

**Cluster 4: Informed Consent, Privacy, and
Discrimination Issues That Relate to Genomic Data Sharing**
Kevin FitzGerald, S.J., Ph.D., Ph.D.

DR. WISE: We will move on to Cluster No. 4, please. Kevin.

DR. FITZGERALD: Money, value, knowledge? This is the 21st century, people. It is about power. Information is power.

So, what we are going to do with that information, how that information is going to be given to people, and how they use that information to make their choices, of course, fits into a concept that we have been working with for quite some time called informed consent, where people are supposed to get all the relevant information they need in order to make an informed decision.

Of course, the problem with personalized medicine is all the information is now relevant and all of it will have to be put together somehow so that we can come up with a comprehensive view of an individual's health status. As we go about pursuing these laudable goals, it is going to raise some really interesting issues that we need to address as far as privacy, confidentiality, and informed consent are concerned.

What we are seeing right now, which is currently challenging, is the pursuit of the large, population-based databases, where a lot of this information would be pulled together. The whole idea would be, obviously, to pull it all together so you can associate various aspects of health and disease in a picture that will of course, as we heard yesterday, create a disease signature.

The question is, what will that signature be, just how individualistic will it be, and how identifiable will it be.

We have already noticed that the evolving research paradigms in this whole idea of personalized medicine may in fact force us into a new conceptualization of informed consent or perhaps a new conceptualization of some kind of way of moving forward in a world where the information perhaps cannot be held in some kind of anonymous state.

This is going to be true for both research and clinical practice, since I think they will be much more greatly intertwined than they have been in the past. Obviously, this will require perhaps levels of vigilance and attention that we have not had to apply up to this point.

This is not anything new, in one sense. There have been activities ongoing, as you can see there, since the NBAC in 1999. But these are areas that other people are looking at. One of the questions will be how will we work with others, or need we work with others, to address some of these things.

That leads us, then, to some of our policy questions. If there are these new issues raised by this data, how do we begin to address that. Are they truly new. Are they just extensions of what we have wrestled with before in the '70s and the '80s when the Belmont Report was looking at the effects of research on human subjects. In one sense, we are all going to be the human subjects. We will all be part of the research, since it is going to be pulling all the information together.

How do we take these challenges to the public? How do we engage them, not just tell them but engage them, in the process of trying to understand this and delineate the issues which are of some significance and importance?

SACGHS Meeting Transcript
December 2, 2008

How do we cross generational divides? We were talking about education. I don't think the next generation is going to be too worried about this. They can't be. All our students have all their information on Facebook already. What is there to hide?

[Laughter.]

DR. FITZGERALD: So, will there be different levels of concern when we talk about information being made public. If so, what do we do about consent needs for these large-scale population studies. How do we consent the population. These are some interesting questions.

Then, how can the consent process be improved? What are the strategies? We can use some of the stuff that Barbara was talking about, and that her task force is looking at. How do we educate and engage people? One strategy is, you may be familiar with what are called teach-backs. You teach somebody something, and then they teach it back to you or to a third party. Obviously, when you come to truly understand something is when you can teach it to somebody else.

What is the role of SACGHS in this? What is the role of HHS? Obviously, these are big issues and big questions. They are probably beyond the purview of both SACGHS and HHS, but obviously we may have a key role to play in these.

As I said, we are wrestling with some new concepts and new ways of looking at these things. What are the implications, especially with computer algorithms that are now out there that we discovered in the journals in August? They can pull individual sequence data out of an aggregated, supposedly anonymized database.

If that is true and we start coming up with these disease signatures, what does it mean when someone publishes a journal article and there is a disease signature article? I can look at that and say there is only one person on the face of the Earth that has this particular signature. All I have to do is link it to that person.

Then, how does the legislation we have now, HIPAA and GINA, affect this process? What about the proposed legislation; what is the pipeline that we need to look at?

These are some possible action steps for ourselves. One that isn't up there that we probably could take into consideration goes back to Marc's emphasis on money. We could start our own personal information website and charge, and make lots of money. But, maybe that doesn't fit.

Sarah, is that allowed? No? Oh, shoot.

[Laughter.]

DR. FITZGERALD: All my best ideas.

One thing we can do is monitor the process, especially for GINA and perhaps other proposed legislation as it comes along, to see how they actually get applied, what the gaps appear to be, and how those gaps may need to be addressed.

Certainly, again, soliciting public input. One of the things I think that could certainly derail this move toward personalized medicine would be if we lost public confidence in the process because the public became suspicious in some way or was worried about the fact that things were being done that were somehow not transparent. How do we do that?

SACGHS Meeting Transcript
December 2, 2008

Then, again, we could write a report, which is what we do well. Can we come up with a report that dives into this, which I think would be a rather complex topic? It would involve, again, ideas of risk. What people consider to be the risks of this information being available publicly.

Again, I would imagine you would have quite a diversity of perspectives on that and a diversity, also, in the sense of what the harms and benefits might be. That, too, would be something that I think would need to be addressed.

Of course, the main thing with all this is how are we going to use that information. Of course, the person following me with Cluster No. 5 is going to solve all those problems, so I'm just going to stop here. No pressure.

DR. WISE: Any questions or comments?

DR. FOX: Just a suggestion. On your first possible action step, I would add VA to the list of organizations you might want to collaborate with.

DR. FITZGERALD: Absolutely.

DR. WISE: Thank you. Other points of clarification?

[No response.]