

National Health Information Initiative
Rex Cowdry, M.D., M.P.H.

DR. TUCKSON: Let's move now directly to our colleague, Rex Cowdry, from the National Health Informatics Initiative, the Office of the National Health Information Technology Coordinator, Department of Health and Human Services.

There's a space right there, Dr. Cowdry. Did you have slides or anything you needed set up?

DR. COWDRY: No.

DR. TUCKSON: Good. On behalf of the committee, thank you very much. You weren't here earlier, but we talked about how important this initiative that you're doing is, and we are very eager to learn a little bit more about what you're doing so that as we go forward we can think about it generally in terms of the work of this committee, but also specifically around some activity that's moving on in terms of the Surgeon General and the NIH regarding family history initiative. So thank you so much for coming.

DR. COWDRY: My pleasure, Mr. Chairman, and it's a pleasure to be with the members of the committee.

I guess I should first ask how you'd like to handle time management.

DR. TUCKSON: Sir, we're glad that you're here, and keep to the time that we gave you. That's fine.

DR. COWDRY: Okay, rather than try to shorten it. Okay.

DR. TUCKSON: Go right ahead.

DR. COWDRY: Good. What I'd like to do is try give you all a sense of why ultimately the President decided that the time is now to move forward with this initiative. Part of it, of course, is the weight of 10 years of recommendations from various groups and committees and publications, but part of it is not just a matter of changing, reducing medical errors, for example. It is really a matter of transforming our health care system and how we organize, finance and think about health care, that this is potentially a truly, if implemented well and properly, a transformative technology.

We know that the business of medicine is in key ways the business of information, and this process of bringing information to the point of decision in a way that produces high-value care I think is our biggest challenge. We know we do a great job of acute care. We know we do great at innovation. We also know that we have problems in the areas of huge costs, efficiency and value in our system. We know that there are quality issues that need to be addressed, both things that are done that should probably not be and things that are undone that should be.

We have a problem of care fragmentation, and the key question is how you can address this, particularly in the care of chronic illnesses. Information technology is one way to integrate a system without integrating it from above. Costs, we know that we're dealing with one-sixth of the economy of the United States, and we know also that technology -- and this is of particular

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relevance to this advisory committee -- is a key driver of the cost increases. What we've seen in a sense is tremendous advances, but also tremendous increases in costs.

This is a major challenge to genetic and genomic medicine, or more accurately genetic and genomic medicine poses a major challenge to cost issues. Now, you all have clearly grappled as a community with key issues of ethics, of privacy, which we share in the health information technology area, with ownership of information and intellectual property rights, which is another issue that we will see bedevils us in the implementation of health IT, and in economic issues that are often just simply not directly addressed. I was actually very pleased to see the material for the report about reimbursement that goes head-on into the question of not just cost but also cost effectiveness or value, because this is a conversation that we as a society need to have more of.

We know health care market is not really a market. It is full of so-called market imperfections. It's partially third-party payments, that divorce, that incentive structure from the time of decision. It's partially the absence or asymmetry of information that we have when we as providers make decisions, when we as patients try to decide on a course of action. We lack information about quality of care from different providers. Often we lack information about outcomes, particularly outcomes that are individually meaningful. Most notably, we lack information about price of the services that we get.

I don't know how many of you have had occasion to go recently, for example, for laboratory tests and have looked at your health plan statement that comes back that has the here's what was charged and here's what we reimburse, which is often -- the most recent one I saw was my own, something like \$230, which warranted a reimbursement of \$23. I felt like I was back in the bizarre, in 1969, bargaining. It is a system that is so unlike much of the rest of our economy, and in part is it an issue of information.

We have an ambivalence about technology assessment and how we put it to use. Who does it? What are the criteria that we use? And then, how does it consider individuality in the process of making recommendations? Most importantly, what's the end result of technology assessment? I think we learned in the '90s from managed care that for that to result in no as a flat-out answer is difficult, probably unacceptable.

So the question is how we can implement this kind of increasing information about outcomes, about value, into a reimbursement system that uses incentives rather than a simple no, that encourages choices based on value.

I think ultimately, from a series of six months of talking with a variety of groups about this, we and the President became convinced that health information technology is indeed a key, if not the key, to a patient-centered and provider-friendly and information-rich system of health care that really empowers patients in a way that they have not been to date, that frees us as providers to do what we do best, which is exercise judgment and compassion, not search for information, to gather information that actually flows both ways, brings information to the point of decision but also gathers information in a way that actually informs us about the kinds of resource allocation that informs guidelines based on information coming from the real world of clinical practice that gives us the kind of surveillance capacities that don't exist today, as recent headlines have shown us.

So the challenge is how to bring about this kind of interconnected system in a way that promotes value, promotes good care, and protects privacy. This is, in a sense, our challenge. Part of it is how to use it to bring about virtual integration of the health care system rather than top-down

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decision-making, and it is not a task without major challenges. I think I'll ultimately close with some of the potential pitfalls.

But let me first try to outline the kind of structure that David Brenner, who was appointed last April to be the national coordinator, has outlined in the framework for health information technology. There are different structures that we need to think through.

The first is how we build a kind of nationwide network for health information sharing. That is, how we layer on top of an existing physical network the capacity to exchange information in a secure way to authorized individuals. So one of the questions -- and I was at a meeting last week where a lot of energy was put into sort of beating down the idea of a national database that would have individuals' health information in it. No one is talking about a centralized database. That just is not in the cards. We're talking about a federated system where provider systems remain the repositories of information but there are ways to access that information with the appropriate security and safeguards.

It involves a kind of not peer-to-peer exchange of information, which is the way health information passes now, but most probably a structure of trusted hierarchies where there are basically organizations that handle information interchange, probably within geographic areas, and then can exchange information with one another. But it's those entities that will build the structures that assure that the person making the request is who they say they are and that they have the appropriate authorization to gather that information, and that the information moves in an appropriate way.

That is the second structure, the so-called regional health information organizations that to date have to some extent been somewhat larger than local regions or states, and I think there are many reasons why states are a natural geographic grouping for doing this. We know that state laws vary with regard to privacy and medical information. We also know that states are the laboratory of democracy, and I think we can see that also in the implementation of health information technology. No one has the answers about implementation. States will have very different approaches, as we're seeing in other areas of health policy, and I think that to some extent we need to encourage that.

What we don't need to encourage is the proliferation of different standards for the exchange of information, and that's one way that a major focus is emerging, both the 24 realms of standards for information that have already been developed, but more accurately assuring that when these are actually implemented, that these systems have ways of communicating with one another that are effective.

The last challenge, of course, is actually adopting electronic health records in the local provider systems. We know that larger hospitals and larger practice groups are much more likely to adopt. They're more likely to find at least the rudiments of an economic case for adopting electronic health records to get efficiencies. We also know that for many practices at the current time, implementing electronic health records is a losing economic proposition, and this is part of the issue. How do we incentivize the adoption, particularly by physicians, because that may pose the greatest challenge, of these systems that ultimately will change the way I think we all practice medicine?

Do you give people money to buy the systems? Well, none of us I think in the administration think that's an effective way of encouraging. But incentivizing use and/or ultimately performance and outcomes is the way to move this adoption process forward. There are some things that you

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can reimburse for gathering information, that is for use, and there are other kinds of performance measures that really only can be achieved efficiently if you have a system of reminders of electronic health information, and of decision support.

So I think those are the challenges, how we build a set of incentives, how we do this collaboratively with the private sector, with health plans, and the government as payer for health care, working together. We need to reduce risk through processes of certification of record systems. We know that one of the real pitfalls, and I'll touch briefly on that later, is that many implementations have failed to date. Kaiser, for example, is on their third implementation of an electronic health record system. This is a problem.

One of the key efforts has to be to develop a way of certifying that systems do what they are supposed to do and what they say they do. So part of that will be a certification process that's formal. Part of it I hope will also be the emergency of private sector consumer reports type of information that not just assesses the formal characteristics of the system but also looks at the actual use of the system that gathers information that can guide wise choices of electronic health records by physicians and by hospitals, but particularly by smaller groups that can't hire a major consultant that's just not feasible.

So there have been a number of strategies to provide this kind of decision support in the purchase of an electronic health records system both through the QIOs in Medicare, which now will have a statement of work that is aimed at providing support to physician practices in support of electronic health records, and similarly the regional health information organizations will have a role in facilitating adoption in a way that works.

What are the challenges and pitfalls? Number one, the one that has to be at the top of the list, is privacy and security. I think there is no question that these issues of identity -- that is, how do you know that this information belongs to this person and not that person -- how do you establish that fundamental issue of identity? How do you establish authentication? How do you know that the person making the request is who they say they are? And then, how do you establish authorization? This person is authorized by the patient to access these data. How do you establish an override system when a person who is unconscious arrives in the emergency room? So these are all key issues.

What are the characteristics of trust relationships that you have to develop? In the peer to peer level, do I trust you to have assured me that the person making the request is actually on your staff and authorized to make that request? Particularly, how do you manage it in the context of differing state laws that have very different requirements for the kind of assurances that have to be provided? Finally, there's an issue in privacy of opting in or opting out, and this is an issue for the individual, individuals who just simply do not trust information systems. What do we do about that? Do we allow total opt out? What do we do about partial opting out, though? What do we do about protection of classes of information that are widely regarded as particularly sensitive? For example, I have no problem talking about my triple bypass in a public setting. Would I feel so free about talking about my psychiatric history? Or, of direct relevance to this committee, what about genetic and genomic information?

How is that dealt with, and do we allow partial opt out so that most of the information can flow if I end up in an emergency room, but not all of it? If you do that, how do you alert the person caring for you that I've excluded certain information, so that the doctor doesn't rely on this being a complete story of my medical situation and leaves out the fact that I'm on an MAO inhibitor and therefore causes my death through drug interaction? I think these are crucial questions. Do we

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flag that? Do we have a way of saying this is the person's record, but certain information in terms of medications has been left off? I think it's crucial to the question of this being a system that we can trust, both trust what's in it and we have some awareness of what's not in it?

How about the ownership of information? Who owns our medical information? I think many of us believe that ultimately the answer to that has to be I own my medical information. But we also know that entities are both protective, appropriately, of our information, but also have a certain intellectual property interest in holding our information. There's a reason that many of the health information systems to date allow you to view your laboratory results online on the Web but don't allow you to import it into your own system. It is a way of building, if you will, a kind of competitive advantage, to provide information and support, but it's our information and support, and it's a way of building loyalty and commitment to this health care system. What it does economically is it makes it harder to move. It makes switching costs higher. It makes portability more difficult.

So these are all very real challenges. They result in a kind of very muddled economic picture. Why has this not moved forward on its own? It makes so much sense in terms of improving quality and reducing costs. What is the economic analysis here?

There's a very real risk that the natural endpoint is silos; that is, systems that don't communicate very well with one another, because there's an economic case for that, particularly larger silos. There is less of an economic case for sharing information. It's hard to see what the business case for that is. So we have to, as responsible payers, find a way of counteracting that, building a kind of economic case.

There's a risk of brain-dead decision support. That is, there's poor input into decision algorithms -- namely, that they come from highly controlled clinical trials but not from the real world. There are problems of how you put guidelines into a form that can actually operate in an electronic health system, how they are actually implemented. There's a problem if we don't have a system of bringing guidelines to providers in a way that is both individualized in relation to that patient but also allows for exceptions, because I can't imagine something that would be more likely to evoke a rebellion than a system of guidelines that has a kind of mandatory rather than advisory nature to it.

We have a danger of wasteful parallel systems for health information. We have a parallel system developing in homeland security, for example, for surveillance. We have parallel systems in CDC for surveillance for a variety of things, both infectious and drug related. We have FDA's surveillance systems. All of these are sort of partial, expensive in relation to the kind of information they gather, but they're what's out there. How do we assure that ultimately we end up with a system that accomplishes all of these aims and in addition facilitates research, both health services research and clinical research, without producing multiple different systems that drive providers and payers and everyone else slightly crazy?

We have a risk of a system that can't generate the kind of deidentified large-scale data that will give us real information about comparative effectiveness and cost effectiveness, that can't track outcomes, that can't identify adverse events, and that can't routinely provide surveillance.

So I think all of these are pitfalls, but they are pitfalls that we can anticipate and avoid. So I think our greatest challenges are going to be privacy and the kind of discussion that needs to go on about that, the cultural challenge of introducing value and cost-effectiveness into our health care

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system through health information technology, and ultimately the question of fairness, access, and cost.

I think I'll stop there to give us some time to talk.

DR. TUCKSON: That's terrific, Dr. Cowdry. Let me just ask you real quickly on this, how do you see, then, given the kinds of issues that you've raised, how we might be able to help inform the process, certainly around this idea of the genetics? You're sort of laying out two things that I see as critical. On the one hand, you're saying that the health delivery system of the future, which is soon, not way out in the future, is going to be a system that's categorized by a lot more patient-centric information, with lots of access to decisionable, actionable information to give you a total comprehensive care opportunity. So that's happening. Meanwhile, you're saying there are real issues around privacy and confidentiality of sensitive information, which is what this committee has to worry about.

So on the one hand we have folks who have chronic disease that are genetic based who are going to need coordinated, comprehensive care. On the other hand, you've got folks with diseases for which there may be some sensitivity. I guess the question ultimately is for us how do we help get into the process to inform that conversation?

DR. COWDRY: Well, I think part of it is exactly through the broader issue that you've already discussed, about genetic privacy issues much more broadly, for which the health information technology is sort of a specialized case. But I think it's useful to have sort of a range of discussions in multiple different settings about the questions of value and also the conflicting rights about information. So first of all, there's the question of what goes in the medical record and how it should unfold about the individual. Secondly, there's a question of support for processes of deidentification that really provide a way of gathering information, including family history and genetic information, and outcomes, in a way that divorces identity from that process. So it's helpful technically to discuss that.

DR. TUCKSON: Your office reports to the Secretary?

DR. COWDRY: Yes.

DR. TUCKSON: So there is a possibility there that –

DR. COWDRY: Absolutely.

DR. TUCKSON: Whose hand over here?

DR. KHOURY: Let me thank you for your presentation. I guess family history is probably one of those low-hanging fruits that this committee can work with you and the various agencies given the interest of the Surgeon General and the various public health initiatives and integrating family history into risk assessment. I think the time is right for that. It's complex because of the issues that you raised, but when you have estimates that 30 to 50 percent of the population have a family history of one or more common chronic diseases for which you can take action to prevent either disease or to manage people more, so we're not talking about genetic diseases only but the fact that people have a first-degree relative with diabetes or early heart disease or the various forms of cancer, I think the various initiatives that the Department and all of us, including CDC, NIH, and the various players will have to work together to find a way to integrate the family history information into the records and how that can be actionable.

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Right now family history is part of the medical record, but it's collected poorly, nobody looks at it, it's not actionable, and it takes time to collect. The providers don't have time to collect it. The patients don't realize -- I mean, from the survey we did at CDC last year, only a third of people go about collecting information that can be used in that regard. So I would encourage this committee to take that on and work with you and your office and all of us in the federal agencies to at least begin to integrate family history into the health information infrastructure.

DR. COWDRY: It's a real challenge, isn't it, trying to figure out what a standardized electronic health record should look like. I mean, there were major fights about this, quite frankly, that different agencies had very different perspectives about, and that providers on the front line will have a very different perspective than researchers or agencies with a surveillance responsibility. Family history is an excellent idea. The actionable component of it, how do you record it in a way that actually allows you to operate on that? Well, doctors will take four times as long to deal with a system where each thing has to be coded in in relation to a particular person, and when they're paid for a 10-minute visit or a 20-minute evaluation, that's probably not feasible.

We probably can't provide in a way that's provider friendly the kind of information that CDC might want, for example, or that FDA might want in its reports. So this is going to be the kind of balancing. But ultimately, I think the North Star initially has to be the provider, because if the providers don't adopt the system, it's not going to happen.

DR. TUCKSON: Thank you.

Let me get one last question from Joe, and then I'm going to try an action step to see if we can take good advantage of this presentation.

Joe?

DR. TELFAIR: My question is just a basic one in terms of a starting point. I was wondering maybe at the macro level in your investigations, have you seen a potential area where precedent exists? In other words, at the macro level, has some small group taken on this issue and worked it effectively, or has it been that formidable even at that level that you cannot generalize it to this group? My question is where can we start? If we have the committee begin to look at this and work with you, are there any case examples where it's been successful?

DR. COWDRY: Case examples of which?

DR. TELFAIR: Where information exchange, where a lot of these challenges that you presented have been dealt with, have been approached and done effectively, maybe at the macro level that maybe can be generalized to a larger level.

DR. COWDRY: Most of them to date have sort of developed as regional organizations, for example, in Indiana, that is based on many of the institutions and is bringing in community providers. There are five states that were recently approved, which I don't have at the top of my head but should, and funded to provide the initial regional health information organizations, and I think it would actually be tremendously helpful to have this kind of input into those discussions at the state levels as well, because to some extent our initial prototypes are going to arise out of these regional health information organizations on the one hand. They're also going to arise out of what the vendors build into their software.

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So I can see that there are several different fronts on which discussions would be extremely helpful, and we can certainly provide some information about implementations in various areas. Santa Barbara has had one. Boston is launching one. Indeed, Massachusetts broadly is launching one. Utah, where the Secretary comes from, he was very active and is extremely supportive of health information technology and health information interchange in a state model. So there are a number of sort of examples that are either moderately well implemented or just under way. In a sense, it's those that are just beginning to get under way that might be most useful.

DR. TUCKSON: Well, thank you very much, Dr. Cowdry.

Let me do two things, then, by way of follow-up. First, I think part of the committee's goals have been already attended to by having a relationship with you and by meeting you. I hope that you will take back to your office the interest of this committee particularly on the specific point that Muin described, which is what is the best way to start thinking about integrating the genetic-based information for family history into the electronic medical record and try to get that as a part of the national standard. So we would appreciate if you would bring that back to your agency and say that there are a bunch of very thoughtful people who are charged with advising the Secretary of Health on genetics, health and society who are making this a pretty big priority and really want to reach out. That will accomplish something today.

Number two, for the ongoing, I think we probably will be sending you a letter or some kind of way to try to get at this in a little bit greater specificity. Particularly, you can expect us to ask about who we should know about in terms of these various committees you've described, whether it's the Certification Committee on Health Information Technology that's trying to get the standards for physicians, interoperability standards and the various things that you've outlined. Which one of those places is the place that we need to drill a little deeper to try to get at this.

Then finally, what things should we worry about in terms of the confidentiality things.

Muin, if I could ask you, since you were sharp enough to raise it, and you know that you shouldn't do that around me, to try to help draft what we might send, in combination with either Francis or Alan Guttmacher -- I see you there -- given that you guys have got the lead on that family history project.

So, Sarah, we'll try to figure out how do we do that with Muin and Francis and/or Alan and get something to you, just again so you'll know who these are. Muin is CDC, and you know Francis and Alan are NIH. These are your brethren. So we can move this along. You can expect that, okay?

DR. COWDRY: Absolutely.

DR. TUCKSON: Thank you very much for your time, very excellent report. We're glad to meet you.

DR. COWDRY: Thank you. Good to see you again.