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Keynote Presentation**

Presenter:

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MS. CRONIN: Thanks for such a nice introduction. I was really happy that I could get a chance to come up and talk to folks who are working in clinical research, since that's really how I spent almost the first seven years of my career while I was in the private industry.

And it's sort of nice to now be working in an area where everything I've done over the last 20 years is sort of all coming together, and clinical research, obviously, is one area that really stands to benefit from widespread adoption of interoperable electronic health records and personal health records and, also, the deployment of a nationwide health information network.

It's not only going to dramatically, potentially, improve the delivery of healthcare, but it also creates an amazing opportunity for not only clinical research, but health services research, because we'll have access to much more granular clinical data that can be captured electronically in a much more efficient way than a lot of the current systems.

So I thought it would be helpful, as Barbara already indicated, to go over a little bit about the Office of the National Coordinator, sort of how we got to where we are in the last couple of years, and really focus on what are we doing, what are our major initiatives to try to reach the President's goal of having most Americans by 2014 have their own electronic health records.

And then I wanted to, also, obviously, touch on some of the real short-term and long-term opportunities for clinical research, so that all of your activities can be sort of put in the context of what's happening in the overall national agenda.

So many of you may know that the office was established through an executive order a little over two years ago. This created the new position of a national coordinator for HIT, similar to some of the other what's commonly referred to as czars, the drug czar or the AIDS czar, where they have broad responsibility across the executive branch, yet they are typically housed within one particular department or agency.

In this case, it's within HHS. But David Brailer has served over the last two years. He recently stepped down. As many of you may know, he was sort of born and raised in the private sector, also, was an academic for quite some time, but he has now gone back to the private sector.

So while he has no immediate post right now, I think he is taking some well deserved rest, after having two crazy years of a lot going on.

But nonetheless, his position was created. He filled it in May of 2004. And the broad vision that was put forth by the administration was to try to have a fully electronic healthcare system, where you have widespread adoption of electronic health records and personal health records, and a way to connect clinicians and patients across settings of care, so that the medical information can follow the consumer and not necessarily be just stuck within a skilled nursing facility or just within a hospital or in an outpatient clinic.

So we really wanted clinicians to not only have the complete and relevant history on a patient, but also have the evidence on a given treatment or on a given diagnostic option available readily at the point of care that is relevant to the patient at hand; not just based on population and statistics, but something that could be actually computable and be relevant to the given patient characteristics.

We also thought that this is a great opportunity to try to start transitioning from a payment system, at least in the federal government, with Medicare and much of Medicaid, that is based on fee for service. So it's volume-based. And if we

want to truly transform over time to a quality-based or performance-based system, we need a way to measure that and, as many of you know, claims data is not going to get us there.

So we need to automate the whole quality measurement and reporting system where we can have readily available access and be able to aggregate this data and publicly report it, as necessary, and then that can inform payment.

This could dramatically improve the Medicare and Medicaid program and a lot of private payers are moving in this direction, too.

So this infrastructure really serves a variety of purposes, not only in delivering evidence to the point of care, but also being able to get the right data out of clinical care, not only for better performance measurement or quality measurement, but also for public health.

There is a huge opportunity to streamline the public health surveillance system now if we design the nationwide health information network in a way that is sensitive and meets the requirements for public health surveillance, and I'll talk a little bit more about that in the near term.

So not only could we be much more aware of an emerging pandemic, but we could also be much more aware of emerging risks in medical products. So for drugs and devices, this creates a

huge opportunity for us to improve what many have said is an inadequate system.

So in the first 60 or so days of our office, when we were first getting this together, we had, through the executive order, the ask of trying to create a strategic plan.

Well, it was sort of impossible to create a really comprehensive, perfect strategic plan within that amount of time, but we did get a framework out there that set all the major goals, objectives and strategies to really try to move this agenda forward.

Electronic health records have actually been out there for quite some time, as many of you may know, just like remote data entry has been out there for quite some time, but we really weren't seeing the market pick it up.

The healthcare system is way too fragmented. It's very challenging to get payers and purchasers to work together to make changes on a system wide basis.

So we really had to look at the underlying causes of the market failure and figure out what is wrong and what can we fix.

So we came up with four major goals. One, to inform clinical care, essentially trying to get the right kind of electronic health records fully integrated into the system, not

just have physicians buy into them and put them in their own practice, but get them integrated into hospitals and into skilled nursing facilities and throughout the system in a way that it really improves the delivery of care.

It's not just technology, but it's a tool to really help you deliver the best care possible.

The next was to interconnect clinicians and, really, we needed to do this not only through having the right of point of care applications, but also in establishing what a lot of people have referred to as the medical Internet or what we call the nationwide health information network.

So it really would let the data flow from one setting or one clinician to another in a seamless way. Also, safe and secure and only appropriate sharing of data, but, nonetheless, that technology or that infrastructure does not exist now, although we are starting to build it.

Then the third major goal was to personalize healthcare, which really was getting at not only the adoption and the diffusion of personal health records that would be interoperable and longitudinal, so it could, ideally, follow a newborn until death. So it would be an incredible tool not only for their own self-management, but to also share with clinicians over their lifetime and, also, to use potentially for research

or other purposes, with the necessary consent.

Then the last objective or major goal was to improve population health and this is sort of where we put everything in the kitchen sink that didn't fit in the other categories, but essentially it was improving quality of care, improving the surveillance system for public health.

But the other major thing that fell into this was also streamlining the infrastructure for clinical research and we recognized that that was an enormous opportunity, given that, at least a couple years ago, the anecdotal data was saying that roughly 70 to 80 percent of the system that existed, both public and private sector, was really paper-based.

So it's highly inefficient. We aren't very good at data management. Even though there's been a lot of improvements over the last decade, it could be a lot better, and we could really could be doing a much better job in doing electronic data capture from electronic health records that are all interoperable, that have the same standards, automatically into an electronic CRF.

So we recognized this was a huge opportunity we didn't want to squander. And NIH was very involved in the development of this and contributed quite a bit to this section.

So the first phase, really, the last two years, have

been very focused on trying to get the market to appoint where we're more interoperable, meaning that all of the software vendors are agreeing on the right standards or at least one set of standards that they can all adopt and that they actually use them, they actually incorporate them into their product, so we can, over time, be able to seamlessly share data.

Two years ago, even now, really, there's no standardization whatsoever in the market. There has really been no incentive for electronic health record vendors and other types of software vendors in this space to adopt the same standards. They're competitors.

So we have really done a lot to try to look at that and figure out, well, how can we change this, how can we get this to the market that we need it to be to reach the President's goal.

So over the last year or so, after sort of a fast and furious startup year, with just a small core team, we have become more institutionalized. We're a real office now. We're hiring full-time equivalents instead of just having contract staff.

But we have really worked a lot with our federal partners not only within HHS, so NIH, FDA, CMS, the Agency for Healthcare Research and Quality, CDC, HRSA. We've also reached

out to the VA, the Department of Defense, the Department of Commerce is actually quite interested in this whole agenda, Treasury, Office of Personnel Management, who funds all of the health benefits for federal employees.

They all have a stake at this. They all have a role to try to reach the President's goal. So we've had a fair amount of interaction with them and have a federal policy council that sort of formalizes a lot of our work.

We've also done a lot of outreach with vendors to try to keep current with what is really happening in the marketplace, so we don't feel like we're in an ivory tower.

We have done a lot of outreach to states, as well. A lot of the activity that's going on across the country, as many of you may know, is at the state level of the regional level. There are now hundreds of organizations that have started up to try to organize efforts around health information exchange on a community, regional or state-based way and they have really made amazing progress.

There's a lot of variation and a lot of lessons to be learned, but enormous enthusiasm, starting with the governors all the way down to sort of champion clinicians within their own communities.

We have also learned a lot from our international

partners. We have been constantly talking to folks from the U.K. and Canada, Australia, many European countries. Many of those are really far ahead of us. They have significant federal investments in their agenda.

They have already done a lot to establish some baseline infrastructure. So we can share a lot of stories and problems and even though we have very different healthcare systems, a lot of the problems we have in common. So that has really been helpful for us in the recent year, in particular.

We have just now restructured our office, which I will touch on in a bit, and, probably most importantly, we've awarded some important contracts to really try to establish a more interoperable marketplace.

So this is just a brief snapshot of our office. David Brailer, as I mentioned, recently stepped down, just two weeks ago. But we do have four permanent directors in place now. One of them is an acting deputy right now, Dr. Karen Bell, who leads the office of health IT adoption, who also came from CMS.

We have an office of interoperability and standards, where a lot of our contracts are managed out of right now. I lead the office of programs and coordination, which has more of an external focus to try to coordinate a lot of the activities that are going on outside of government.

And then office of policy and research, which has more of an internal focus. So we're focusing on what regulatory changes we might need under CLEA or potentially HIPAA or other statutes.

So as I mentioned, we do have this ten-year goal. So by 2014, we have to get to perhaps 50.5 percent of Americans having electronic health records, which we think is absolutely doable.

We have a variety of major initiatives underway, one of which is the American Health Information Community, which Secretary Mike Leavitt chairs. It's an advisory committee that is made up of leadership across the public and private sector, all the major stakeholders of healthcare, to really take on the major issues that we are struggling with and advise the secretary on how to move forward.

And they have also prioritized some of our efforts on a short-term basis, which I will talk about in a bit.

We've also tried to support a standards harmonization process, recognizing that there is a lot of activity going on across standards development organizations that is not coordinated.

The Health Level 7 board often does not communicate very much with, for example, NCPDP or other SDOs that are really

active in some very critical areas and they don't necessarily think about strategic planning together or how they're going to really make sure that all the gaps that are out there in standards or the duplication that exists with standards is going to be resolved.

So that is largely what that process and that contract is going to do.

We also recognize there is a need to certify products in the marketplace. A lot of the problems with our market failure is due to the risk of implementing these tools. A lot of physicians have been burned over the years because they have spent a lot of money and a lot of time seeing reduced revenues, reduced productivity in the process of getting these EHRs into their practice, and then they don't work very well. They just can't get the workflow to work right.

So we really needed to improve the overall quality of the products, make sure that there is a minimum floor for the features of these products, and that they also become interoperable over time and make sure that privacy and security features are incorporated.

So we also have a lot of work that has been funded recently on privacy and security, given that HIPAA has established a good baseline at the federal level, but there is a

lot of variation at the state level. States have their own privacy and security laws, which presents a lot of problems for health information exchange, potentially.

And I will talk, also, a bit about the nationwide health information network prototypes. We have four of them that we are funding. We also have some projects to look at the impact of health IT on fraud and abuse in healthcare.

We have a research initiative to standardize methodology on how to measure adoption of health IT. So over time, we know if we're reaching the President's goal or not.

We also are proposing regulatory changes to the Stark and anti-kickback statutes, which are barriers to adoption right now.

So as I mentioned, we have been supporting a standards harmonization process. This is actually through a contract to ANSI, which has created and convened the health information technology standards panel.

So this panel really is made up from leadership across the SDO community and their job really is to figure out a harmonization process, but, also, in the short term, name some standards and develop implementation guides for those standards for some of our top priorities that were identified by the American Health Information Community.

So we expect by the fall that those will be available and they will also be a big push for the federal government to adopt those formally through all their procurement and all the funding mechanisms.

So you will probably be hearing a lot more about that in the future.

The NHIN is something that -- obviously, the concept of this has existed for quite some time, but we really wanted to make sure that if we were going to fund anything in this area, that we really knew what the experts across the country thought we should do.

What does this look like? What should it do? How should it be operated? How do you develop the policies for it?

So we did a request for information about a year and a half ago and got 500 responses from various experts across the country and really had an enormous effort across the federal government. Many people from NIH, across the institutes, were involved in reviewing all the input we received and some of the concepts that emerged were that it should be a nationwide utility that allows for secure and seamless health information exchange.

It should be a decentralized architecture that is built using the Internet, but linked by uniform communications

and a software'd framework of open standards and policies.

It should be governed by both public and private stakeholders. So it really has to serve in the public's interest, but this is really both a public and private effort and, obviously, needs to reflect the interests of all the stakeholders that are involved in that governance.

We need to make sure that there are sufficient safeguards so that people don't tamper with the data, that they can't -- we have to actually do a very good job not only on the security of the data, but to make sure that privacy or confidentiality is protected, as well.

This is particularly sensitive given, I think, many of you are probably aware of all the discussions and negotiations that went on during HIPAA. There are certain constituents in this country that feel very strongly about this and we really need to engage them in an open discussion over the next year to make sure we get this right.

We also need to be using existing technologies. There is a lot already out there in the market. The four consortia that are working on the prototypes now are using these existing technologies, but a lot of the public input also called for federal leadership to really start to define what does this common infrastructure look like.

We also know that there are a lot of regional efforts going on across the country, I mentioned before, some of which are operational; not many, but some.

There's a lot to be learned from them, what works, what doesn't work, and we also recognize the importance of certifying the software. So not just electronic health records, but also other point of care applications and then the NHIN over time.

So the prototypes that are now under development are in a phase where we have already completed the use cases. There are three of them that, again, were sort of in line with the recommendations from the American Health Information Community.

We have an operational plan that will be due over the summer from each of the four consortia of technology vendors that are involved in developing four different approaches.

They will have revenue and cost models. A lot of the people yet don't fully understand how we are going to create a business model around this. Who is ultimately going to pay for health information exchange? Is it the payers? Is it the purchasers? Is it the provider? Is it a combination? Should it be transaction-based? Should it be tied in to the payment of healthcare delivery?

There's a lot of different approaches that people are

thinking about and there's no answer that is definitive right now. It may end up being sort of a market-based determination, but part of their contract is to figure that out.

They will be completing their architecture in the fall and then will actually be demonstrating some type of health information exchange across 12 different markets.

So each of the four consortiums are working in three different markets and they have an obligation not only to do health information exchange in one market, but also be able to share across the markets.

So in the next year, we expect to expand this effort and hopefully do statewide demonstrations to show that this can be scalable across the country and that we could have something that would really work across the nation.

We also think it is important to have some type of mechanism to make sure that this architecture and the standards are uniform as this gets deployed.

So our mechanism to do that will be certification, similar to what we're doing with electronic health records.

I mentioned before we've already proposed some regulatory changes and we're in the process of finalizing two regulations right now to allow for hospitals and other designated entities, through Medicare, to donate electronic

health records to physicians.

There's a lot of large hospital systems that would like to do this now, but they are prohibited under current law.

So these regulatory changes will allow for the dissemination of these tools more readily, along with the training and the support that is necessary to implement them.

The certification effort is being led by a certification commission for health IT. This has been up and going for over a year and a half now. We have more recently supported it through a federal contract, but stakeholders really came together nearly close to two years ago to get this effort started, because they recognize how important it was and how much we needed it to really move things forward.

So the first set of electronic health records that are certified will be on the market in July. We expect there will be about two dozen and there's a lot of other vendors that will likely be right behind.

So we're off to a very good start. This is not the perfect set of criteria to reach a fully interoperable electronic health record that will not only have the robust clinical decision support we need to deliver all the evidence, support and care. It also won't export the perfect data set for clinical research.

But it is a very good first step that everyone could come to agreement on and we expect each year to be able to introduce more rigorous criteria for interoperability, for functionality, and for privacy and security.

So after they finish their work on ambulatory electronic health records, they're going to move to inpatient. In fact, they already have started to. So the next certification process will be for inpatient EHRs.

Then we expect, at least it is in their business plan right now, not under the contract, to have certification for personal health records. And then in 2008, they will be taking on the certification of the NHIN to make sure that everything connects together, so that the interoperable or certified EHRs can share information with the NHIN.

So as I mentioned before, there is an awful lot of state level variation with privacy and security laws and there is also a lot of variation with the way businesses or enterprises interpret these laws and implement privacy and security solutions, which are all collectively barriers to health information exchange or potential barriers.

So we just awarded 34 contracts to 34 different states to do a real careful legal analysis, but also sort of a practical market analysis of what is really happening out there

and what exactly are the barriers and how might we be able to find technical solutions to overcome these or could we potentially or would we need to do some type of statutory change.

So we hope that over the next six to eight months, there will be a lot of good lessons learned from this effort and then they're going to develop some consensus solutions and finalize those in February of next year.

I mentioned that Secretary Leavitt is chairing an advisory committee that is, in many ways, sort of governing this whole activity. We have some high level leadership across HHS, as well as hospitals, physicians, nursing groups, really, across the board, all the major stakeholders.

We, unfortunately, don't have all the federal agencies represented. Dr. Zerhouni, ideally, would be on this, but we had a cap of the number of members that we could appoint, but we certainly want to represent research interests as we meet in our public meetings.

But they have been convening for the last eight months now and their initial recommendations were to come up with some short-term priorities. So what should the office be doing and funding and supporting in addition to these longer term contracts that really deal more with infrastructure and

interoperability?

They thought that it was important to show some kind of demonstrable value to consumers, because ultimately we really need consumer buy-in to have them fully engaged in using a personal health record or going to a doctor and expecting them to have an electronic health record that actively maintains all the health information they need.

They guided us to focus on four different areas, one of which is bio surveillance. This is very much in line with Secretary Leavitt's priorities around pandemic flu preparedness; and, consumer empowerment, meaning how do we get information out to consumers in personal health records and initially focusing on what kind of medication history or other types of information would be most valuable to them that they could use.

Electronic health record option was, obviously, a priority and the short-term focus there was trying to get lab data exchange in a patient-centric manner, because right now a lot of the information is exchanged based upon proprietary interfaces.

So if you have a portal or an interface through LabCorp or Quest, then you might get the labs that are coming from that one lab, but any given patient who may see various different providers, you're not getting the complete picture on

all the clinically relevant labs that could have been done in various different labs.

So we wanted to be able to create the infrastructure and the incentives needed to have patient-centric lab data flow.

And then chronic care monitoring and the short-term focus there was on trying to connect both patients with their physicians through e-mail, through structured e-mail or secure messaging.

So we have four work groups that really focused on these four areas over the last five months and we had about 70 to 80 experts across various disciplines that really tried to, with a laser focus, really get down to the real issues and try to figure out what are the barriers, what does the federal government need to do to enable all these, but, also, what does the private sector need to do.

So they did present recommendations about two weeks ago and we're actively trying to implement those now.

Many of the recommendations for bio surveillance were focused on how to resolve the variation or the different approaches at the local, state and federal jurisdictions.

There is a tradition in public health, which many of you may be aware of, that much of the work that is done, particularly in leading outbreak investigations, really is at

the local level, but there's variability across the country in how that is done and the CDC certainly has a role in situational awareness and trying to understand, across the country, what is happening and also support outbreak management and response management, when it is necessary.

So we agreed to set up a data steering committee that would identify a definitive data set that would be captured across clinical care providers involved, initially, starting off with lab companies, clinical labs and also public health labs, but then, also, try to get as much data as feasible from emergency departments and hospitals and, also, to the extent feasible, ambulatory care.

But we believe that this data steering committee will be able to get the right experts from public health together, along with clinical care, to identify what's a responsible data set, what's going to provide the most value to public health over time, and then evaluate that, have a rigorous evaluation plan where we would be able to ascertain what is truly valuable and what is not for certain types of public health functions.

Then as we learn from that, we will be able to figure out how we might be able to do a nationwide system that would actually be bidirectional. So not just getting information from clinical care, but being able to communicate safety alerts and

other important messages to clinicians, as necessary.

I think probably most of you are familiar with the fact that a lot of our public health surveillance right now is either disease-based or silo'd and it's that way for many reasons, but we really have an opportunity to create a real time surveillance system and I think the work group and the community is really excited to do their part in trying to realize that.

So for consumer empowerment, I mentioned the short-term focus was on medication history and, also, on a registration summary. How can you get some core demographics, eligibility benefits, and other important information that would typically be captured when you encounter the health care system?

So we thought through a lot of issues around how do we standardize that, how do we identify the right data elements and make sure that all payers and all systems across the country are capturing this information and have recently deferred a lot of the work to the health IT standards panel.

Through electronic health records work group, they did come up with some recommendations on how to look at both CLEA and HIPAA and try to figure out how to remove the regulatory barriers that are now prohibitive to having more patient-centric lab data flow.

And then in chronic care, a lot of the recommendations

were focused on how can we develop the evidence base and create the incentives for physicians to start e-mailing more routinely their patients.

There is a workflow issue here. There are some progressive payers across the country that are starting to reimburse for e-mail and they are showing very good success in certain markets where they have a large market share.

But if you are only reaching, say, 20 percent or even 10 percent of your patient profile or panel, you are not going to really be able to convince a physician that he needs to change or she needs to change the way that she practices.

So there is an issue of trying to make sure that there is sort of a uniform reimbursement policy across payers to really move this forward.

I think they are now starting to transition to the broader charge to figure out how can we enable remote monitoring across the board. So that might involve certain types of health IT that would allow patients to receive care in their home or in the community as opposed to being in a skilled nursing facility and would also involve the interoperability of the products to enable them to do that.

So there's a lot going on in terms of what are we doing to support the long-term transformation of the industry

through standards harmonization, certification, and the development and deployment of the NHIN, but we also need to be mindful of showing the sort of shorter term success, so that healthcare participants and, importantly, consumers and patients really understand that this is meaningful to them, that this is really going to make a difference in their care and their health.

So we have a variety of mechanisms in place to try to coordinate these activities and we are doing that right now through the federal policy council that I mentioned before.

So we're meeting every two weeks to try to figure out how we're going to work on the regulatory changes that have been identified by the community to enable the type of health information exchange that the NHIN will allow for.

We're also trying to identify the types of standards that the health IT standards panel needs to focus on. So starting off, it's bio surveillance, it's the areas around the personal health record that I mentioned earlier, and it's lab data flow that's in a patient-centric manner.

So a lot of our efforts internally to coordinate all these activities are helping piece together what's going to be happening on the outside, as well.

So one of the things that became obvious in the last

couple years is that this is not going to be sort of a big bang project. We're not going to all of a sudden change the whole country. It is going to have to be done incrementally and there's a lot of experience being gained on a regional level.

Right now, there are, as I mentioned, a couple hundred of what at least people are claiming to be regional health information organizations. There's a handful that have really gained some traction and have governance in place, but, essentially, a lot of people are looking at this as a good first step to move forward, to get something accomplished on a local level that will make it meaningful to the local healthcare market.

So these organizations are meant to be non-governmental, multi-stakeholder, and they really provide the policy and technical framework that is needed for health information exchange.

They are intended to cover large geographic areas. In some states, like Rhode Island and Delaware, they cover the whole state, which is relatively easy in those states. There are other states, like California and Florida, where there's multiple RIOs starting up across a state and then it will be up to the state to figure out how they want to coordinate those efforts to make sure that there's an ability to share

information across the regional efforts.

But they do really bring to the forefront this issue of a sustainable business model for health information exchange. They need to figure it out, because they need to make it work. If it's the CEO of the major hospitals and the large physician groups on the boards or the governance bodies of these organizations, it is their bottom line that is going to be impacted.

So they need to be really accountable for that business model.

So there's also a lot of activity through the state legislative process. Over 30 states have introduced or passed legislation that has created either a statewide organizing body or just an overall initiative to really advance this agenda.

There's a lot of states, probably over 40 at this point, that have funding through HRSA and AHRQ. There are over 60 RIOs that are somewhat operational, meaning they have some degree of real health information exchange through deployed technology or they have some type of relatively mature governance structure.

They also have many formal efforts underway to develop -- well, many states have developed more than one RIO, as I mentioned before. So California, Texas, Florida Tennessee,

Washington. There's really a lot of states that have seen sort of an embarrassment of riches. Massachusetts is another one.

So, now, really, they're struggling with how do we try to coordinate across very disparate activities. In Tennessee, for example, there's very different activities going on in four different areas of the state and now the governor and the governor's office is trying to figure out, okay, now, how are we going to blend all these together so that we can have some kind of cohesive infrastructure.

So we have learned a lot in the last two years. There are some real leaders in the country, Boston and Indianapolis have been working on this for quite some time. Indianapolis, in particular, has a lot of lessons learned, because they've spent a fair amount of time over the last 15 years trying to develop some information and now deploying it across the state.

But we really don't know yet how to replicate these organizations or the infrastructure in a cost-effective way. How do you make it a viable organization in a variety of different markets and how should these organizations best relate to what is happening both at a state and federal government level?

How can the states and federal government support them and how should our priorities fit into their priorities?

So we think that states really are a very important sort of unit of organization, if you will, because of so much activity going on across the country. It is virtually impossible for anyone to really coordinate it actively on a day-to-day basis.

But the state governments right now are very interested not only in improving their Medicaid programs and their public health programs, but also trying to take advantage of just making the healthcare system a better place, make it more efficient, improve the quality, improve the safety.

They also have the ability to change state laws. There are a lot of policies and laws right now that could potentially be barriers and they have the ability to resolve those barriers.

There are also a lot of organizations, like the National Governors Association, the National Council for State Legislators, and other like entities that have the ability to lead a lot of change in policy and practices from their organizations. So they are interested and engaged and really moving forward on this.

So with all this activity, we thought it would be helpful to come up with some principals for what regional health information should be or could be, and we feel there really should be at least one of these entities in each state.

For the states that do have more than one, like many of the states I mentioned, there should be some type of overarching health information organization that has statewide responsibility for coordinating a lot of those activities to try to resolve the differences in the approaches to technology and the policies that govern the health information exchange on a local level.

So there really should be a state level framework, both a technology and policy framework that others should try to work from within. It should be a collaborative effort, but nonetheless, it is necessary to do that to improve the flow of information across the state.

We also think that there should be a minimum set of best practices that these organizations should follow. We actually are funding some work now to get at this, but there are issues around governance, around financing, the technology, how do these entities or how does the network that they oversee function, what are the appropriate operational policies, and then how do they ensure their transparency over time.

If they are ultimately accountable to the public, how can they make sure that their activities are transparent?

We also think that they should be following, to the extent practicable, the recommendations that are coming from the

American Health Information Community, since leadership from all stakeholders is really represented on that and we are working collaboratively to try to resolve a lot of the problems.

So we are currently funding and supporting research to find out what is really happening for these state-based organizations, what are the roles they are playing, how are they actually handling the issues around financing, operations, policy.

Right now, we are in the process of developing some early or draft best practices. Many of them are emerging. They are not really quite at a best practice stage, but we will be having a consensus conference in July to talk about these. So we can have sort of our first round of best practices or principles and emerging best practices so that other states who are less far along in this whole effort can follow those and learn from them.

But we also think it is important to really be monitoring progress and encouraging collaborations to develop the right business models.

As I mentioned, there is not going to be any one given type of business model that is going to work across a variety of markets right now. So we really need to be mindful of how that is going to mature and what the federal government needs to do

to support it over time.

An issue that is much more relevant to clinical research is how these regional health information organizations or the states that coordinate a lot of the activities are going to look at secondary uses of data that's going to be coming out of the new infrastructure that we are building.

As many of you know, HIPAA, I think some would say HIPAA caused some confusion when it comes to research and I think everyone is mindful of that and wants to provide all the clarity that might be necessary to resolve this.

But we're really getting into a whole new world now, at least we will be over the next five years, and we really need to think, well, what is the right set of policies that will oversee the access and aggregation of this data for a variety of purposes, and clinical research being an important one, health services research, population health monitoring, vital statistics.

There's a lot of very important secondary uses of this data that need to be considered and the risks and benefits of accessing and aggregating that data need to be fully accounted for as we take on more careful consideration of what policies might be needed to further define this area.

The American Medical Informatics Association is sort

of acutely aware of this issue and has recently convened a blue ribbon panel. Many of the folks in the research community are represented on the panel and they're writing a white paper now to try to inform what the next steps should be.

We also have a privacy and security group under the American Health Information Community that will be looking at these issues, along with authentication and authorization and a lot of very sensitive issues around confidentiality and security over the next six months.

So I think you'll probably be hearing more about this soon.

There are some obvious opportunities for clinical research. I'm sure many of you are involved with a lot of exciting activities to try to use informatics to improve the quality and ability to do robust clinical research.

But I think some of the efforts that are already underway through CDISC, through NCI, and the FDA, in particular, have really gone a long way to try to bridge what is happening in industry, academia and government and I think that the more that can be coordinated across those sectors in terms of standards for clinical research will really help advance the agenda in terms of when it goes to the health IT standards panel to name standards for clinical research and to identify the

right implementation guides.

But work and coordination that's already been done through CDISC and other like organizations will really facilitate that whole process.

So if, down the road, there is a use case specific to clinical research that is going to perhaps guide some of the work not only for the health IT standards panel, but for the certification commission and through the NHIN deployment, I think it's really important early on to have a coordinated effort on what are the standards that are needed in the clinical research community.

We also have a public meeting coming up the end of June. So for those of you who are interested in knowing more about the functional requirements for the NHIN, there will be a two-day meeting on the 28th and 29th to focus on what are they. I mean, there's over a 1,000 at this point and they need to be vetted. We need input on what is important, what needs to be refined, what should be further defined.

Then there will be an additional vetting process through another advisory committee over the summer.

But if you feel that the clinical research needs are important to be represented at this point, I would encourage you to attend that meeting and to learn more about what's happening and express your opinion.

And there's also, as I mentioned, going to be demonstrations in 2007 and, likely, 2008, with the further deployment of the NIHN, as we have a common architecture. So,

again, that presents another opportunity to see how the data that's necessary for clinical research could be exchanged through the NIHN.

And if this is going to be the infrastructure of the future, it probably makes sense to think about how the clinical research infrastructure is going to be either merging or migrating to this over time.

So those are just some closing thoughts and I'd be happy to answer any questions.

DR. MOLD: If you're going to use this kind of data for clinical research, actually, for clinical care, I would think that one of the most important issues is capturing outcomes.

I haven't really heard much talk about capturing important outcomes; for example, mortality. I mean, it's traditionally very difficult for us to find who is dead. You would think you would care about that, but that's a whole different data set.

Cost is another issue and while we can capture costs and, I suppose, through the national health information infrastructure, we should be able to capture all the costs, it would be nice to be able to do that.

Right now we can capture our own charges from our own

office, but to capture overall costs is difficult.

DR. SACHS: This is being taped. Would you identify your name, please?

DR. MOLD: I'm sorry. I'm Jim Mold, from the University of Oklahoma.

So outcomes like mortality and cost would be nice to incorporate in this for clinical researchers. I would think it would also be helpful for clinicians.

MS. CRONIN: Those are great points. I think that there is a keen interest in trying to determine how electronic health records and the various data sources that will be sort of the backbone of the NHIN, so to speak, how can they be collected, aggregated and analyzed in such a way so that we can understand the health outcomes of given patients.

And as I mentioned before, the performance-based or quality-based payment system that we want to move to is going to be dependent on that.

So there are actually a lot of efforts underway now through the Ambulatory Care Quality Alliance and other organizations, AHRQ and CMOS are sponsoring some projects to determine how we can use these electronic data sources in such a way that we will be able to accurately measure health outcomes.

So that's being carefully considered. I don't know

that the mortality issue is going to be resolved anytime soon, because I think that there's obvious problems around death certificates and registries and I think that there is a state-based solution that is being initiated and I don't exactly know what the status is.

But more and more folks are talking about the need to integrate vital statistics into this agenda and I think we'll be looking at that moving forward, too.

Part of our challenge is that there are so many needs in so many areas. We're a relatively small office and HHS is large and rich with resources and experts, but it's going to take us a little bit of time to really prioritize all of the needs and make sure they are all addressed.

But I think, clearly, the measuring of health outcomes is critical, from a variety of perspectives, and we're on.

DR. HARRINGTON: Bob Harrington, from Duke University. Thanks for the presentation.

When you showed your diagram of the organization within the Office of the National Coordinator, you list these four divisions that are led by a director, but I didn't see one for research.

I'm wondering where the research responsibility lies and who is it that takes responsibility for making sure that the

research agenda is being considered in all of these efforts.

Because what I worry about and I think what many of us in the research community worry about is that we're an afterthought and how does research fit into this, instead of really being forward-thinking in terms of how do we integrate the whole process of both research and clinical care.

And I wonder of thought has been given to creating a division at director level for research responsibility.

MS. CRONIN: It's a great point. After doing clinical research, I did health services work. So you're preaching to the choir here.

But the office of policy and research is supposed to be looking after the research needs of the office. We have not gotten to the point through the American Health Information Community that they have agreed to prioritize research.

So we haven't yet made it a use case to drive a lot of the work for the contractors. But it's very likely that over the next six months, we are going to do some type of priority setting process where we'd have to get testimony from the research community for them to really express their opinion and communicate really the benefits that could be achieved if, in fact, this were made a shorter term priority.

So I think there is a place in ONC to look at this,

but more importantly, if we really want priority setting to be done to incorporate clinical research, we're going to need to get a lot of public input and some testimony that can then feed into the American Health Information Community.

DR. HARRINGTON: Thanks.

MR. HUNT: Jim Hunt, from University of California-San Francisco.

One of the questions that I have for you is how your office views clinical research and clinical care and the differences with that data.

We're often informed that clinical research has a different granularity or reliability of the database that they use versus what clinicians use.

Do you or does your office have views of the differences in data that clinicians need and clinical investigators need or do you think that can be harmonized and how would you propose to do that?

MS. CRONIN: It's a great question. I don't think we've thought enough about the issue, to be honest.

I think that over time, the intention is to have standardized nomenclature. So that, ideally, SNOMED will be adopted in all electronic health records and we'll have the terminology that will be sensitive and specific enough to not

only allow for really robust clinical decisions to support healthcare delivery, but, also, that can transfer into the right type of database for a variety of different research purposes.

So I think right now we're probably not at a point where we have maybe consistent granularity across the system that's emerging, but we hope, over time, to really progress to that.

Part of the challenge with that is that physicians and clinicians using these tools don't necessarily want to be slowed down by choosing all the terms and taking that extra time away from patient face-to-face time to really make sure that he has the perfect terminology captured in his EHR.

So I think there will be a balance that we will have to achieve over time to make sure that we're not hurting adoption by forcing the adoption of certain standardized terminologies, but that we really need to get there, for a variety of purposes; not only to improve clinical care, but to really make the data available for all these important secondary uses.

So I don't think there is a definitive path find. One of the things that I think is clear is that I don't think the clinical research community has been engaged enough to date in many of the activities that are going on.

So I think, over time, it's going to be important for the voice to be heard at the certification commission, the health IT standards panel, and, to the extent that NIH can make their views known, too, to the department, that will help quite a bit, too.

DR. ALVING: I think we have time for one more question and we'll take Minnesota. Then there will be a one half-hour break and if you have some time that you could spend at the break, I'm sure there are others who will have questions for you.

DR. PETERSON: Kevin Peterson, the University of Minnesota.

You've mentioned many things that kind of reflect some of the English system, a single system with birth-to-death records.

One of the things that they have in England that we don't have in the United States is a national medical insurance number.

Is the identification of a universal ID a solvable problem here?

MS. CRONIN: It's probably one of our most challenging issues right now. We are probably not going to be -- the federal government, at least HHS, is not going to be pursuing a

unique identifier. I think we're prohibited by law to do that right now.

But we can be looking at a standardized way to identify patients and to also match patients to their records. So there's now algorithms that are being fielded and piloted in a couple regions in the country to determine how can we maximize the success rate in matching patients to their records using a certain number of data elements that represent uniquely that patient.

So that is really one of our critical focuses right now. Over the next several months, we're likely going to be taking this on through a variety of public meetings, to really figure out how to move this forward, because it's a critical issue and it's time-sensitive.

We need to figure it out if we really want to move forward.

DR. ALVING: Kelly, I'd like to thank you very much for an outstanding presentation. I hope many of you were thinking of ways you can interact at a state, regional, national level.

I know they're already plotting to show you the importance of clinical research and we're doing the same at NIH.

So perhaps we can work together and try to help you in

your efforts and I think this is an incredible national agenda.

Many of the individuals in this room are closely allied with just patient care, in addition to clinical research. So we're really all working for the same goals.

So thank you so much.

[Applause.]

DR. ALVING: There is now going to be a break until 9:45 and then Jody Sachs will lead our next session.