

INFORMED CONSENT ON GENOMIC DATA SHARING

Session Purpose and Overview

Kevin FitzGerald, S.J., Ph.D., Ph.D.

DR. FITZGERALD: Thank you, Steve. Actually, it is great when you get to go a little later in the day because there are normally many references to the topic and the spectrum that you wish to address.

I have a lot of people to thank. I want to thank Greg Feero for leading us right into this, asking for next ELSI steps. I wanted to thank Robinsue, but I think she disappeared on me, for talking about the need to focus in on privacy. Is it a problem with the law; is it a problem with public understanding; is it more than all that; and if so, how do we describe that terrain. Also, we heard from Christy White about the lack of public awareness of legislation like GINA.

Finally, I would like to point out what Phyllis was talking about briefly. If you do go to those challenge grants and look in the bioethics area, every topic that is listed has some connection to this area that we are going to discuss now. You have informed consent and data access policies, unique ethical issues posed by emerging

technologies, ethical issues in health disparities and access to participation in research, ethical issues associated with electronic sharing of health information, ethical issues in the translation of genetic knowledge to clinical practice, ethical issues raised by blurring between treatment and research, and recontact issues in GWAS-like studies.

All of these things are going to impinge upon informed consent, privacy, confidentiality, potential discrimination, all in the sharing of data.

What we would like to do today to dive in the deep end, since we don't have enough time to wade from the shallow, is take a look at two areas that have already had some work done in them by other organizations that work in parallel to SACGHS.

Our first presentation will be by another person who is well known by this Committee, Rod Howell, who is with us representing the one group in government that has a worse acronym than we do for trying to pronounce as a word.

[Laughter.]

DR. FITZGERALD: I'm not even going to try to pronounce it, but it is the Advisory Committee for

Heritable Disorders in Newborns and Children. Rod is at the University of Miami. He is the professor of pediatrics and chair emeritus in the Department of Pediatrics in the Leonard Miller School of Medicine. He is going to enlighten us as to the efforts of our sister group.

Thanks, Rod.

**Informed Consent Issues of Concern to the
Advisory Committee for Heritable Disorders
in Newborns and Children (ACHDNC)**

R. Rodney Howell, M.D.

[PowerPoint presentation.]

DR. HOWELL: Kevin, thank you very much. I'm delighted to be here. Actually, our name has improved with the revision of our charter, which was just signed this February. Our name used to be the Secretary's Advisory Committee on Genetic Diseases and Heritable Disorders in Newborns and Children. Apparently, the folks that think about high things decided that "heritable" and "genetic" were redundant, and so they dropped one in the new charter.

I'm delighted to be here this afternoon. I'm going to spend a fair amount of time actually talking about this Committee. I'm going to talk a little bit about what

we have been trying to do. I'm going to spend quite a lot of time talking about the discussions of the Committee about how conditions are actually recommended for the newborn screening panel, which is one of the things you have been talking today about, the value and utility and so forth of various and sundry genetic testing.

Let me comment at the beginning of this that our Committee, although it has a fairly broad charter, has spent much of our time on newborn screening. There are several very interesting things about newborn screening that I think this Committee is very aware of but that I would like to remind you of again.

Each year we test 4.1 million babies in this country. At the current time, the average number of tests done on the baby is about 30. So we are doing about 120 million straightforward genetic tests using genetic technology.

The other thing that is very interesting is that all of this testing is done under the aegis of the state health departments. These are public health programs. Although we focus and try to recommend national standards and national policies, the ultimate decisions about how

they are implemented and what the take-up is reside with the states.

Let me just comment briefly. The Committee was authorized under the Children's Health Act of 2000. That is the same act, as a matter of interest, that also required the establishment of the Children's Health Study that is currently going on under NICHD. The Committee first met in June of 2004 and has basically been functioning for about five years.

At the time the Committee was founded, one of the driving forces that was going on, and a problem, was the fact that, as I mentioned, newborn screening is a state program. There had been extraordinary variability. This was becoming a tremendous problem, with some states screening for handful of conditions, others screening for many.

As people moved around, this created very real problems. If you had a child that was born in Connecticut and identified with a given condition, and you moved to Virginia, which was one of the slowest states to move along, they were not screening for it. You had a new baby, so what did you do. It was a very big issue.

Let me show you what has happened since we started work in the summer of 2004. This is just a snapshot showing that at that time about 28 of the states in the country were screening for under 10 to 20 conditions. As you see, in December of 2008 those fewer than 10 and fewer than 20 have fundamentally disappeared. Virtually all the states in the country are currently screening for what has been recommended as a core set of conditions.

Fundamentally, this statute has said that we are supposed to come up with ideas and recommendations for a state screening program that would meet "federal guidelines." The Committee also was required to establish a grant program, which I might point out never had any money in it until last week. That will be an interesting thing.

Now, when we first started working on this, one of the discussions that came up in this august group that I have the privilege of working with is that we were making all these recommendations but, since newborn screening is a state program, we could make all the recommendations we wanted but nothing was ever going to happen. The first

slide I showed you has shown that not to be true.

Basically, what has happened is that once national standards and so forth are recommended by a group that thinks them through carefully, the states tend to pick them up with their review committees. Also, I will not get into it, but parental work at the state level has been very important in moving this along.

A bill was recently passed in 2008 to reauthorize this Committee. It is reauthorized under a very large bill called the Newborn Screening Saves Lives Act of 2008. It was passed, unanimously I might point out, by a voice vote in both the House and the Senate and signed by President Bush in late 2008.

It has requirements for the Secretary of HHS to ensure quality of laboratories involved in newborn screening and to develop a national contingency plan for newborn screening. This became a very big issue during Katrina, when the state laboratory of Louisiana was completely wiped out in the hurricane. You had all of the operations of the state, et cetera.

It also had specific discussions about the National Institutes of Health carrying out research in

newborn screening, including new technologies. NIH has already been doing that, but it has a lot of language that directs the NIH and also names the program at the NIH the Hunter Kelly Newborn Screening Research Program after one of the big advocates for this bill.

The Committee has spent a great deal of time considering how conditions should be added to the panel. The nomination process has been worked on and approved by the Committee. It was felt that there should be broad access to the process, that anybody should be able to nominate a condition. The process should be very transparent. There should be consistent criteria, and there should be a structured evidence review group.

This is one of the more exciting things, I think, that the Committee has done. That is, there have been never been traditional evidence reviews of rare conditions because they are rare, and the traditional patterns of review don't work terribly well. The Committee has contracted with Dr. Perrin at Harvard to organize and do evidence reviews in a systematic way of anything that comes to the Committee. The three areas of consideration are the condition itself, the test, and the treatment.

This is the nomination form. It is in your briefing book here. I won't spend a lot of time going into it, but it has a section discussing the incidence of the condition, the timing of the onset, and the severity. It has a lot of information about the test itself, as you have been discussing today, as well as how the test is to be used, the validity, the laboratory performance, confirmation, the risk, and the treatment. That includes modality, urgency, efficiency, availability, et cetera. It has a core set of references.

This is very similar to the nomination form that was used by the American College of Medical Genetics, but it has been polished and so forth. The very big thing is the evidence review committee.

The condition is nominated. The Advisory Committee looks at a nomination form like you just saw. The Committee and a subgroup of the Committee will look at that and decide based on the information there whether it looks like a reasonable nomination and is sufficiently meritorious that it will be sent for an evidence review.

The evidence review is a big deal. It is expensive. Everything that comes along is not deemed

worthy of an evidence review because of the money and time that it costs. Fundamentally, the Committee has approved that.

This is just a very simple thing. The nomination form comes in, and it goes through a federal administrative review at HRSA. Dr. Puryear is executive secretary of the Committee, and she resides at HRSA. Her staff looks at the nomination just to be sure it is complete. They do not make decisions, but all the stuff has to be there and so forth.

The Advisory Committee looks at it and then sends it for an evidence review. It goes through the evidence review and then comes back to the Committee, and they send a recommendation to the Secretary.

These are the questions that are in the evidence review. They basically are taken heavily off the nomination form, and I won't go into that. They include the benefits of the treatment, the harms or risks, and the cost.

The evidence review has a decision model and evidence questions. The search methods that are to be used are defined. Dr. Perrin's group reviews peer-reviewed

literature only, English only. They, however, do look at gray literature from pharmaceutical companies and so forth. They exclude case reports, which is a problem with rare diseases, but they do exclude those. They review consensus statements as guides but not to abstract those.

They do standard quality assessment methods. I might point out it is a traditional evidence-based system. They analyze any raw data that they can acquire from unpublished sources. They also routinely have focus groups of experts. They have investigators and families. Then they synthesize the data and provide it to the Committee.

They look at any rationales in treatments. Fundamentally, it is to provide timely information for the Committee so that the Committee can make specific recommendations.

The results come back to the Committee. We have had a chance now to have several of these reviews come back to the Committee. They summarize the key findings and they indicate, which is extremely helpful, where evidence is absent, what evidence would be most critical, what we don't know, the level of certainty, and new information.

The expert review group is independent and does

not make decisions. It provides detailed information that comes back to the Committee.

The decisions by the Advisory Committee, I might point out, will be published. They are all on the website, but they will be published in journals as they come along.

Here are the recommendations that the Committee might make. Once it goes to the evidence review group, it comes back to the Advisory Committee. The Committee can review all that and make the following recommendations.

We can recommend adding to the core panel. That means that all the information is there, the data is there, it is convincing, it works, the treatment is there, et cetera, and we should recommend that it be added. We have not yet had a condition come to the Committee that has met that level, I might point out.

The second is, we can recommend not adding to the panel but doing additional studies. The kind of information you would get back is that this is an important condition, the treatment really looks good, the test looks like it works, but there hasn't been a test done in a public health laboratory in a large group and so we really don't have sufficient information to recommend going to a

core panel.

The third is recommending not adding to the panel but additional evidence is needed. That is very different because there just doesn't seem to be enough information there to make a decision. In other words, we don't know enough about the condition. Basically, you need to get this together and come back.

Finally is recommending not adding to the panel. That last recommendation is a level of certainty. In other words, the data are there. It does not seem to justify being added to the panel with certainty. That is a level of certainty. The first and fourth would be certainty.

Now, at our meeting very recently we had two major discussions that I would like to describe to you. It is very much what you are dealing with here. The first was translational research policy, with introduction and discussion of institutional review boards and informed decisions. An extraordinarily important area that we discussed was residual blood spots and their policies and use.

The institutional review board discussion was moderated by Jeff Botkin. We had presentations and

discussions by Ed Bartlett from the Office of Human Research Protection and from Alan Fleischman, who serves as ethicist on the National Children's Study. He is medical director of the March of Dimes.

Jeff Botkin provided an overview of the regulation and oversight of research with children. Dr. Bartlett discussed the regulatory options for multi-center research, meetings on alternative IRB models, and proposals to hold the IRBs directly accountable. Then Alan discussed the translational research and how we can make it work. He also provided an overview of the California and Massachusetts models for obtaining informed consent.

Let me comment just briefly about the California and Massachusetts models of obtaining informed consent. When California was introducing tandem mass spectroscopy, it was deemed, since this was an experimental technology, that they would need to acquire informed consent in a large pilot project. That turned out to be extremely complicated, and they got only a very small portion of the people that they asked to participate. That has obviously been discussed a great deal, but about 25 percent participated.

On the other hand, Massachusetts had a similar type of program in that they had what I will call their usual pattern of screening tests that they were doing. As they decided to expand the panel, they did that with permission. Interestingly enough, they did this for a number of years, and it turned out that nobody was turning them down. In other words, they were getting permission from virtually everybody. Obviously, the method of getting permission was different, but that is a very interesting area.

Now, one of the reasons we are particularly interested in institutional review boards and research is that at the current time, as we move into new conditions that might be used in newborn screening nationally, we will be doing multi-center research programs. In other words, our Committee will not be, but the group that we work with will be. Obviously, these become very, very important issues to discuss.

Now, our final discussion was residual blood spot policies and usage. Harry Hannon, whom many of you know, has been responsible for the operation of the quality assurance program at the CDC for newborn screening for

decades. Harry reviewed with the Committee the current patterns of storage retention and use of residual dried blood spots in the country.

I think that this group is aware of the tremendous interest in the dried blood spot at the current time. Obviously, it is used in newborn screening for looking for certain metabolize enzymes, but it is obviously used for genome-wide studies in certain conditions.

Some states do not retain these spots at all. In other words, they will discard them promptly. The major reason they discard them promptly is they don't want to deal with the question of how to store and use them. The safest way to get around that is to throw them away.

At the other end of the spectrum, there are states that preserve them in perpetuity in very careful conditions. California is certainly a good example of that. With 500,000 deliveries a year, they have literally millions of spots on hand.

I might point out, states will keep them for a huge variation, either weeks, months, or years. How the states use them was addressed by Jeff Botkin. They have commonly been used by state laboratories in establishing a

new test. For example, if you want to set up tandem mass spectroscopy, it has been traditional that those spots would be anonymized and brought into the laboratory to see if your test is working and are you getting results. They have been used for that.

They have been used in an anonymized fashion by many, many states. Obviously, for them to be used with their name attached has historically always required parental permission.

In talking about dried blood spots, it would be a travesty not to mention Denmark. Denmark has been retaining their samples for over 25 years. They have one of the most well organized and well monitored repositories in the world at the State Serum Institute there, operated by Dr. Bent Petersen. They have federal legislation dealing with those spots.

Those spots have proved invaluable in Denmark for a variety of studies. Number one, they can find all their people. People tend to stay in Denmark, and so they can find people for a long time. If they find a given condition in someone who is 20 years old, they can go back and retrieve that spot and identify things. It has really

been a valuable repository.

For example, one of the things that they are considering doing at the current time, which we don't do in this country, is looking at the cytomegalovirus and how important it is for hearing difficulties. Denmark has an incredibly well organized hearing program. They know everybody in the country who has hard-of-hearing situations and how hard of hearing they are. They are preparing to go back now and look at their dried blood spots to see how many of those might be related to CMV. They use those in a very efficient way. I might point out they have very discrete and well-defined federal regulations about what they can do.

Our Committee in the coming weeks is going to be drafting a white paper that will discuss some of the issues about institutional review boards. After considerable discussions, we obviously are going to make some recommendations to the Secretary about policies for retaining blood spots and informed consent for stored samples. I think these will be very key issues as we move forward in the coming weeks and years. Thank you very much.

DR. FITZGERALD: Thank you, Rod. Thank you again for a marvelous presentation, which I'm sure is going to raise a lot of questions. We are going to hold the questions for now. We will go to our second group, which is being led by Larry Gostin, who was the chair of the Institute of Medicine Committee on Health Research and the Privacy of Health. That then led to a report which is Beyond the HIPAA Privacy Rule: Enhancing Privacy, Improving Health Through Research. Larry is also one of the editors of that report.

I have to tell you that Larry is a faculty member of a peerless academic institution here in Washington, D.C., often known as Georgetown University. With you, if I'm not mistaken, are a couple of others. Stanley Crosley is an attorney and chief privacy officer at Eli Lilly. Dr. Tom Croghan is senior fellow at Mathematica Policy Research here in Washington, D.C. Andrew Nelson is the executive director of Health Partners Research Foundation.

**Institute of Medicine Report: Beyond the HIPAA Privacy
Rule**

Larry Gostin, J.D.

[PowerPoint presentation.]

DR. GOSTIN: We decided, since we have a relatively short amount of time, that we would dispense with all of us giving the remarks. My colleagues, who will come up and stand in the back, will hopefully be able to answer any of your questions.

I will take about 10 minutes or so to familiarize you with the report and then we will take questions. I have to ask your forgiveness before I even begin because I do have to leave a little bit early. I have another appointment.

The Institute of Medicine had the following charge. We were asked to make an assessment as to whether the HIPAA Privacy Rule undermined or interfered with health research. If so, what recommendations might we make for the reform of the HIPAA Privacy Rule.

Clearly, this rule is of very great importance at the moment. The stimulus package gave a good deal of money for health information technology and also tried to firm up some of the provisions in the HIPAA rule. Similarly, it sent the rule back to HHS asking for some reformations, so we believe that our report is timely and important.

In answer to our charge, we found that the HIPAA

rule did in fact undermine important and valuable health research. We therefore made a number of recommendations about privacy relating both to the HIPAA rule and to the Common Rule.

We took the view that there were two exceedingly and equally compelling values in society. One of those values of course is privacy and security, so that patients must have strong expectations that their personal information will be kept in a private and secure way. At the same time, we thought there was an equally compelling individual and societal value in research because, without good quality research, the public is less safe and less healthy. It thwarts important scientific discoveries. We as a society have equally powerful interests in both.

The IOM Committee therefore made recommendations which we think will do both, which is to improve privacy and also to maintain and indeed facilitate important and valuable research in our society. We took the view that the HIPAA Privacy Rule and the Common Rule were actually intended to protect privacy, but in fact don't protect privacy very well at all. At the same time, they have the adverse effect of really impeding important research that

we need to do in the country.

We therefore made two sets of recommendations. One is a bold, innovative approach to changing the entire framework or paradigm of how we think about privacy, consent, and research in the United States today. It is something that doesn't follow the same model of autonomy, control, and ownership of information which has been very much a part of bioethics and law for a long time and, frankly, what the public expects. We are very clear that we face an expectation of the public that doesn't conform with our views of how this should be protected.

At the same time, as we have delivered our report and as we have talked to bioethicists, lawyers, and policymakers in the country, while not everyone agrees with it, everyone thinks that we need to have a new, fresh, careful approach to privacy and research.

The second part of our report was under the recognition that not everyone will agree with our innovative strategy. Even if they do agree, and we believe that many will agree, the political obstacles of doing that are extremely difficult. We therefore made a number of very careful, detailed, and, I believe, thoughtful

recommendations for reform of the HIPAA Privacy Rule and the Common Rule which would have the effect both of improving privacy and facilitating research.

Let me very briefly give you an account of these two approaches. First, the bold approach. Why do we say that the current model of authorization and each individual's control of information is not protective of privacy. There are several reasons. One is the fact that the Privacy Rule and the Common Rule are what lawyers call under-inclusive. That is, they only apply to a certain number of patients and transactions, leaving many other patients, research participants, and other transactions who are not covered under the rule virtually unprotected. So you have a rule that protects some and doesn't protect others.

The second reason is that we found that the Privacy Rule and the Common Rule are highly inconsistent and have extreme lack of uniformity. In any given situation, depending upon which rule applies or how the rule is interpreted by an IRB or a privacy board, what will happen is that you will have opposite or inconsistent results.

The under-inclusiveness -- that is, who should be protected and who shouldn't -- and the inconsistency -- that is, two different people or two different circumstances of like circumstances being treated differently -- we found had no ethical, legal, or other principle that justified them. It was simply a question of happenstance in how these rules evolved over time, but there was no even colorable ethical reason why you would treat these situations so differently.

Finally, we find that the current model doesn't protect privacy because it is mostly formalistic and not meaningful. When a patient goes to a doctor's office, for example, and is given a privacy notice, most of us don't read it. I'm a law professor, and I barely understand it. It really wouldn't matter if I did understand it because if I didn't sign it I wouldn't be treated anyway. That is really only a formalistic way, the accounting for disclosures, the privacy notices. It is really substituting form for substance.

We wanted to go to a model that really was not something that was form but substance. We made a lot of proposals for essentially two things. One is to have very

strong privacy safeguards to make sure that institutions that hold data for research purposes are certified and are trustworthy. Secondly, that they have privacy practices as to who they would authorize getting that information which are consistent and strict. Third, that there are very detailed and careful security provisions.

If you think about what patients or research subjects should be worried about, it is really those things, not having absolute command and control over every bit of their information.

At the same time, we found that having this idea of consent doing all the work in this area thwarts research in very significant ways. We discuss many of them in the report, but one that I want to point out is the problem of selection bias. If each and every individual controls all of their information and some of them would be more likely to opt in and some more likely to opt out, it means that the results may be wrong or skewed in the wrong direction.

There are other reasons. For example, researchers may not need to have names and so forth, but they may need to be able to follow individual research participants over time. To do that, they have to have a

means of linking. We suggest that in our report in a way that we believe would be very helpful.

Finally, if you have any individual patient, or 10 patients, or 100 patients or subjects, or 1,000, or, in genome association studies, tens of thousands, if every single one of them could say, "I agree to this piece of information but not to that," or "You can use it for prostate cancer but not for breast cancer, or for heart disease but not AIDS and STD," to me, that doesn't make common sense. It really isn't protective of what we are trying to protect, which is to make sure that insurers, employers, family, and friends don't get this information in ways that harm or embarrass.

We make a number of very bold proposals to change the paradigm, but we also recognize the political problems and that not everyone will agree that we ought to change the model. We understand there are genuine differences of perception. We therefore make very detailed proposals about how we could change the Common Rule and the Privacy Rule either by more clarification in interpretation and guidance by HHS and OCR or by changes in the HIPAA rule. We notice in the stimulus package, as I mentioned, HHS is

being asked to reopen that, so we think it is timely.

Finally, only if it is necessary, we will ask Congress to make some changes.

We tried to have a gradualist approach and make it as easy as possible for policymakers, if they agree with our approach, to be able to adopt it in ways that make sense.

We thank you very much for allowing us the opportunity to present our report to you. We will have a paper in JAMA summarizing our conclusions and adding additional observations in the first week in April. We will invite our staff and committee members to come up and answer any of your questions. Thank you very much for having us.

DR. FITZGERALD: Thank you, Larry. That was excellent. We would like to invite the staff members to come up, please. Rod, if you would please come back up, that would be great.

I think the presentations will probably engender a good deal of comment or question from this normally shy and retiring group, so I will throw the floor open at the moment. Sylvia, you get to go first.

Question-and-Answer Session

MS. AU: I just want to clarify something that Rod said. For the California program, actually what happened was it wasn't 25 percent of the participants gave consent to go for the pilot project for tandem mass spec. What happened in their state is that they decided they needed to go through the IRB of every single medical facility that was going to be in the pilot project. They didn't have the time or the manpower to actually do that with every medical facility, so only 25 percent of the newborns that were born in the state actually could participate because the other 75 percent were born in institutions that they didn't complete the IRB for. So it wasn't that it was 25 percent of all of the families that were asked to participate.

The only reason I know this is we were trying to do a comparison study with them. In Hawaii, we actually did active informed consent for our pilot, and we had people actually talk to parents for 20 to 40 minutes about tandem mass spec and newborn screening before they consented. We were going to compare it with the California program, who handed them a brochure and had the nurse say,

"Are you informed? Do you want to participate?"

We couldn't do that in the end because the California people realized that some of the nursing staff were sticking the "yes" sticker on without asking the patients if they really meant yes.

DR. HOWELL: I think Sylvia's comment brings up the issue of when you are trying to do informed consent for something that is national or state-wide and you have to deal with so many IRBs. It is a deadly problem. That is obviously a significant thing.

I think the other thing that Michelle reminded me of is that in Massachusetts they use an informed dissent program, which is a little bit different side of events. Again, many of us in the field feel that probably the best way to look at the informed consent in newborn screening is basically to have a very good information program and then have people dissent who do not want to.

DR. TEUTSCH: Before we leave the newborn screening, I have a quick one, Rod. It is great to see that this is getting on a much firmer evidence-based footing. Going forward that should strengthen things. Are you going to have a chance to go back and look at the ones

that were already recommended and reassess those to see how strong the evidence base is for those? I know that becomes a challenge.

DR. HOWELL: That has been discussed. At this point in time I don't think any decision has been made about that, period. It has not been made.

DR. FITZGERALD: Just following up on that issue, actually I'm intrigued by the body language here. Were any of you involved with working with Larry before?

[Laughter.]

DR. FITZGERALD: Anyway, in the report one of the issues I'm sure which is going to be huge to wrestle with is the database issue. The VA has a huge database. So does DOD. The Indian Health Service has a very interesting database in newborn screening. How are you addressing that particular issue with this idea of restructuring our way of looking at privacy?

DR. CROGHAN: The Committee has discussed the issue of linking databases, which is really a main part of what you just mentioned. It is very important to health services researchers and will be increasingly important to all of us, particularly with genetic information.

There were several recommendations. The one I want to mention is to have some sort of certification of organizations that had met all of the criteria that Larry mentioned, such as security, privacy practices, and so on, who would then be trusted to take data from various data sets, link them in sensible ways that made them research-usable, and then make them available in a deidentified manner or in a limited data set manner, depending on what was most appropriate for the research question.

DR. FITZGERALD: Just as a follow-up to that, one of the issues that has come up before this Committee is this idea of how to define "deidentified" anymore. If we do start sequencing genomes for \$1,000 and it only takes 70 SNPs to identify somebody, is there a set of criteria that you have for that particular issue? What are you going to use as a standard for deidentification?

MR. CROSLY: The Committee looked at a lot of different resources when we did this. One of them was to look outside of the U.S. as well. As you may know, the 27 member states of the European Union have an organizing body around data protection called the Article 29 Working Group, referencing the article of the European Directive that

created the group. They have written a paper, WP139, which references in fact genetic information.

Their assessment was at this point sequencing of data and genetic information in general is still not identifiable without the reference.

That doesn't directly answer your question. Your question is, five to 10 years from now, 50 SNPs, 70 SNPs, whatever the number, how will that be created. I think that one of the recommendations from the Committee, apart from the Privacy Rule having its own model, enables you to be more nimble and to be more flexible in your assessments without all of the other entanglements of the rest of health care which the Privacy Rule has to consider as it makes changes.

I think Tom was explaining there are protective mechanisms around reidentification that the Committee focused on some, versus what is truly deidentified. We are setting up the model to prevent the harm rather than trying to pursue an elusive concept of continually updating the deidentification criteria.

DR. FITZGERALD: Thank you. I just wanted to point out to everybody, in spite of our efforts to

deidentify Tom, he is still identifiable because he is the only one left on the list who has not been identified.

Any other questions from the group? Yes, please.

DR. CAROME: I had a question for Larry and your colleagues. Separate from the issue of lack of coverage of the Common Rule, that it doesn't cover all human subject research involving data, and separate from the inconsistencies between the Common Rule and the Privacy Rule, were there specific provisions of the Common Rule that you identified as being problematic? That didn't come across clearly to me in looking at the Committee's recommendations.

MR. NELSON: The Common Rule is an HHS-wide adopted Common Rule. At the same time, trying to harmonize that with the Privacy Rule sometimes confuses IRBs. Oftentimes when confusion happens at a local level, then more conservative decisions are made. So you have less organizations, less individuals, and less IRBs who are willing to do multi-site studies. Therein lies the complication.

DR. CAROME: So you really are focusing on the lack of harmony between two rules. If the Privacy Rule

didn't exist and you only had the Common Rule, which applies to multiple federal agencies in addition to HHS, would there still be a problem? That is what I'm getting at.

MR. CROSLY: Yes. There are a couple of things. One is a more comprehensive privacy regime to accompany the Common Rule and the acknowledgement that privacy and research are equally critical and equally important. The Common Rule isn't specific enough and doesn't go far enough in its privacy protective regime. So it is a marriage of the privacy regulations under HIPAA with the Common Rule.

Then there were some very specific security recommendations, regardless of which paradigm was used. I think that is probably the most significant.

Also, there were areas like secondary use. There is a potential overreliance on the Common Rule having figured out how the IRB should advise on whether the consent form was sufficient to apply to some secondary use. Certainly, there was an understanding that expertise would exist within the IRB to solve some of the issues that we already have with the Common Rule, I think.

MR. NELSON: The final thing is that the Common

Rule only covers what is funded by the federal government.

We feel very strongly that this should apply to all

research, no matter what funding source.

DR. FITZGERALD: Using a very complex and powerful algorithm, we have now identified Tom. We just wanted you to know that.

[Laughter.]

DR. FITZGERALD: Sue, did you have any comments?

MS. McANDREWS: Yes. In terms of full disclosure to complete the Georgetown control of this whole conversation, I did get my law degree from Georgetown Law. We now have all sides of the triangle there, and we rule.

On behalf of the Office for Civil Rights, I did want to thank the IOM for their report and their recommendations on how to improve privacy and security in the research context. We do appreciate their efforts in struggling with the very difficult balancing that we have dealt with in trying to design the HIPAA Privacy Rule in terms of individual interests versus societal interests. It is a matter of balancing the need for the data and the need of the individual for privacy and confidentiality when exposing their data and being willing to share their data

in order to get the treatment that they need and deserve.

We do not want fear of secondary uses to interfere with their ability to get care in the first place.

I want to just say that we have, since the beginning of the HIPAA Privacy Rule, endeavored to work with the research community in aligning the provisions and that we did make substantial realignments back in 2002 which did go to two of the areas that still showed up in the IOM report as needing further reconciliation. Those are the accounting for disclosures as well as the simplification of how you can go about waiving the authorization requirements, largely for access to information as opposed to clinical trial interactions with the patients themselves.

In part, I would ask to what extent the report and the recommendations in those two areas really took into account the steps that were made back in 2002 and focused on the practices and problems that may have continued to reside in those two areas, as opposed to simply being a reaction to people's opinions back in 2000 when the rule was first issued.

DR. CROGHAN: I will start. First of all, in the

interest of disclosure, I'm also a faculty member at Georgetown.

Secondly, I want to point out, we recognize the challenges that OCR faces. The Committee was of the strong opinion that privacy and health research are both private and public goods and that neither one occurs adequately without the other one. We really were trying to improve or enhance both in all of our recommendations.

With regard to the specific comments on notice about disclosure and so on, we did hear from OCR. In fact, they were very helpful in our discussions. We were aware of the changes prior to the 2003 implementation.

We also heard from the research community. They are still barriers. Not as much as they would have been had the changes not been made, but they were still getting in the way of achieving our goals of enhancing privacy. We did hear from organizations who, because they didn't understand or correctly interpret, would not release records. Researchers had these experiences.

In fact, in our last meeting we also heard that the accounting for disclosure rules actually have a cut point of 50 records or something. There are in fact many

research projects, including one that I recently had, where we were getting two or three records from a hundred physicians. Something like a third of the physicians just didn't understand the rules and therefore didn't give us the records.

So we did take the changes into account. There continue to be barriers. We think that they could be improved upon.

DR. FITZGERALD: Following up on that, when we look at some of these research programs that are going to use databases and the information that is there or can be gathered, the newborn screening database actually might be one which is somewhat representative. Much of what we have right now as data is not truly representative of the diversity within this country.

The groups that have been marginalized up to this point may have good reasons within their groups for suspicion of benefits coming from any major research projects, but it is still my understanding that in order to get their information into these research programs in a way that will take into account their lack of representation, they actually need now to be overrepresented in the

research programs that go ahead.

It seems you have a potential issue there that could really gridlock the system as we move ahead. Any thoughts on how to address that particular challenge?

DR. CROGHAN: I will start. We did some public surveys through the Harris Public Poll, and we had members on the Committee who represented patient groups. The most vulnerable groups, those with AIDS for example, those with mental health problems, those who had the most reason to be concerned about their privacy because of the potential for harm, were actually the ones who were most likely to endorse releasing their data without prior consent and to endorse participating in research. Now, remember this is a public poll, so that comes with its own problems.

The members of our Committee who were engaged with these patient groups with chronic diseases, actually said, if you think about it, they also have the most potential for gain. They are the people who are seeking our help the most. In fact, they were the ones who were making this important decision. I think that was telling.

Andy has something to offer.

MR. NELSON: I really enjoyed your presentation

about the potential for multi-site studies when you are looking at newborns. This capacity is a new capacity. When we look at intervention studies versus database studies and being able to aggregate large sets of data without bias, it is an extremely important societal benefit. We were very cognizant of wanting organizations to participate in that process. Right now there is fear among organizations for collaborating because they worry about any disclosure that those researchers might produce, even if it is just the data-driven pieces.

I think we are looking for some supportive guidance from HHS to help organizations that are locally based to more clearly understand and more clearly give permission to contribute to the societal good.

DR. CROGHAN: We didn't absolve the researchers, by the way, of their responsibility. Part of this, we also found out in our polling, is that the public does not really understand research.

In focus groups, we understood that often people who had participated research did not hear back from the researchers. They didn't know what the results were. We make the recommendation that no matter which course is

taken to improve on privacy that in fact researchers and others have the obligation to educate the public about research processes and the results of research.

DR. FITZGERALD: I have Gurvaneet next.

DR. RANDHAWA: In the discussions of the Committee I don't know to what extent you considered different models of data aggregation from the centralized, deidentified aggregate databases. The other model would be small federated databases where the data is all identified and controlled locally but there can be distributed queries specific to a research question or project so you don't have to aggregate data in any one centralized place.

I wasn't sure if the Committee had gone into the privacy issues for these two models and if one was better than the other one.

MR. NELSON: Yes, there is an increasing ability to conduct research through these federated data. In the example of the HMO Research Network, for instance, the identifiable data never leaves the firewalls of those care-providing organizations, but a query might be sent in from the outside and analysis would then be done inside with a large population. Only the aggregated deidentified results

then transfer to the researchers outside. That is an increasing capacity, and it is very much encouraging in terms of protection and safety issues.

The second is, there are organizations that don't have that capacity because it takes quite a large effort to map and configure data that way. There has to be the ability to be doing both the federated data consolidation approach as well as working with organizations that don't have that capacity.

MR. CROSLY: The other thing I would add is that one of the models that we discussed and included in our report was having a certification agent, modeling it somewhat on the Ontario privacy law that has qualified entities who can hold reidentification keys. Certainly you can have that encryption key exist at the data level. You could also have a federated query authority as a trusted agent or an authentication agent that could then do the same thing.

I think the model certainly anticipated distributed data sets and having trusted agents or third parties who would in some manner be certificated to enable the research across those data sets.

DR. FITZGERALD: Joseph.

DR. TELFAIR: Thank you. I appreciate the presentation. I have probably contingency questions. This issue comes up a lot. I appreciate the presentation by Dr. Howell on newborn screening.

The one thing that is there as an example of the others is the actual question of follow-up and longitudinality. You talked about maintaining longitudinal databases, but you also talked about working with the public and with vulnerable populations. I think one of the last things was the issue of scientists reporting back to the population itself.

Taken as a whole, the implications for that have a lot to do with the willingness to have these long-term databases and the ability to refresh those and go back. For example, you have someone who was picked up on newborn screening but then you had to go back to them at some point. The question really is, you did a lot of work on their sample early on but now you have to go back to them to re-consent. Were there any recommendations in a very practical way of how you would really do that?

I haven't heard a lot about it. It is a very

tough problem. Given the recommendations you already have made, that seems to be something in line with what you have been thinking about. I was just wondering whether anything concrete may have come out of that recommendation-wise. Do you understand what I'm asking?

DR. CROGHAN: Let's take a little bit simpler case first, which is an adult who can actually give consent. Here the Committee found a real discrepancy between what is in the Privacy Rule and what is in the Common Rule. People, under the Common Rule, can give consent to future research. Now, there are some boundaries around that, and the Committee did not get into the details about where to draw the line.

In the Privacy Rule, you cannot do that. That is one area of harmonization.

Now, we did not discuss at all the special issue of children and newborns, where the model is more you can assent children. I don't know what age is the bottom rung there, but that is something that we will kick back to you all as a Committee, and to others, to have that important discussion. I would imagine at some point there would be some talk about the need for consent.

DR. HOWELL: Let me make a brief comment. We did not discuss it at all today, but it is an important thing. The National Institutes of Health have just funded a major newborn screening translational research network.

The background is that when children are detected with rare conditions, be they in North Dakota or South Carolina, right now they basically are identified and their treatment is begun and then they are out of the system. The plan for this would be to identify and follow these children in a systematic way all over the country so that you would have all of the children with some rare condition. There would be plans to follow them, and there would be protocols.

One of the issues that has come up in a big way early in this is of course the data system. Early thoughts would be that the data would be retained locally but there would be an infrastructure, working with caBIG from the Cancer Institute as a model for doing that.

Anyway, this would be a very interesting thing. Steve asked if we are going to go back and so forth. We will have the prospective data on these conditions and we will know what happens to them and how they are treated,

but the translational research network will be an exciting new program.

Again, a child will be detected. The parents will then be asked. They will go back to the child, but the state, of course, always goes back to the affected person and asks, would you like to participate in the program, protocol, et cetera. They will be invited at that time to participate in the follow-up treatment protocol.

DR. TELFAIR: That is similar to the multi-site study models from multiple places. My other question may be even more difficult. I was thinking of the whole spectrum for the young person from birth on. They are very young, so of course their consent is given by their parent. Children and adolescents can assent, but they still have to have consent by the parent.

The other question is the vulnerable adults, those who cannot sign for themselves. You get a sample from them, and then you try to get a sample 20 years later but the person who signed for them is no longer there, for example. That is an adult-related problem. To me, those are real questions that are being asked.

I know you spoke about the European model, but I

have looked at a lot of what they have and I didn't see that come up. I'm wondering is that, again, something you would kick back to us or do you actually deal with it?

DR. CROGHAN: The Committee drew a distinction, and I think it is an important one, between interventional research and information-based research. Interventional research is the types of things that Rodney may have been referring to, where the research subject actually has something done to them, often in a randomized way, but there is some intervention that occurs. Our way in America of looking at those types of research is in fact consent.

The Committee drew a distinction between that and information-based research. If you have a sample about a child and you know something else about them from their administrative healthcare records over time, can a researcher access that information without ever needing to talk to or intervene with the research subject, even when they are an adult.

Now, we thought that with the appropriate controls, as Larry outlined, that could happen. We made the recommendation that that could occur within some boundaries.

MR. CROSLY: With IRB oversight.

DR. CROGHAN: IRB oversight, appropriate security, and all the types of things we have been talking about.

DR. FITZGERALD: David.

DR. DALE: I really appreciate this discussion. The HIPAA rules are national rules, but the IRBs are locally controlled. Did you take a position on national IRBs, particularly related to rare diseases, where if you do a study you have to do it in multiple places?

MR. NELSON: We didn't go into that specifically. We did want to see, and made the recommendation on the Committee's behalf, to harmonize so local sites could have an easier way of interpreting things. Though this multiple-site IRB problem is not going to go away by the recommendations of this report, we think that better harmonization of rules so that local sites can interpret, and developing some templates that IRBs could follow, would be very helpful. Right now they are on their own.

MR. CROSLY: We also made a recommendation that, regardless of whether it was the new model of research being pulled out of the rule or whether it is changes to

the rule itself, IRBs be given some layer of indemnification protection and liability protection. We saw from the research that came in that there was a vastly different interpretation of the Privacy Rule based on the constituency in the IRB and from one place to another. Those caused significant issues.

We tried to resolve that, as Andrew mentioned, by getting better guidance and some best practices that would be eventually blessed or sanctioned by HHS to give them freedom to operate within that sphere. The liability protection we thought was also a very important layer to give them the freedom to make good judgment and rely on their judgment in the circumstances.

DR. FITZGERALD: Michael, Sue, any further comment or questions from your end? No? Thank you.

One last question, then, for all of you. Going ahead, this Committee is going to continue to look at these issues of informed consent, privacy, discrimination, and all that. We have already touched on some of the areas that you have mentioned that you didn't particularly focus on, like children, newborns, adults that don't give their own consent. Are there any other areas that you would like

to see this Committee address from the perspective of the IOM report but also from the perspective of our sister committee? I will just throw it open to you.

DR. CROGHAN: The Committee's charge didn't include recommendations about genetics, so I'm now only speaking for myself. I think the issues that were raised here today, particularly with regard to integration of genetic information, how those data are maintained and how they are integrated with other protective health information and made available to the research community, are going to be an important part of any deliberation and something we need to think about.

We didn't consider genetics because they are not currently part of the HIPAA Privacy Rule.

DR. HOWELL: I think the thing that would be most helpful would be looking at the mechanisms of informed consent. When you have multi-site studies and the whole background that surrounds that as far as harmonization, a central IRB absolving the local IRBs of risk so that they might more readily do that I think is going to be very important. As Sylvia pointed out, even in the State of California, you try to go to multiple IRBs and it just

doesn't work. Solving that will be important.

I gather that the big issue with a central IRB is the fact that the local IRBs are still holding the bag, so they are really not willing to hear what a group of talking heads in Washington has to say on the issue because they have to deal with things back home. I think solving that and figuring out a way to do that in an ethical and legal way will be very important for genetic studies in general but particularly for newborn screening, where we are, again, looking at 120 million genetic tests a year and not 1,000 BRCA genes.

MR. NELSON: One other comment that the Committee did make is on this issue of transparency in the field of genetics, the use of phenotypic and genotypic data together, and the transparency of the discussion on the trust that has to come from the public. We really need to engage the public and figure out a way to engage them in a way that has their support. We need to communicate clearly the intent of what we are doing. We need to come up with a community-supported approach to this privacy issue.

I think those discussions are extremely important and [constitute] a new science area where we have tools

that are dramatically different than we have had in the past that expose privacy and security issues beyond what we have had to take care of in the past.

MR. CROSLY: My final comment is not necessarily a recommendation on an area but some learning that we had in the composition of the IOM Committee. We had privacy advocates, patient advocates, people who suffered from chronic illness, and public and private researchers, and that constituency was incredibly powerful in sifting through the issues and making sure all the voices were heard.

I'm sure you are taking those things into consideration as you deliberate on these incredible topics because privacy and ethics, personalized medicine, it is an incredibly important and critical area. I think that we can't go very far unless we really start talking about it.

DR. FITZGERALD: Gentlemen, thank you very much. That was wonderfully interesting and informative. I thank you for your participation.

[Applause.]

**Committee Discussion of Issues and Next Steps Related to
Informed Consent on Genomic Data Sharing**

DR. FITZGERALD: I have my charge from the boss. He wants to know where you want to go next on these issues.

As we heard, there are areas that were just mentioned, some of which we have begun to address in some of our earlier reports. Certainly, public engagement has something that we have continually been bringing up, including the large population studies, the pharmacogenomics, and the genetic testing and screening.

There is also the question of, how will informed consent be reconceptualized, redescribed, and redefined. That does seem to be an area that is going to be rather neuralgic as we continue to go forward.

Would people feel it would be best that we get more information on a particular specific area? Do you feel ready to become a task force focusing on something? Where are people leaning at this point?

Just to let you know, Charmaine Royal, who will be coming on the Committee as I'm being voted off the island, has agreed to do anything and everything.

DR. TEUTSCH: You know you can never leave.

DR. FITZGERALD: You never get to leave, right.

DR. TEUTSCH: That is what we need to hear. We

have a lot of priority areas, and this was one of the ones that was important. Are there things that we can do now, long-term, short-term?

DR. BILLINGS: Maybe I missed it in the discussion, but do we know what the Institute is going to do with their work? Obviously, with all these people with these Georgetown connections, there is a certain institutional bias in the information that we got. I suspect that the other august institutions of law and ethics out there may have slight variances on the model.

DR. FITZGERALD: There are others?

DR. BILLINGS: Yes, yes, there are. Before I can say what I think should happen, I would like to know a little bit more about what is happening and how broad the range of difference of opinion is.

DR. TEUTSCH: Perhaps what is proceeding on the federal side with these issues, too. I don't know if either of you can speak to that.

MS. McANDREWS: I certainly can't speak globally on that. I will say that last week the IOM did present the same report to the Secretary's Advisory Committee on Human Research Protections. That entity, SACHRP, has made

recommendations on privacy and the intersection of the HIPAA Privacy Rule and research in the past. I suspect that they will be looking at their prior recommendations in light of this new report and will be propounding additional recommendations to the Secretary based on that.

Within OCR itself, as was mentioned and as you may otherwise know, we have a fairly full and ambitious regulatory agenda that has been handed to us courtesy of the HITECH Act which will be occupying our time and resources for the next year to 18 months, both in terms of regulatory changes and studies.

There is good news and bad news in that. None of the legislative changes in fact go to research at all. It wasn't really touched on in the HITECH Act.

In addition to those mandated statutory changes, and I would throw GINA into that mandatory statutory work that we are engaged in, there may be some synergy in certain areas. A study of deidentification is one of the mandated areas that may allow consideration of what that term may mean in a research as well as a healthcare setting. There may be other things in the way of accounting for disclosures, although it is tending in an

opposite direction from the recommendations of the IOM. That is broadening the areas for the accounting rather than taking items off the accounting.

Authorizations and other things may be areas that we will have an opportunity to work on in conjunction with our statutory mandates.

DR. FITZGERALD: Thank you, Sue. David.

DR. DALE: Is the full report available?

DR. FITZGERALD: Yes, it is.

DR. CAROME: The Secretary's Advisory Committee on Human Research Protections, SACHRP, met last week. They received a similar briefing on the IOM report. SACHRP previously made a series of recommendations about the Privacy Rule several years ago that are still undergoing deliberation and consideration by the Department. Those recommendations fairly well align with many of the recommendations, or at least the general framework of the recommendations, that the IOM made. They tend to reinforce one another in terms of the concerns and issues that have been raised.

All of the recommendations of SACHRP to date are directed at the Privacy Rule and would require action by

OCR, with input and consultation with others in the Department.

They mentioned today that they have concerns about the Common Rule. They focus on a lack of harmony between the Common Rule and the Privacy Rule, and that has been obvious to many for years, and a lack of coverage for all research involving human subjects that involves private information. When I pressed them on that, it is still unclear to me, if you didn't have the Privacy Rule and if the Common Rule covered all research, what problems the Common Rule poses to the type of research they are involved in. I'm still unclear on that.

They talk about not wanting to have the Department or the government go forward with prescriptive solutions, but by their very nature regulations are prescriptive.

The current regulations we believe offer a lot of flexibility in this arena. There is a lot of research activity that isn't covered by the regulations either because the way it is done doesn't involve human subjects or the way it is done is exempt. For research that is not exempt and is covered, there are procedures for waiving

informed consent, which have always existed. I believe those allow a lot of this research to go forward if the waiver is appropriate.

With regard to the provisions on privacy, there is one basic provision, and that is that when the IRB reviews and approves research it must ensure that there are appropriate provisions to protect the privacy of the data collected. That is a fairly simple provision which gives the IRB and investigators great discretion to design appropriate privacy protections. That can be along the lines of the privacy protections the IOM talks about, such as stronger protection and control and restrictions over release, but you can do all that now within the framework of the current regulation.

DR. FITZGERALD: Gurvaneet.

DR. RANDHAWA: Since we are at the information-gathering stage, one community we haven't heard about is the health information technology community. I'm sure they have wrestled with some of these issues from their perspective. It may be useful to engage with the successor of AHIC or somebody similar to give you some information on what is going on there.

DR. TEUTSCH: What I'm hearing is there is already some action being taken to flesh these things out. Just as a reminder, we had this session because we knew this report was going to be issued. That is why we wanted to defer the decision. It sounds like a fair bit is going on. There are a few loose ends but not major ones. There are some that relate specifically to the use of genetic information and privacy, as well as some data-sharing issues with the electronic medical records and information sharing there.

The question then becomes, do we monitor all of this at the moment or do we form a little workgroup to sort out whether there is something here that we can actually begin to do that will help inform this discussion? That is what I would like to hear.

DR. WILLIAMS: Joe.

DR. TELFAIR: Thank you. I appreciate the information because it narrows the gap a little bit. I guess my outstanding question in terms of a direction to go is, what can we make in terms of a contribution. I would recommend looking at the question related to the last item they discussed, which is vulnerable populations. How does

this work within those groups.

I think much of what is being discussed is general population issues, but one of the things we do have a charge for is also looking at whether there is discrimination in working with vulnerable populations and then the permutations that have to do with that.

I don't know if there is a grant area around the whole thing. It seemed to me that we can focus on this one area. Maybe we can look at some of the other ones, but this seems to be a reasonable one that we can put on the table given that so much else is being covered. That is just a recommendation.

DR. BILLINGS: In response to your comments, Steve, I think it was fortuitous that you had Rod Howell there, too. The point about what can be done with the Guthrie cards, that issue has been out there for a long time. I can remember an article by Phil Riley about this 15 or 20 years ago. That seems to me to be a practical genetics issue for this Committee, in conjunction with the activities that Rod is leading up, however they might proceed.

It is an important issue. We were talking about

all these new technologies that can be applied. You can sequence the whole genome off these cards, maybe. What would that look like. What would the opt-in/opt-out rules look like for that, if any. How would it be used. As you said, it is a really nice non-biased population as well because it is broad. There are some positives and negatives to it. It seems to me that is a really interesting, specific issue which has been out there. It doesn't seem to be answered in policy yet, so we may actually have something useful to say.

DR. FITZGERALD: The question there would be how much of that is going to be addressed by that NIH grant that went out for the translational work in the newborn screening. I don't know that. We could ask Rod or we could ask ACMG.

The other would be taking that and saying, in a sense, that too is vulnerable population. Getting back to what Joe just said, depending on how we define or delineate vulnerability, that could be an issue that would be important to look at. That does raise in particularly emphatic ways some of these issues that, when you look at it more generically, don't necessarily get highlighted as

strongly. I would say that would be something that would be a possibility.

DR. WILLIAMS: This goes off of what Gurveet mentioned about the AHIC successor. The other thing is that there was just an announcement that came out about another Secretary's Advisory Committee on Health Information Technology that is going to report to the Secretary of HHS. Now we have, by my count, four Secretary's advisory committees that have some piece of this pie.

It seems to me that one tangible suggestion would be to create a formal liaison group between the different committees that can assess where there is overlap and then perhaps in some ways divvy up the work so we don't all end up doing the same thing. It might be good to have that group have the responsibility to say we are going to charge SACGHS with this and the Newborn group with this and Human Subjects with this. It might be a possible way to move forward.

DR. TEUTSCH: I agree. The Guthrie test issue and what we do with it longer term sounds like something that your Committee, Rod, is grappling with and falls

naturally in that sphere. If you had something that could inform that, I think it would be good for us to know.

Would you have a concrete recommendation for next steps?

DR. FITZGERALD: I think the idea of coordinating with the other advisory committees is key. I think that is going to be important. I don't know if the other committees have the same charge as we do with regard to a group like vulnerable populations. We are genetics, health, and society, and that would seemingly be within our purview. Depending upon how that gets delineated, maybe that is the next step. If there is going to be some information gathering in this area, the step between now and the next would be how are you going to delineate vulnerability and what is that going to mean.

As was mentioned here, certainly you have populations that are vulnerable because of particular medical conditions they may have. You have populations that are vulnerable because of historical or socioeconomic situations, like Native Americans or the poor. It is going to be important to figure out first how to delineate that and then see where you want to run with it.

DR. TEUTSCH: We also have the whole topic of vulnerable populations under our population health component. The issue here is that of privacy, research, and consent for those populations, which is a discrete subset. The question is, do we look at that more broadly in some other way.

DR. BILLINGS: I was just going to point out that the Common Rule has provisions for vulnerable populations as well. It is consistent in that sense as well.

DR. WILLIAMS: In terms of trying to make our work efficient and not to necessarily transition us into the next topic, one of the groups under education and training has a focus on educating the public. I think we heard loud and clear from all the folks up here that we need to be engaged with the public and we need to have some role there.

It seems to me that there could potentially be some overlap with what we are going to hear about from Barb in a couple of minutes regarding what that task force is up to and how we could add in perhaps a piece of that and work together.

DR. TEUTSCH: I'm fine with that. I also think

that I'm hearing a lot of concrete suggestions but nothing I think we are ready to quite talk about in a major way. We may ask you, Kevin, and maybe a couple of other folks, like Charmaine, to come back to us in June with something more concrete. We can learn about whether there is interest in having this consortium of the other agencies or the other committees. I'm not sure we are ready to proceed with those at the moment.

DR. FITZGERALD: I would certainly be happy to come back tomorrow, but June, I don't know.

DR. TEUTSCH: You have June and you have October.

DR. FITZGERALD: I would be happy to work with Charmaine.

DR. TEUTSCH: Then we can explore some of those other issues.

DR. FROSST: I would like to follow up with a point relevant to what he said, which is that I have been mulling over since you said it the idea of these other Secretary's advisory committees and the vast amount of effort it takes to put together one of the reports that we do. I wonder if perhaps the other committees don't feel the same way about the herculean task that they take on.

There may be a way to merge a few of the committees together on a topic that is of relevance to more than one. I think to hit all four would probably be overly optimistic, but fantastic if we could. So this committee takes this view of it, and this view of it, and this view of it, and we come together at the end with something that really benefits the Secretary or whoever it is that is really looking at our products.

I have to say that in terms of process of doing this, I'm not sure exactly what the best way is to do it.

DR. TEUTSCH: We can certainly put feelers out and have discussions with them before we actually recommend doing something to see what the receptivity is to that. Yes, David.

DR. DALE: I think this is a really important issue. I'm an active researcher. Almost every day this issue is in the way of the research, particularly for multi-institutional studies.

In my work, I have a compartment of isolated computers for clinical data and isolated computers for genetic data, and I have difficulty in linking them. I have another filing cabinet full of paper records which I

can't look at between the people working in the space.

This is multiplied by the multiple institutions. We have trouble cooperating with Canada because of our HIPAA regulations. It is just a mess.

I think it is a very constructive thing they have done. I don't quite know what to do because I haven't read the report yet, but I think that at our next meeting we should talk about this substantially.

DR. TEUTSCH: I do think we need to have some of these discussions offline. Kevin, if we can wrap you at least into some of that with a twist. Charmaine is obviously going to be interested in some of that as well. We need to get her up to speed. People need to have a chance to review this report and tie it to either work of these other committees, the vulnerable populations, and some of the data sharing issues.

I think there is plenty on the table here. It is just what we can bite off that is not going to add to the noise and be constructive.