there are other task force members or, David, unless you violently disagree, I'm inclined to propose this back to the task force as a set of potential edits. Are there members of the task force who have perspectives, opinions, feedback on the discussion that we just had?

David McCallie

For 3C?





Arien Malec

Yeah. For 3C but then, broadly A, B, and C for Section 3.

David McCallie

Oh, okay.

Arien Malec

Okay. I think from a process perspective, we may, unfortunately, need another meeting just to formalize and memorialize language and get to broad task force consensus. I will take a pass at trying to memorialize the output of this conversation and see if we can get to a proposed set of language changes for Section 3 that are sort of material to the conversation that we had today. I really welcome additional task force members who have any additional commentary. Okay. Hearing none and hearing no objection to that approach to proceeding, first of all, I want to thank our panel participants from the AMA and from NCVHS. I think they really helped address some important background and context. I really want to thank Clem. I think Clem pointed out the NCVHS language. And I think that was a helpful context for the deliberations that we're making as the HITAC. I'm on record as saying, in general, that the NCVHS and the HITAC should be better aligned because we both make recommendations on important matters of interoperability in slightly different areas that are themselves converging.

So, I think it's really helpful to get the broader input from the two sister FACAs that make recommendations to HHS in this space. And with that, unless there are other task force members who want to raise their hand or who are on the phone who want to provide input, with that, I will maybe suggest that we open up for public comment.

Unknown

[Inaudible] [01:14:14]

Arien Malec

Yeah. Go ahead.

Unknown

I don't know if it's appropriate or me to jump in. But I put in the chat box there were some edits in 3D and 3E if you scroll down. I think there was a page break. There should be another page to this.

David McCallie

What's showing now is that.

Clem McDonald

That's right.

David McCallie

This is D, E, and F.

Arien Malec





Got it. Thank you for that. So, terminology curators. I see, Clem, you're proposing striking SNOMED CT and ICD-11 harmonization. Harmonization is probably fine.

David McCallie

The issue there is diagnostic codes and clinical descriptor code harmonization, is it not? The problem that we have now is you bill with one set of codes and you describe the problem with a different set of codes. And that's untenable to physicians.

Arien Malec

Yeah. It's just not helpful.

David McCallie

So, we need something to capture that harmonization whether we reference SNOMED and ICD-11, I think, is less important. It's billing and clinical problem list or clinical descriptor. Would it not be? Clem, do you have a thought?

Clem McDonald

NCVHS really describes something like that that we want to have an easier pathway. And that's such a split between those two. And from what we heard at other meetings, it isn't clear who finds it untenable at the present time. But that's another story. I think the chairman of the other HITAC committee had a slightly different view. But I think we really should work at not having to mess with two different coding systems.

Arien Malec

Yeah. I think that's the point is we really should work at not having two different code sets.

Robert Wah

Clem, I think your point was overall harmonization is a goal, not necessarily just citing those two organizations.

Arien Malec

Yeah. That's helpful.

Clem McDonald

Thank you, Robert, for helping me remember.

Arien Malec

And then, I think we've got a whole lot on the executive summary version that, frankly, the intent of the executive summary is to get to an executive summary of the detailed recommendations. So, I think we should get the language of the detailed recommendations right before we wordsmith the executive summary version.

Robert Wah

Yeah. We tried to just reflect the changes above into the executive summary. I don't think there is anything new in the executive summary. It just reflects the changes that were made above.





Clem McDonald

It may be too bulky though, Robert, now when you look at it.

Robert Wah

Yeah. I understand.

Arien Malec

Okay. Thank you for calling out that there was another page to this document. I think the sentiment still stands that we'll do the changes to the detailed recommendations that we contemplated as a group. We'll see if we can get group consensus, task force consensus, on it prior to bringing it back to the HITAC. Unfortunately, I do think we're going to need another meeting on this one, which is fantastic. And then, once we've got consensus on the detailed recommendation, we'll do the appropriate work to make sure that the executive summary follows the detailed work. Thank you for the call out. So, now with all of that being said, are there any additional task force members who have got a perspective here? Going once, going twice. Maybe we should just go for public comment then.

Public Comment (01:18:49)

Michael Berry

Great. Sounds good. Operator, can we open up the line for public comment?

Operator

Yes. If you would like to make a comment, please press Star 1 on your telephone keypad. A confirmation tone will indicate your line is in the cue. You may press Star 2 to remove your line from the cue. And for participants using speaker equipment, it may be necessary to pick up the handset before pressing the star keys. One moment while we poll for comments.

Michael Berry

And while we're waiting, I'll just note that, as Arien said, we'll reconvene next Thursday at 2:00 Eastern Time for a follow up meeting. Operator, do we have any public comments?

Operator

There are no comments at this time.

Michael Berry

Great. Thank you. Arien?

Arien Malec

Excellent. Well, thank you so much and we look forward to same bat time, same bat channel for, hopefully, finalizing our Section 3 requirements and getting a good clean draft off to the HITAC. Thank you so much.

Adjourn (01:19:50)

