Federal Perspectives on the Need for a Large Population Study
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DR. TUCKSON: Now, let me invite Stephan Fihn from the Department of Veterans Affairs. Stephan will be followed by Alan Guttmacher, and then by the committee's own Muin Khoury.

DR. FIHN: Hi. I'm Steve Fihn. I'm going to try and make this very brief, because I know you are running behind schedule. Some of the material I have overlaps with what has been presented. I have to say that our planning is in the very early rudimentary stages. Really we don't have a formal plan. It is a great honor and privilege to come and talk to you all, just to sort of give you an idea of what we've been thinking about.

Basically this has been an idea that has been evolving with the Department of Veterans Affairs now for about two or three years. Many of you may not know that this is the largest integrated health system certainly in the United States, and potentially elsewhere.

We do have an integrated intramural research program. So to many people, it is thought to be sort of a natural thinking to whether or not the notion of both research in genomics, as well as clinical genomic medicine, could be brought to bear in a system like ours.

The goals of this program really would be three-fold. Much of what has been discussed is research and development related to genetics. This would be particularly in regard to clinical programs that would target drug response and prevent adverse reactions.

We already know now that there are commercially available tests that relate to genetic susceptibility. There is no doubt that there will be many more coming onto the market in the scientific marketplace in the very near future.

One of the questions we have is how do you implement these sorts of things in an actual clinical health system, and can we early in this process develop the research and development for these kinds of tests and intervention within a clinical health system? Obviously we'd like to pursue the same kinds of research that have been described here in terms of understanding better roles of genetic factors in both the prevention and causation of disease.

Then we need, like everyone else, to think about what the information systems look like for collecting and making these data available.

The obvious question is why would the Department of Veterans Affairs be doing this. I think that's a reasonable question. As I said, it is a large, integrated health system with a very relatively stable patient population.

The turnover within our system is far, far less now than in commercial care these days. It is a very large system with somewhere around 5 million active users. We probably have the most advanced electronic health record in the world which collects copious amounts of data, clinical, administrative, and demographic.

As I mentioned, we have a very large intramural research program. Many investigators are already doing genomics at a very small scale. One of the goals of course would be to coordinate and pull much of what is being done together into a more organized and centralized activity.

Again, as a health care system, we can't ignore this sort of incipient issue, the clinical issues that are I think on the horizon. The other thing is we have actually now had an opportunity to discuss with veteran service organizations and with patients, and somewhat surprisingly, we often hear about patient concerns.

There is also a great desire among patients in our system that we've heard obviously done with all of the necessary ethical and administrative controls and governance. But given that, they think this would be an important part of the medical care they receive, and actually have given a lot of support and enthusiasm for thinking further about this effort.

There are a lot of existing resources, as I mentioned already. We have already got several sanctioned DNA repositories. Many of these have emanated from ongoing clinical trials or other research. I suspect, like many research organizations, there are probably other smaller biorepositories in our system that really aren't registered, and that we don't know about. That's one of the issues, to try and get a handle on all that is already out there.

We are very, very early in the planning. Of course, it has been very interesting to read and hear about what other people are thinking technically and technologically. We have a lot to learn and gather, I think. Possibly by being a little bit behind the curve here, we can, as was mentioned, benefit from the work of others, and do things in a way that will be congruent with other studies that are ongoing.

We are looking at a number of collection techniques, as well as obviously we are not going to go out, as was suggested in the biobank, and immediately enroll 5 million people into a database. We discussed all sorts of phased entries and variable specimen collections, and probably, like the other studies, will settle upon a hybrid approach which involves a combination of those.

One of the issues, again, as we're in a slightly different position because we're not exclusively a research organization, we're not a private foundation or corporation, we are a federal health care system, we would obviously insist on absolute control and ownership over all of the materials and information that were gathered as part of this effort.

We already have in place because we are a research organization, a fairly stringent set of policies for human subjects, protections, intellectual property, conflict of interest, privacy, and scientific merit evaluation.

We are also in the process of designing additional further protections for this in particular, which would, again, like the other projects, involve an independent, separate oversight board composed of both federal and private representatives.

Issues that we've struggled with are no different than what it sounds like that everyone else has struggled with. Governance and protection of confidentiality. A particular issue, such as some of the other studies, is one of our strengths we think would be to link any data that we collected with our electronic health record.

Of course, this presents lots of questions as far as confidentiality and privacy. They are not completely new to us. Our health record obviously already has a lot of extremely sensitive information in it about a patient's HIV status, drug and alcohol, and so we really feel like although we need to be absolutely certain, this isn't completely new ground for us.

We are particularly sensitive to the notion of exploitation of patients. As I said, we've got a very loyal group of patients. Enrollment in our studies, the agreement to enroll is often in the neighborhood of 80 to 90 percent of patients who volunteer for studies, and retention rates are often in the mid to high 90 percent.

So I think because of that, we feel a very special reason to make sure, because veterans tend to feel a special bond to the Department of Veterans Affairs, that we have to be absolutely sure that there is no sense of taking advantage of patients, either with their participation in the study, or the use of information that is gathered.

We are working hard on collaborations. We are talking to several other federal agencies, particularly in this period of budget austerity. We think it is really important for us to think about what we can do collaboratively as opposed to independently. We are, as I said, looking very carefully at the logistics, who the patient sample would be, and how it would be enrolled.

Our thoughts are that we will actually do this through our clinical programs. I mean, essentially we've got labs, 800 labs already around the country that could assist in specimen collection. Of course, we have to deal with transport, storage, and all the rest. It has been discussed.

We need to think about what additional unique exposure data we would have to collect from patients, and how that would happen. Cost is a big issue. We have not figured out precisely how this would be funded. Our current research budget in and of itself is insufficient to fund this effort. My suspicion is it would be through special programs through the Department of Veterans Affairs, as well as collaborations with other agencies.

A big issue that has come up early in ours is the intellectual property issue. There are strong commercial interests in this kind of information. We have really had to grapple early on with that.

I'll just stop there, since I think the issues are similar to other folks.

DR. TUCKSON: Stephan, thank you very much for your presentation.