# HIT Standards CommitteeHIT Policy CommitteeImplementation and Usability HearingDRAFT Summary of the July 23, 2013 In-person Meeting

## Attendance

**The following members were in attendance:**Implementation Workgroup

* Elizabeth Johnson
* Christopher Ross
* Anne Castro
* David Kates
* Wes Rishel
* John Travis

Meaningful Use Workgroup

* Paul Tang
* George Hripcsak
* Paul Egerman
* J. Marc Overhage (covering Charlene Underwood)
* Michael Zaroukian
* Amy Zimmerman
* Greg Pace

Certification/Adoption Workgroup

* Marc Probst
* Larry Wolf
* Joan Ash
* Paul Egerman
* Joseph Heyman
* George Hripcsak
* Paul Tang

**The following members were absent:**

Implementation Workgroup

* John Derr
* Timothy Gutshall
* Joseph Heyman
* Tim Morris
* Stephen Palmer
* Sudha Puvvadi
* Kenneth Tarkoff
* Micky Tripathi
* Gary Wietecha
* Robert Anthony
* Kevin Brady
* Tim Cromwell
* Nancy Orvis

Meaningful Use Workgroup

* David Bates
* Christine Bechtel
* Neil Calman
* Arthur Davidson
* Marty Fattig
* Leslie Kelly Hall
* David Lansky
* Deven McGraw
* Latanya Sweeney
* Charrlene Underwood
* Tim Cromwell
* Joe Francis
* Martin Rice
* Robert Tagalicod

Certification/Adoption Workgroup

* Carl Dvorak
* Elizabeth Johnson
* Charles Kennedy
* Donald Rucker
* Latanya Sweeney
* Micky Tripathi
* Martin Rice

## KEY TOPICS

### Call to Order and Roll Call

Michelle Consolazio, ONC, opened the joint hearing of the Implementation Workgroup, Meaningful Use Workgroup, and the Certification and Adoption Workgroup with the Federal Advisory Committee (FACA) announcement. She referred to the opportunity for public comment and said that a transcript of the hearing will be posted on the ONC website. She reminded members and panelists to identify themselves for the transcript before speaking. Members and staff introduced themselves.

### Opening Remarks

Liz Johnson, Chair, Implementation Workgroup, said that experience with Stage 2 can inform Stage 3. The majority of providers now use EHRs. Paul Tang, Chair, Meaningful Use Workgroup, thanked the ONC staff. He thanked MacKenzie Robertson, who is retiring from her role as FACA project lead, and Consolazio for agreeing to take on new responsibilities. Stage 3 will focus on outcomes. Implementation, usability, interoperability, and information exchange continue to be challenging. Draft Stage 3 recommendations will be finalized in September 2013.

### Meeting Objectives and Outcomes

Cris Ross, Co-Chair, Implementation Workgroup, referred to a similar hearing held last year on moving from Stage 1 to 2. The Implementation Workgroup is concerned with practical application. The FACAs advise ONC. Marc Probst, Co-Chair, Certification and Adoption Workgroup, said that usability is important to adoption. Usability has advanced over the decades. Modifying even one menu item can create havoc.

### Vendor User Centered Design Processes

Raj Ratwani and Terry Fairbanks, National Center for Human Factors in Healthcare, MedStar Health, reported on a subcontract with ONC. A team of human factors experts including physicians visited nine different EMR vendors to learn about current user centered design (UCD) processes and to understand the challenges and barriers to incorporating usability in the EMR product development cycle. The vendors were of diverse size, both in terms of number of employees and market share, and included both inpatient and ambulatory products. Fairbanks explained that there are two bins of usability: user interface design, which includes displays and controls, screen design, and clicks and drags, and cognitive task support, which is workflow design, data visualization, and functionality.

The vendor UCD project was intended to understand vendor UCD processes and challenges. UCD is any formalized process for incorporating user needs throughout design, development and usage. On-site meetings were held with usability experts, business analysts, and product managers. Fairbanks described problems that can occur when frontline workers’ experiences are not taken into account. Ratwani described three categories of vendors. Those that had no UCD in place focused on customer requests, assumed that responding to user feedback is UCD, and had no formalized method for incorporating and testing user needs throughout design and development Vendors that used a basic UCD approach: understand UCD and its importance and strove to implement UCD processes, but could not fully integrate UCD. A well-developed UCD means that a rigorous process is in place, efficient testing methods are used, and an extensive infrastructure is in place. Each type has challenges; but in general the challenges are the rapid and rigorous timelines imposed and the summative testing of safety. Testing at the end of the process development leaves no time to correct that version. It is very difficult to add new functions to a legacy system. In the future, how usability can support patients will be a topic. He pointed out that customization in response to providers’ requests can result in significant change to the certified EHR and the result is much different from what was certified. He reminded them that training cannot make-up for usability shortcomings. Training is often offered as an added cost and some are not willing to pay.

#### Q&A

In response to a question about moving UCD to users, Ratwani noted that in other environments the end user is not given this responsibility. End users do not always have the best insight into what will work. Focus groups are not adequate; observation is required. Clinicians must be observed very early in the design process.

Johnson asked how vendors communicate with end users. The presenters said that the well-developed UCD users do engage with providers. Few vendors are doing any pre-analysis with early adopters. It is very time intensive.

With regard to the characteristics of vendors that are using UCD and advice to workgroups, vendor resources are an important factor in UCD. The project did not examine the relationship between resources and end results. Size was not related to UCD processes. They recommended more rigorous inspection of the UDC processes in place by vendors. Summative testing uses resources that could be better used at earlier stages of design.

Joe Heyman inquired about usability as meaningful use (MU) criteria, saying that in his experience each new criterion made the EHR less usable. The presenters acknowledged that often the new criteria are not well integrated into systems. They went on to respond to another question, saying that purchasers and vendors share responsibility for usability. Workflows are not that different across settings, although the perceived wants and needs of users vary. Also, information should be shared across adopters.

Cris Ross asked about objective measureable standards for usability to apply in certification. They said that usability is applied in other industries, such as by the FAA. Usability can be quantified but it is difficult. Typically, the process of determining usability is what is examined. Standard data sets alone are not sufficient.

Tang wondered how much customization is really needed. Is it required for every specialty? How should responsibility be divided between the vendor and user? They responded that customization is very much needed for specialties. But customization for differences in similar settings, such as EDs, is not usually necessary. Guidelines are possible.

A member asked about mass customization in health case, compared to the flexibility of mobile apps. This is a time of rapid change: How long will it take to get to a steady state? The presenters agreed that moving to a more apps-like environment will be positive. Users think they need more customization than they really do. And so much variability adversely affects usability.

Johnson declared that the time for questions had been exceeded. They continued.

Anne Castro asked about ratings. Where can one get information about high usability products? They informed her that ratings are not available. Self-reports by users are not sufficient. There is a need for someone to examine products and match them with UCD processes.

Wes Rishel declared that regulations are incremental and short term and need to be reasonably objective. Has anyone measured usability in a way that it could be integrated with certification? The presenters said that FDA and FAA staff looks at the processes to determine usability. Time spent in terms of key strokes can be used as a proxy, but its validity is questionable. Work is being done on measurement.

### Panel 1: Eligible Professionals (EP)

Moderator: Larry Wolf

Expectation: The Eligible Professional Panel will help to inform how to enable EPs to be more successful in their efforts to meet Stage 2 meaningful use, and enable more providers to be able to participate in Stage 3 of the program.

Chris Tashjian, River Falls Medical Clinics, showed slides. The greatest challenge with core measures is expected to be 50 percent patient electronic access. Practices in rural area with edge coverage for mobile and dial-up for Internet will be handicapped. In a large geriatric practice, the VDT item will be difficult. He reported that practitioners are trying to engage families, which is time consuming. There are also security issues that must be taken into account. Among core measures, he anticipated that summary of care record for referrals will be difficult. He reported that having the ability to search for the secure, encrypted DIRECT e-mail address would facilitate use of this capability. Currently, his organization does this with NPIs. The menu items provide very little choice insofar as he does not have the capacity for imaging results, cancer registry, or syndromic surveillance. Only with the help of the vendor is his organization able to meet specialized registry. He reported that the pain of changing and implementing Stage 2 is greater than the reward. In moving from Stage 1 to Stage 2, many providers have said their vendors cannot supply them with the needed tools. Tashjian was appreciative of having selected a national vendor with ASP support. He urged ONC and CMS to continue to adopt standards. He stated that he supports deeming.

Craig Bradley, Texas Tech University HSC School of Medicine, reported that he expects VDT to be the most challenging measure since it is not in the hands of the physician. He said that he and others are concerned that vendors and EPs may have to build into their patient portals semi-automated responses. Although not necessarily a bad thing, it might allow EPs to meet the requirement technically while still not achieving the goal of more engaged patients. His organization is aggressively marketing the patient portal to two populations, patients (a receptive market) and EPs (somewhat less receptive in many cases). Measure 1155 transition of care will be difficult. What is a transition of care for an orthopedic surgeon or any other specialist in the ambulatory setting? How will we identify transitions in our EHR? What about the transitions that we find out about via records request, but do not initiate? Can (or should) one transition from a hospital to another setting count for both the EH and the EP? This measure is also not in the complete control of the EP, as electronic transmission requires a receptive partner. He said that his EHR partner group (two multispecialty practices and a hospital) partnered with the other major health care entity in the service area to create a local HIE which will include approximately 80 percent of the area population.

He noted that much of meaningful use does not apply to specialists and, more generally, that the entire system is not built for efficiency or centered on patients. In terms of increasing participation, he explained that in smaller groups, the $44,000 total incentive split up over five years is not enough to invest the amount of work required. Without a dedicated EHR adoption team at the ready, how could a small group be ready to roll out new workflows on very short timelines? In terms of actions by HHS, he made several suggestions that would make it easier for providers to deal with the many reporting requirements they face. For instance, a federal entity could serve as a clearinghouse for this reporting. Then, a state or local entity has only one interface to build. Additionally, certification of solutions was a concept created to set a minimum standard to which vendors must comply and to remove the risk from EPs and EHs in selecting an EHR. The ability to use a piecemeal certification process was a concession to accommodate health systems or practices that were already using multiple solutions. He said that his institution and the majority of EP practices use the complete EHR solution from a single vendor. Unfortunately, essentially every aspect of MU which they had not already built when MU came along is an opportunity for additional licensing fees. The burden of certification has not only been pushed from its intended target, vendors, out to the EPs and EHs, but those vendors have also leveraged a new revenue stream. He said that the measure to allow patients to request online amendments to the record is an excellent idea in spirit. But without a great deal of specificity, the solution will be to simply add a free text messaging functionality from the online pages where a patient is participating in VDT. He suggested having a measure that requires reporting of clinical decision support statistics—the number of alerts they override compared to the ones which result in a modification of behavior. Vendors should be required for certification to allow for the recording of genetic information in some way.

Paul Kleeberg, Stratis Health, reported that smaller facilities do not have easy access to resources outside of the services extension centers provide. The expanded number of CDS interventions may prove to be difficult for those that do not have the technical skills to produce interventions that they find valuable or do not have a true understanding of the breadth and depth of what constitute CDS interventions. The default language is “alerts” and the narrower “pop-up” window perception of what constitutes CDS. Additionally, subspecialty appropriate CDS interventions are not likely to be built into standard EHR software. Regarding HIE, organizations will be turning to their IT support staff as well or the experts in HIE at their vendor’s help desk. Other issues include having to pay more for new interfaces, uncertainty about when and whether the state will provide the infrastructure to exchange data with other organizations and to send, as an example, immunization data to the state, how to capture all the data elements listed for transition of care documents, and where in the workflow providers can remove diagnostic test results before an AVS goes to the patient portal. Imaging results may be another area where technical assistance will be required. This may depend largely on the topography of the organization’s systems and the ability to interface between the EHR and imaging system. For small provider groups, the transmission of imaging results will be more complicated for those that have a contracted radiologist come onsite to read films and studies or read them remotely. In many cases the contracted radiologists work in a group that has its own imaging reporting system that needs to be interfaced with the clinic electronic record for which they are providing outreach services. Providers are concerned about how they will motivate patients to respond to information online provided through a shared portal or online options, despite the relatively small percentage required. Privacy and security, and everything related to interoperability will be challenging. The challenges can be addressed via TA and education. For resource limited organizations, the support can be provided by the local AHEC, an extension center, or the provider’s vendor. As an extension center worker, he said that the approach is to provide education for clients and build cooperation among similar organizations. However, continued funding is required. Non-participation among specialists could perhaps be reduced by pressure from primary care providers who want referral information to come back electronically and from patients who want their health information to all be in one place. Consequently, the continued outreach to patients so that they demand their providers use electronic health records would be of value. Also patient demand will increase when they are able to compare performance and quality numbers for providers, clinics, and hospitals. He suggested that having the immunization registry provide information to the provider as well as predicting the immunizations that are needed would help with reporting to PHAs. Calculating what immunizations are needed can be especially difficult in the pediatric population when children fall behind in their immunizations. Rather than having each EHR vendor or clinic build it, building it once by the CDC and distributed by the states to take into account local shortages or outbreaks would be a value add for providers.

The number of clinical decision support interventions, patient reminders and patient lists by specific condition are three measures appropriate for deeming, which he supported. MU could support patient’s consolidation of the record from multiple providers into one place, which would require standards. Helping providers see how patient engagement will make their job easier as opposed to just making it more complicated would go a long way in overcoming this barrier.

John Bowman, OrthoVirginia, speaking for his subspecialty reported that EMRs are not designed for their use. Receipt of lab data and secure messaging are not yet available. The chains in his service area (Richmond, Virginia) will not share data. The cost of duplicate, unnecessary testing continues. Many objective data can be obtained with portals. But small groups cannot afford the initial costs. Costs of upgrades are also burdensome. A possible solution to address the interoperability issue is to create incentives for a common portal standard for the basics of patient registration. Over time, this common shared patient specific data set could then be incorporated with MU elements such as smoking status, immunization status and recent vital signs. This would enable specialists to provide specialty care rather than re-recording a common dataset that patients must give to every health care provider. MU stage 3 should reward all providers of radiology services for developing the ability to make imaging studies available electronically to any physician chosen by the patient for follow up care.

Regarding patient engagement, he said that without interoperability and standard data sets, patients will be frustrated. In rural areas many patients do not have broadband. Plus, patients with several providers will be subject to numerous portals. He urged more flexibility with menu items, such as clinical analytics for performance measures. Vendors should combine required reporting. Other needs are to incorporate ICD 10, better help desk support, a better prescription process for narcotics, and a listing of audit requirements for each measure.

#### Q&A

John Travis inquired about measures and their impact on usability. Kleeburg talked about voluntary testing with scenarios as an iterative process. Someone observed that EMRs are becoming more adaptable, particularly regarding e-prescribing. Although it may be impossible to measure usability, it has improved. Another panelist noted that usability is not always the issue. It must apply to existing products.

In response to a question about built-in audit prep tools and the role of CMS, Bradley talked about having an audit workbook, which includes functional reports from EHRs and other systems; EHRs should generate the PDF of everything needed for an audit. These requirements should be pushed to vendors.

Tang observed that bin 2 is hard to do. What about crowd sourcing? A panelist said that vendors should share and end users should share. Vendors should share with vendors on usability. Currently, there is no sharing across vendors, such as between Epic and Cerner. It may be necessary to encourage or force a standard.

Christine Bechtel responded to Tashjian’s concern about the summary of care and the lack of trading partners. She said that federal requirements drive referrals. Since by Stage 3 adoption is expected to be wider, what is an appropriate threshold? He said that CMS should allow a direct e-mail box: Do it like NPI.

Regarding UCD and mass customization, a panelist said that subspecialists must accept responsibility for putting pressure on vendors to design something appropriate for their needs. Another panelist acknowledged that his Application Service Provider (ASP) was a godsend. Providers do not always know what they need. With ASP, one always has the most recent version. Another panelist, who said that he used a heavily customized system, observed that users always struggle with change even if it is an improvement. One panelist explained that some users do not have the bandwidth to customize. Customization can occur at the local work flow. Another panelist recommended that the use of current functionality should be certified.

Amy Zimmerman referred to the description of multiple portals and asked how to implement a portal so that the provider’s information gets to all other providers. A panelist said that a common data set is used. Specialists can add information via pen and paper responses. A common data set can be defined so that data can be shared intra- and inter-organizationally. A portal manufacture has done that with demographic data. Standards are key. The CCDA defines elements that could be shared. Having a patient identifier is necessary. Someone must be the source of truth.

Regarding barriers to willingness to exchange, Bowman repeated that the large institutions in Richmond are very proprietary. Smaller groups cannot pressure for sharing. Another panelist referred to Epic, saying that clinicians share because they want the data. Some find that faxing takes less effort. It is not always in a provider’s interest to share patient specific information. Another panelist said that vendors are the problem.

Someone asked the panelists to say how much of the relative responsibility lies with vendors and purchasers. One panelist called it a 50-50 split. Another said 90 percent of the responsibility rests with vendors. Someone responded that 80 percent of the responsibility lies with the leadership of the organization. The other panelist replied that vendors need to do better job; they bear 30 percent of the responsibility.

Rishel revealed that he had blogged about matching fax machines. He is hearing that Direct will not work without a national provider directory. Faxes work without a directory. How critical is a directory? Panelists expressed different opinions. One said that a directory is critical. E-mail must be secure. Another panelist talked about the problem of spam. Although a directory may not be a requirement, an e-mail address is required. Another panelist described his system, which identifies the patient and the information shows up in his e-mail box. It works better than fax.

David Kates inquired about the challenge of reporting to several organizations. Someone replied that varying standards is one issue. It is an unnecessary problem. Another panelist agreed. One panelist talked about inaccurate quality reports. Finally, a panelist noted that in an academic institution, it is difficult to know who owns which patient.

### Panel 2: Eligible Hospitals (EH)

Moderator: Liz Johnson

Expectation: The Eligible Hospital Panel will help to inform how to enable EHs to be more successful in their efforts to meet Stage 2 meaningful use, and provide input on proposed Stage 3 requirements of the program.

Tom Pagano, HCA Capital Division, did not submit written testimony in advance. He talked about the important role that nursing staff plays in implementation of new HIT. However, given the nursing shortage, taking nurses out of direct care and administration affects patient care. Another challenge is design. His organization spent a lot of time on testing, which involves travel. Physician advisory groups played a role. He declared that he supported meaningful use and expects HCA to be successful in Stage 2.

Pamela McNutt, Methodist Health System, reported that the most difficult requirement will be patients accessing their records in the patient portal. Also difficult will be: data exchange at transitions of care; fully automated medication reconciliation; summary of care electronically exchanged 10 percent of the time; and creating completely accurate quality metric data directly from the EMR. The biggest issue is that there is not enough time to implement and exercise the 2014 certified software. McNutt described concern with unintended consequences due to a hasty implementation of starting the 90-day Stage 2 reporting period by July 1, 2014. To illustrate, she described some of the several steps that will be required after delivery of the patient portal. She argued that although stage 2 should start in October 2013 for those that are ready, many providers need an extended timeframe for compliance, well beyond September 30, 2014. She strongly urged ONC and CMS to consider proposals by the College of Healthcare Information Management Executives and the American Hospital Association on this issue. She suggested that HHS encourage HIEs to be vehicles for public health reporting and for state and local agencies to embrace HIE feeds. Stage 3 should focus on measures that support the creation of accurate and complete continuity of care records to improve the chances that HIEs and other methods of exchange can thrive. Accuracy of medication lists and robust discharge summaries should be encouraged.

She went on to note that compared to the level of understanding and debates CIOs were engaged in months before Stage 1 started in 2011, there appears to be a lack of deep understanding of the Stage 2 measures. More educational sessions are needed.

Rod Dykehouse, Penn State Hershey Medical Center and Health System, reported that summary of care/transition of care (10 percent) to be electronically provided will be the most difficult objective. The lack of data standards is a problem as is the lack of a database of providers to determine which communication channel should be used. SNFs and home health care agencies are not able to accept information electronically. The transition to ICD-10 will affect the capability to respond to quality measures. After waiting for and scheduling the installation of the vendor system upgrade (due out in October, 2013), the implementation team must then review and determine the necessary workflow refinements and modifications. It is difficult to prepare because so much is dependent on the final vendor product.

Randy McCleese, St. Claire Regional Medical Center, said that the objectives that require capital dollars for implementation cause the greatest concern. Small and rural hospitals survive on razor thin margins and capital is hardly available for those items that provide direct patient care. Additional money will be needed for interfaces such as those for public health. The patient portal will also cause significant problems from two directions. First, there must be implementation of a technology that many underserved patients do not know how to use or do not have ready access to use. A patient portal to access the patient’s continuum of care record that is housed in multiple systems is a significant capital outlay. (The alternative to implement multiple patient portals for all systems causes great concern because a patient would have to learn more than one portal.) Patient matching is an issue as well. The multitude of state and federal agencies and organizations that require reporting is significant and there seems to be little in the way of standardization of how they want their data. The adoption of standards for matching patients and treatment consent are the two areas for which ONC and CMS should provide significant support and resources. Patients are treated by multiple providers and each provider’s vendor system utilizes its own method of patient identification. There needs to be a standard method of matching patient data among all providers and vendor products.

#### Q&A

In response to a question about changing the timing of Stage 2, McNutt referred to CHIME’s recommendations.

In responding to another question, panelists talked about the time required for online documentation. The collection of information is also an issue and must be redefined for Stage 2. McNutt reported that physicians want to do progress notes in free form. They complain that clicking boxes for exceptions is repetitious and makes for unnecessary work. Another panelist said that physicians say they may be doing too much too fast thereby adversely affecting patient care.

David Kates referred to having a vested interest in the use of HIE. According to McNutt, patients want a PHR but they do not know what it is. Patients will not want to deal with multiple portals. For Stage 3, patient data should be consolidated. Pagano said that documentation slows down physicians. They need a lot of support.

Anne Castro asked whether the panelists have the same issues that were brought out in the EPs’ testimonies. She also wondered about the needs of subspecialties. Dykehouse said that his vendors are trying to meet the needs of both EPs and EHs. They are spending a lot of time on making audits work. McNutt said that optimization is a never ending process.

Bechtel talked about the portal and wondered about solutions, saying that the workgroup was aware of the same issues mentioned by panelists. One panelist said that the portal is most useful when there is a longer term relationship, such as with the PCP. Bechtel interjected that EH patients should have online access, especially for the transfer function. McNutt responded that being an ACO requires yet another portal. Probably the portal responsibility best be with ACOs. Another panelist said that having a portal and help desk in the hospital will be required with a population not set up for access. Pagano noted that significant education will be required.

A member said that clinical documentation requires structured documentation. There is tension between what is required for MU and the transition to ICD-10. What usability standards would make documentation doable? What about natural language processes? Dykehouse acknowledged that his organization struggled with the issue. He is working on natural language processing. There is a constraint regarding what can be done within the bounds of ICD-10.

Cris Ross said that he had not heard much about the technology, which is under ONC’s purview? He asked about challenges of attestation of technical support. A panelist responded that attestation is a bigger challenge. Providers must learn how to use the technology. Technology must support the best health care, not simply providers’ work flow. McNutt explained that ONC and CMS are moving too fast to Stage 2. Hearing about the Stage 1 audits is frightening. So much time is spent in defending what was not well understood. Providers are dropping out because of fear. Another panelist agreed that audits are punishing. Rewards should be used.

Another member asked about security requirements around implementation and usability. McNutt referred to tension between ease of access versus security requirements. Another panelist agreed that there is always a tension.

Tang exclaimed that ONC must push for everyone to do something in order for anyone to win. Trading partners are necessary for exchange. Stage 3 will reward providers for doing good by deeming and consolidation. Johnson asked about e-mail, which McNutt indicated would be a good idea. Pagano indicated that corporate headquarters will respond to requirements. Regardless of the measures, security and audits must be considered.

### Panel 3: Health Information Exchange and Interoperability

Moderator: Christopher Ross

Expectation: The HIE and Interoperability Panel will assist in identifying innovative approaches to achieving the interoperability required for meaningful use Stage 2 and possible interoperability requirements for Stage 3.

John Blair corrected the agenda to say that he was testifying on behalf of MedAllies. He explained that provider on-boarding to Direct networks through the EHRs has to be easy. This means identity management must balance security needs with reasonableness of effort, and the provider registration processes need to be consistent with current industry approaches. Providers need to easily find all endpoints on any accredited Direct network; therefore, directories need to be federated between HISPs and kept current at the provider organization through HISP/EHR synchronization. Finally, interoperability means clinical workflows within each organization’s EHR need to comport with those of EHRs in other organizations for clinical use cases dealing with transitions of care. If this can be achieved, then providers should meet the 10 percent electronic transition-of-care requirement for Stage 2. Regarding challenges because EHR vendors may require the use of a specific HISP, he responded that his company does not anticipate problems with EHR vendors using specific HISPs, provided those HISPs transact with EHNAC DTAAP (Electronic Healthcare Network Accreditation Commission’s Direct Trust Agent Accreditation Program) accredited HISPs. If that occurs, all provider endpoints on all accredited HISPs should be accessible to any provider on an accredited HISP. He recommended continuing to enhance the workflow functionality that leverages interoperability across different providers.

David Whitlinger, NY eHealth Collaborative, reported that New York has embarked upon a multi-year strategy to end the state’s Medicaid fee-for-service system and replace it with a comprehensive, high quality and integrated care management system that will lower costs and improve health outcomes. High quality and integrated care management requires integrated health care IT systems to facilitate coordination and workflow. In a highly fragmented health care system like New York, this requires both public and private health information exchanges that work together to share patient records and provide the tools necessary for coordinated care. He said that through an extensive workflow development and requirements gathering process with the New York Medicaid Health Homes, the following needs were identified:

Patient Record Look-up or Query Based Exchange: the ability for a provider or care manager to have access to all of a patients records through a simple query from either a connected EHR or a secure web portal.

Direct Exchange: the ability for a provider to securely send a patient’s records from their EHR to another provider’s EHR to facilitate a transition in care.

Notifications and Alerts: the ability to notify the care manager or other providers associated with a patient when that patient interacts with the healthcare system. Example: when a patient is admitted to the ER, notify the care manager and primary care provider.

Care Plan Management: the ability for providers to share a common care plan for a given patient across different provider organizations and care settings.

Patient Engagement: the ability for patients to have access to all of their clinical records in a single on-line location.

With ten community health information exchanges in operation since 2010, approximately 80 percent of the hospitals are connected to an HIE; 25 percent of the population has given consent; and a few of the communities will have over 50 percent of all health care providers in their community connected by the end of the year. More and more data are going online and more and more data are available to providers – at great expense. Rochester, one of the more mature health information exchanges with higher adoption rates, is already seeing significant savings across the community: 55 percent reduction in 30-day hospital readmissions when the HIE is accessed by health care providers after hospital discharge; 30 percent reduction in hospital admissions from emergency departments when the HIE is accessed; 35 percent reduction in duplicate radiology testing when providers use the HIE to look up patient information as part of the care. He explained that given the size and scale of the New York health care system, the costs of connecting all of the data sources are daunting without technical interoperability standards. The staff worked with 19 other states and dozens of EHR vendors to put together the EHR-HIE Interoperability Workgroup in order to develop “plug-n-play” standards for both Patient Record Lookup and Direct. ([www.interopwg.org](http://www.interopwg.org)). The objective was to enable the industry to create interoperable products whereby a provider can buy an EHR product that is fully interoperable with their local HIE (public or private) without requiring costly custom connectivity. He recommended moving towards nationally adopted full plug-n-play Query Based Exchange standards, Directed Exchange standards, and Care Plan standards. The standards need to be developed with “plug-n-play” (no engineering integration required for connectivity) as a requirement and require robust technical interoperability testing. Coupled with a certification and logo program, this work will greatly enable broad use of HIE in the delivery of care, regardless of how a community may be formed.

Tim Larson, Mayo Clinic, explained that Mayo has links to two peer-to-peer based networks, one regionally based (SE MN Beacon) and the other nationally based (Care Connectivity Consortium). Both are in operation and both are CONNECT (pull) based exchanges. He indicated that they will continue to be used. However, Mayo is also looking at establishing a DIRECT (push) based solution by the end of this year. As the new DIRECT solution is implemented, an initial decrease in efficiency is expected. The paper and faxed based processes currently in use are deeply embedded into staff workflows and over the years, these transitions of care processes have become very efficient. It will be a challenge to implement the new technology without it being a burden to clinicians’ workflow. Mayo is relying heavily on the EMR vendors to deliver DIRECT solutions in a timely manner. This is a challenge as EMR vendors faced with new MU mandates typically deliver solutions “just in time” to meet the minimal requirements. This creates a challenging situation for the EMR customer who must install a major software update before being able to pilot and refine the functionality. When vendors require the use of a specific or proprietary HISP, it reduces interoperability. When vendors create proprietary or closed networks, or use proprietary technology for exchange, it reduces interoperability and limits the expansion of HIE. Mayo officials look to organizations such as DirectTrust.org and HealtheWay to help set the direction for connectivity and to enable a nationally based, open-exchange model. Mayo Clinic endorses: national patient identifiers; a standardized patient authorization process rather than multiple state-based laws; more data-rich exchange payloads; and open source HIE solutions.

David Horrocks, CRISP, acknowledged the help of his colleague Scott Afzal in preparing the testimony. He said that CRISP’s Encounter Notification Service can enable a hospital to route structured clinical documents (CCDAs) to ambulatory providers that have subscribed to their patient panels. CRISP can help hospitals in meeting the 10 percent requirement for delivery of CCDAs by receiving the document via Direct, “un-packaging them,” then routing the document on to subscribed practices. He acknowledged that many organizations are planning to meet this measure independent of CRISP.

As the statewide HIE in Maryland, CRISP currently offers HISP services and issues Direct accounts to providers, which they access through a web-mail-like portal. Almost all of the current use of CRISP Direct services is in support of the Encounter Notification Services. Most providers are likely to use their EHR vendor’s native HISP service or that vendor’s exclusive HISP partner to meet their Direct-related MU objectives. CRISP’s current Direct service, accessed through a separate portal, will never be easy enough to use in routine clinical workflows. Building Direct capabilities into the products is a step in the right direction, but it must be paired with workflow usability that will foster a willingness (through ease of use) to share clinical documents outside of the practice. Horrocks expressed concern that EHR vendors that do not support other HISPs will complicate the rollout for larger organizations that are unlikely to be wed to a single EHR vendor, but will want a single Direct service for their employed or affiliated providers. HISP-to-HISP trust as existing service providers quickly on-board users is a broader challenge.

He said that the focus on CCDA documents and Direct represents a significant opportunity from an interoperability perspective. If ambulatory EHR vendors could send and receive CCDA documents in efficient workflows leveraging the Direct protocol, significant progress could be made in the ambulatory HIE efforts. Interoperability should be addressed where data originate and where data are consumed, rather than by a patch work of middleware that ultimately will be unsustainable over time. As an HIE, CRISP can facilitate the movement of information among disparate providers, but progress on producing and consuming CCDA (which include standard clinical terminologies) and being able to communicate that document over Direct is a critically important step towards true interoperability.

#### Q&A

Ross noted that the panelists were more optimistic than the earlier panels. He wondered about achieving the 10 percent summary of care and patient engagement objectives. One panelist said his level of confidence was between worried and can probably make it. EPs are in a difficult position because of the disconnect of EP and EH timing. He is advising providers to identify other providers in the community to whom they will be able to transmit. Another panelist indicated that he was optimistic because more that 80 percent of providers are connected. His organization is hanging a patient portal off the HIE to make patient engagement easier to achieve. Another panelist said the price for getting Stage 2 done will be high. The other panelist said that workflow will be a challenge.

Rishel asked Blair what constitutes a good HIE vendor and what is the back-up plan when some do better than others. Blair said that when systems are too difficult, problems will result. He is worried about on-boarding small practices. The many administrative requirements may pose barriers. Some functionality is more usable than others. There are many products out there.

Zimmerman asked about state requirements for quality assurance or a transition form. Do such requirements affect support of the MU transition of care document? Blair responded that it works because not many patients opt out. There is currently no state regulation for a document. But in Maryland that could become important as priorities and initiatives change. He is working with public health officials on their priorities. Larson replied that for a transplant center, different state requirements are a problem. Another panelist expressed hope that being an opt-in state will drive resolution of liquidity of data. Ross asked Whitlinger about the landscape in the other states collaborating with New York. He said that there is variation in infrastructure and resources. The state representatives unanimously decided that Query Exchange was important. All participated and voted on the final work product.

Castro said that she was confused regarding the cost for certified EPs and EHs to connect. Blair explained that when certified, they sign an agreement to be on the Direct accredited network. Most vendors incorporate the price into their product although there may be a charge for connectivity. Horrocks wondered about interoperability to achieve what. Data can be received. Ambulatory providers are not charged. He disclosed that MedAllies is the vendor. There are costs involved in the changes in workflow. Some vendors charge toll fees. Regarding Query Exchange, 80 percent of hospitals belong. It is difficult and very costly to build interfaces without standards.

Larry Wolf asked what brought Whitlinger’s coalition together. He responded by saying that the industry has not embraced interoperability. They brought together states that were interested in information exchange. Vendors saw plug and play as something to differentiate their products.

Ross asked about Direct and Query. Some workgroup members are interested in augmenting each with other standards. Should Direct be ubiquitous? Whitlinger referred to the reduction in repeat labs and images in Rochester which could only have been done with Query. Standards would help. Another panelist agreed with the benefits of Query.

Heyman reported that physicians want Query over Direct. They want clinical data from a central source. For small organizations, interfaces can be expensive. What about some MU or certification requirement that would make it cheaper to use Query? Someone said that exchanges cannot occur in that way. The CDA can be sent to the patient’s health vault. Heyman asked whether the information in the CDA in the health vault is importable. The current cost is about $25,000.

Things that would make interoperability faster are: strict plug and play interoperability standards to provide the plumbing; a product packaged with proper connectivity; and open source HIE solutions from vendors.

### Panel 4: Usability

Moderator: George Hripcsak

Expectation: The Usability Panel will help inform how to support EHs and EPs as well as vendors by identifying usability challenges and potential innovative solutions related to CEHRT products.

Art Swanson, Allscripts, reported that workflow and customization are the greatest challenges. Workflow data comes from customers, creating a self-reinforcing system. Workflow research outside the scope of any one vendor is an issue. Customers demand customization. Independent research from a third party would help. One of the core components of any thorough usability evaluation is the concept of measuring a representative sample that would produce generalizable results. Because EHRs are functioning as a form of enterprise productivity software, ensuring that customers can effectively modify and configure the software to meet their changing needs is important to stay competitive. However, this flexibility is often at odds with standard approaches to usability and usability evaluation. Additionally, to design and evaluate the usability of a product or service, one needs to understand the users, the workflow, and the context of use. Because these elements are so dynamic in the health care domain, it poses significant challenges to design for optimal usability. For example, to test the usability of a prescribing system as would actually be experienced by customers, it would be necessary to evaluate the usability of all the permutations of configuration that any client would use. Allscripts leverages UCD processes in its current releases that have been measured to prove usability improvements over previous releases. However, these processes are evolutionary and will not address all of the usability issues immediately. This is a process that will never be done. As indicated previously, the complexity of addressing usability issues in a highly customized environment with numerous user profiles, workflows and configuration options is significant.

Alicia Ray, CCHIT, described her organization’s usability testing experience. CCHIT adapted a description developed by NIST, defining usability as the effectiveness, efficiency, and satisfaction with which the intended users can achieve their tasks in the intended context of product use. This reflected the perceived usability of an ambulatory EHR as rated by its content experts (i.e., three testing jurors, at least one practicing physician) during an inspection process that follows a typical clinical workflow. CCHIT tested over 75 products based on CCHIT’s published criteria, test scripts, usability requirements, and other materials to guide vendors as they developed their products. Current ONC testing and evaluation of usability design methods is not constructed around a comprehensive clinical workflow since it is meant to be executed criterion by criterion to allow certification of EHR technology modules for which there is no expected integration testing. She described CCHIT’s earlier recommendations. There must be an objective assessment of an EHR that is subject to inter-rater reliability. Test design should not be developed by “software usability experts” alone; clinicians should be included. The science of usability should support, at a minimum, the floor of this design. More robust usability beyond that which tests for basic presentation and use is necessary and should address specific outcomes such as: improved patient safety, improved provider productivity through easier work experience, and quicker access to well-organized patient data from across the health care delivery community. EHR design and its accompanying usability testing should be unique to diverse care settings and for differing specialty practices. Usability testing should not be tied directly to criteria required to support meaningful use. To support voluntary adoption of usability testing and reliance on its results, successful proponents will need to demonstrate a link between usability and improved outcomes, and educate the provider community regarding these benefits. She also described safety enhanced design.

Colin Buckley, KLAS, described his organization’s recently published research findings on providers’ perceptions of vendors’ usability. Interviews were conducted with 250 CMIOs and CMOs. The Association of Medical Directors of Information Systems (AMDIS) partnered with KLAS in developing the questionnaire and engaging its members. There is often a wide variation in satisfaction from provider organizations using the exact same product. One of the most frequently mentioned reasons for success was the relationship between the provider and the vendor. Providers that were most satisfied said their vendors took an active role in guiding their efforts toward high levels of usability both during and after implementation. Not only did they provide hand-holding and sharing of best practices that they had gathered from experience with hundreds of customers over the years, but they often came to the table with a best-practice configuration to give providers a head start rather than leaving providers to configure their system from a blank slate. One of the most frequently mentioned reasons for failure was poor code quality. Several of the vendors have had difficulty delivering stable upgrades, while others have rushed clinical functionality to the market. Providers cannot see past these issues. Other than code quality, a pre-requisite to achieving high usability is that systems must be configurable. For the most part, providers said that their systems were highly configurable—even some of the lowest performers. What they lacked was the time and expertise to do it all by themselves. Self-help was more realistic in the past. In fact, one of the top performing hospital vendors was rated poorly for usability at go-live. The customers reported a 92 percent success rate today, but only 32 percent felt that way at go live. The difference was an average of 9 years to live, learn, and adjust. With meaningful use and payment reform, that is a luxury providers do not have today. Most vendors offer a mobile component, but even if they have good design elements, they lack functionality. It is frustrating for providers to be able to see patient data, but not be able to submit orders. Providers rated usability on a number of meaningful use areas and the three lowest rated areas were medication reconciliation, problem lists, and physician documentation. Regardless of vendor, however, providers laid part of the blame on themselves as they saw many challenges as the result of user actions (or inactions) and could not conceive of how vendors could solve all of those problems. The biggest issue with medication reconciliation is the difficulty of getting data from multiple sources, not the least of which is the patient. To some this is more of an HIE issue and until that is solved it is simply a manual process. None of the vendors are good at terminology in problem lists, but third party solutions have been successful at helping physicians look up the right terms and codes for documentation. The major plague of problem lists is that they gather so much data over time and across care settings that it is difficult to sort through the lists to find information that is most relevant to a physician at the point of care. Providers would like to see vendors add various types of filters, such as tagging problems as temporary and acute versus long term and chronic problems. But these sometimes prompt complaints about too many toggles and fields and options. When it comes to physician documentation, providers are torn between structured documentation and free text. Structured documentation misses nuance and text documentation takes too long. In many cases, however, they are not choosing between the two. Instead, they are offering multiple options to their physicians. The most common compromise is voice dictation software. He acknowledged that it seems as though the speed of meaningful use comes at a cost in terms of usability.

After describing the sources of information for her testimony, Nancy Staggers, HIMSS, said that data on implementation and usability are informal and uneven. The driving force today is to hit the target dates for attestation and assure funding. Vendors are focused on functionality for MU criteria, so usability is not fully on the radar. If summative testing is being done, the results may be discounted due to confusion about responsibilities. Vendors indicate that site customization precludes changes or that the issue is too vexing for one vendor to address (like alert fatigue). If clinicians take the time to report a system change request, any usability issues are merged with everything else. Change requests will receive a high priority if they include significant patient safety issues. Specific development priorities are not typically made public across vendor sites. Any usability testing results are stored informally within one vendor or site. She pointed out that although the ONC HIT strategic plan has a learning system as the pinnacle, what that actually entails is not described. She presented ideas for what that might include. Lack of interoperability is a key usability issue among clinicians, the strategic plan, and to achieving MU in the future. EHR starter kits could be provided. The HIMSS Usability Taskforce developed a Usability Maturity Model to help organizations incorporate usability into their operations. The model is comprised of five stages from unrecognized to strategic usability and five dimensions—education, management, infrastructure, resources, and a focus on users. Regarding patient safety, she spoke about an evolution from summative testing to identifying and fixing patient safety issues, reporting performance metrics, and benchmarking for critical tasks. Summative testing is too late in the process to impact the product before release. The Safety Enhanced Design process should place more emphasis on early testing, iterative design, and resources and efforts for formative, task-based activities. Usability testing results should be transparent to users.

Kevin Fickenscher, AMIA, said that he agreed with 90 percent of what other panelists had said. He referred to a written report. Interchange among people and technology is important for usability. In aviation, design inconsistency was solved by the major manufacturers, not by government. Standards are needed. Differences across specialties must be recognized. For instance, dermatologists depend on pictures rather than lab tests. Consistent standards are required for system integration. Customization gets in the way of integration. Adverse event reports should be standardized. He recommended establishment of a central place for the collection and dissemination of best practices. A public–private partnership is needed.

Steven Stack, AMA, asserted that many of the current certified products degrade physician efficiency and interfere with the doctor-patient relationship, and this has effects on the quality of health care and can also impact patient safety. Not all clinical data lend themselves to structured documentation. For instance, the history of present illness and medical decision-making portions of the clinical record impart clarity and nuance to the patient’s narrative that is lost when physicians are compelled to force complex and subtle stories, analysis, and synthetic thinking into inflexible structured data templates. Systems that force the documentation of these types of clinical information via drop-down lists and check boxes can be distracting to the physician and disruptive to clinical thinking. He recommended a stage 3 certification requirement that structured and non-structured data can be executed in the same patient record, allowing physicians to choose the method that better suits their clinical workflow. Physicians should have the ability to use their discretion on what clinical data are best for structured documentation while also taking into consideration the needs for secondary uses of data. He asked that ONC recommend to vendors that they not include gag clauses in their contracts and that ONC post online which vendors require these terms. Vendors should also provide contractual, pre-defined specifications on data migration fees and good faith plans on maintaining certification requirements. ONC should require vendors to report to ONC when a product has failed certification with one ONC ATCB and make this information publicly available online. ONC should urge vendors to include independent (vs. vendor employed) physicians and other end users during the development and testing process, take into account different training levels and appropriate specialist designation, and to disclose their process for incorporating end users in design and acceptance testing. All vendor test reports should be posted online. ONC should work with CMS to obtain data on physician satisfaction with their EHRs and publish findings by practice size, specialty type, and geographic location and incorporate this feedback into future certification processes.

#### Q & A

Regarding a suggestion for standardization of displays and a national EHR that everyone can use, one panelist talked about a public-private partnership to discuss and agree on solutions and areas to work on. Ray agreed. Another panelist said that the NHS in UK did it. It was a huge effort to agree on standards. Now NHS is rolling back those standards.

A member talked about his concern with the replacement of summative by formative testing. He talked about the importance of consistency and workflow. NIST is working on standards for workflow. They will soon be published. There is a need to increase efficiency of workflow on the screen to support the workflow of the doctor. A panelist explained the need for both summative and formative testing. Another panelist talked about the importance of functional consistency regarding workflow in the clinical setting being built around paper. New work should not be created on top of old work. A common workflow should be agreed on. Another panelist suggested that someone identify a test for each function and then provide a library of these tests.

Zimmerman asked whether structured or unstructured data were best for usability given the variation in how and where information is reported. Stack responded that he wants to see the conclusions of other clinicians, not their test results and evidence: just display what is to be used. Another panelist indicated the need for more research on clinical documentation. Some data are best structured. But narratives are also needed. Another panelist said that one should not be forced over the other. Structured data should be personalized to the system. Someone said that context and task must be taken into account. Swanson noted that flexible clinical documentation structures make reporting more difficult.

Wolf briefly described the track changes approach that is under consideration as a recommendation and asked for the panelists’ opinions. Stack replied that although it could be done, it is most likely of greater interest to auditors than to clinicians. Another panelist agreed that a contextual approach is important. Part of the problem is a lack of interdisciplinary debate on context. Swanson said that in integrating data from different sources, trust and province become more important.

Rishel asked which is most important to address with blunt instruments: improved transparencies on usability; process level certification; a plug in standard library or repository of workflows; or a public- private consortium. Stack talked about recognition for and crediting the less than perfect, and said to leave the decision to the individual setting. Fickenscher selected a public-private consortium and, in response to Rishel’s probing, said that his organization would be willingly to send its best people. Staggers said that a vision was first needed. Buckley and Ray selected transparency. Swanson favored sustainability in consideration of human factors in certification.

### Committee Discussion and Next Steps

An in-person, combined workgroup meeting is scheduled for July 24, 2013.

### Public Comment

None

## SUMMARY OF ACTION ITEMS

None

## Meeting Materials

* Agenda
* Submitted written testimonies
* Questions
* Presentation slides
* Bios