Overview of Priority Setting Process and Outcomes to Date
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DR. TEUTSCH: If not, then we are on to the focal point of this morning's discussion, which is the work that's been going on by the Priority Setting Committee which Paul has so ably led.

DR. WISE: Thanks so much, Steve.

Basically, you remember that back in the February meeting the committee for setting priorities was established with a primary goal of facilitating and guiding the process of identifying new priorities for this Committee for the coming several years.

The Committee is made up of these individuals, as you can see.

The goals for this morning, particularly for the discussion. Number one, to review the priority-setting process that we have employed. Second, is to review and to discuss the issue items that you all voted on and an exploration of the results, and how to best put together and digest those results. To reach preliminary consensus on the high-priority issues, or categories of issues, worthy of developing a further issue brief over the subsequent few months, and to review and agree on the next steps in the process.

[This is] just a timeline to remind everybody. Beginning in February at our meeting and then in subsequent activities that I will go into greater detail in a moment, 73 issues were identified for assessment by the taskforce. The items were listed and sent out to the members and ex officios for voting and for scoring in June. The results were then tabulated. The hope for today is that we come to some approval of the process and some general consensus on categories of the 73 issues that merit further exploration by the full Committee.

From July through November the issue briefs will be developed and sent out to the full Committee for review and deliberation. In the December meeting, final decisions will be made on the study priorities.

Now, the process for identifying the issues for consideration had several different elements. The first was the discussion that we had back in the February meeting. Careful notes were taken and issues that were brought up were put together as part of the general list of issue items.

We then solicited additional items for consideration from the full Committee, particularly the members, and then a conference call with the ex officios to explore even further potential issues that should be considered by the Committee. A request for public comments also went out that generated a large number of very helpful suggested items. Also, conversations with people that we called horizon scanners, people who are thinking about the future of how genetics will interact with societal forces.

The request for public comments went through the usual mechanisms, including the Federal Register, the website, and the distribution list. However, it was also supplemented by special outreach efforts to reach a variety of different organizations, including consumer organizations, medical associations, groups particularly focused on healthcare disparities, and representative business groups and payers.

The horizon scan activity was basically a prolonged interview with some selected people who travel in this arena. After taking suggestions from members, discussing it, talking with the

potential availability of a variety of these people, these five people were interviewed by taskforce members. You can see their names and affiliations here up on this slide.

We then had to make some sense of how we would begin the prioritization process, and that was done through the scoring of the issues. Of the 73 issues, the majority came from the public comments. Sixteen came from the horizon scanners. The Committee, staff, and ex officios generated 18. Office of the Secretary generated five. One of the articles that was discussed back in February suggested one. This generated the full list of 73 issue items.

These 73 items were then sent to members and ex officios for scoring based on a simple one-through-five scale, one being not important, five being very important.

The criteria for the scoring were the same as had been used in the past that accompanied the request for public comments. [They] accompanied the request for scoring. Just to quickly go through them: the urgency and national importance of the issue; the extent to which the federal government has jurisdiction and authority over the issue; the need for federal guidance or regulation on this issue; whether the issue raises concerns that only the federal government can address; whether the issue raises ethical, legal, social concerns that warrant federal government involvement or leadership; whether the Committee's policy and advice on this issue would significantly benefit society.

Continuing, whether the failure to address this issue would prolong any negative impact the issue may be having on society; whether there is sufficient data about the issue that exists for the Committee to developed informed policy advice; and whether another body is already addressing the issue or is better equipped to address it. Lastly, whether the issue is within the charter of this Committee.

Basically, the scoring was built on the scorer's general summation of these issues rather than voting on each individual criterion.

This is a histogram of the results. It basically shows here the two lines which point out the top 10 and the next 10 rankings of the issues, where they fall in the general distribution of the scores. These are scores that are the total average scores for the members and ex officios' scores

These are the top 20 items that were scored highest by the Committee members. I'm not going to ask you to memorize this list. We are going to go through it in some detail over the next few minutes. But you can get a sense that some issues scored higher than others and also that many of these issues relate to one another. There are certain clusters of issues that were identified as high scorers just by the simple one-through-20 ranking.

Now, the taskforce had to come to grips with, okay, how do we begin to make sense of 73 issues, all with individual scores. We could just take the top 10 as they are listed here and just hand them off for the development of issue briefs, more detailed exploration of these issues for consideration by the Committee in voting in December.

However, it was pretty clear that not only just on their face many of these issues relate to one another but also that there were likely to be patterns in the voting that would also help us to assess the clustering of some of these issues into categories worthy of further development.

So what we did was basically employ a mechanism to look at the profile of voting patterns. This is just a heat map.

[Laughter.]

DR. WISE: It shall be explained. The geneticists in the audience will recognize exactly what this is.

Basically, what this pattern does is the deep red are fives and the very pale, beige-yellow is a one. You can see that this doesn't become totally clear at this point.

[Laughter.]

DR. WISE: But, that you can begin to see that in fact that some of the members, which are arrayed here along the bottom, and the issues over here, voted in very similar ways to other members. In fact, when you look at the voting pattern and how well it matched, it sort of looked like Eharmony.com. It really says something about your personalities as well as the issues that you voted upon.

But these brackets to the left and along the top are actually graphic depictions of how tight the relationship and the voting patterns are between different issues and between different voters.

I will move on and blow up one just randomly selected portion of this graph and magnify it. You can see that a very tight bracket here with a very short distance from the margin implies a very tight fit. A long distance, like this cluster versus this cluster, with very tall brackets implies not a very good match, in fact dissimilarities between the two.

When we begin to look at the clusters of the issues to see which issues look very much like other issues based on the voting patterns rather than just the face validity of the substance as we would see it from these issues, you begin to see clusters emerge.

What I have done here is put in the red arrows the top 10 issues as they emerged from the voting. The brownish-yellow are the next 10 in the overall voting score. What you can see is that in fact there are clustering of high scores in certain arenas. What it did was it allowed us to not only look at the top 20 list but also begin to see that in fact there was clustering of voting patterns that would also, or should also, inform the way we put these issues together for further consideration.

The red are the top 10, the brownish 11 through 20, and then the next 10 are the yellow. I'm going to go through this in detail, so if you can't see, this is just to show clustering, not to go into the elements of the clusters.

Basically, of the 10 20 to 30 highest-ranking scores out of the 73, this is the general pattern that began to group these together. I will go through these in detail.

Basically, the names I have chosen are not catchy. In fact, they are supposed to be as boring as possible because, really, we just want them as generic descriptions of the categories. But you can see that genetics and healthcare reform represented a cluster. Ensuring the clinical utility of genetic information was another. Some people might read this as more of a translational set of activities. The public health applications of genomic research, consumer access to genomic information, informed consent for genomic data sharing, coverage and reimbursement for genetic services, education of health professions on genetics, and genetics, minorities, and health disparities.

Now, interestingly and importantly, many of the individual, if not most of the individual, issue items that hit the top 20 as well as the ones that populate these areas were suggested by the public comments.

Now, looking at the genetics and healthcare reform cluster, these are the issues that were rated highest: the role of genetics in healthcare reform, integration of genomic information, clinical decision support, incorporation of genetics into electronic medical records, and implication of structural changes in healthcare delivery.

Now, these are all in the materials. They are all outlined in greater detail in the book that accompanied the scoring for each issue item. But I'm really just putting this up on the screen to get a sense of how the clustering seemed to take place and that it has some face validity. It makes sense; people did not vote randomly. In fact, they elevated things that tended to fit certain patterns.

Ensuring the clinical utility of genetic information. These were all heavy hitters. They all came up in the top 10, except for this last one that fell somewhat below, into the top 20.

Yes?

DR. EVANS: I understand that these ended up being clustered by voting patterns, but I don't think that necessarily means that they indeed belong together. For example, while I think evidence development is extraordinarily important and the impacts of personalized medicine on health care are extraordinarily important, I don't really see those as being in the same category from a logic standpoint, not from a voting standpoint.

DR. WISE: Right. Ultimately logic will have something to do with the priority setting process.

[Laughter.]

DR. EVANS: We are hoping.

DR. WISE: But we must dissociate the logic from the voting at some level.

The clustering that I'm suggesting is a starting point for the discussion, not an endpoint. In fact, the voting and the clustering that I'm suggesting should provide guidance to the process but nothing more. We have the ability in the discussion today as well as subsequently to rearrange these, to move them, to create new clusters or new categories that are worthy in and of themselves for the development of issue briefs. This is merely a starting point. This is to provide guidance.

But it does provide guidance. The scoring did result in, definitely, the elevation of certain issues and the devaluation of others. That guidance is important, but it is merely guidance. We will have time to rearrange these.

The public health applications of genomic research.

DR. TEUTSCH: Joseph, did you have something?

DR. TELFAIR: Yes, sir. Dr. Wise, I just have a question.

DR. WISE: Please, Paul. Only my mother calls me Dr. Wise.

[Laughter.]

DR. TELFAIR: Well, you don't live where I live.

The question I have is based on your last statement. Does that mean that the criteria we used that guided the voting would also be part of that consideration when we decide the prioritization of these items as well?

DR. WISE: Yes. The suggestion is that the criteria for voting would also be the guiding force in how we ultimately decide by December on the most pressing priorities for the Committee's subsequent action steps.

DR. TELFAIR: Thank you.

DR. WISE: Consumer access to genomic information. Again, some heavy hitters in the top 10 can be identified here. Again, some of these we could pull out, some of these people may find are not appropriate because of certain other criteria on the list. Others may be brought in or explored differently, but based on the issue items and their voting pattern and their voting priority this area seemed to be extremely important.

Informed consent for genomic data sharing was another arena. Coverage and reimbursement for genetic services was felt to be important but did not rise to the top 10. It was in the 11 through 20.

Education of health professions on genetics was quite important. In fact, it was among the very highest scorers, and that is good because we have a standing taskforce dedicated to address this issue. I will talk about that in a minute.

Genetics, minorities, and health disparities. Clustered, it was not among the top 20 but was very close to the top 20. It fell between the top 20 and 25.

Next steps. Basically, the next step would be a discussion here to both comment and find consensus and general approval of the process that the taskforce pursued in generating this list of important potential priority items for the Committee and the development of issue briefs: in other words, the clustering or categories of issue items that are worthy of further exploration by the Committee.

This we would coordinate intensely with the Evaluation and Education Taskforces. The Evaluation Taskforce name may undergo some change, but it was clearly recognized that many of the issues that we were identifying as very high priority would likely fall into the purview of what we are calling the Evaluation Taskforce. In speaking with Mara and Steve, the suggestion is that the development of the issue briefs for categories of issues that likely relate to the purview or the charge of the Evaluation Committee and the Education Taskforce will in fact be done in close coordination with these taskforces, taking advantage of their expertise and commitment to explore these issues in greater detail.

DR. TEUTSCH: Just a reminder for those of you who may have forgotten. We did have an agreement about a year and a half ago to create a taskforce based on some issue briefs that dealt

with a series of translation, evaluation, and economics issues. That was deferred. It was approved by this group but the committee's work was deferred to get on with the oversight report.

Mara has agreed to lead that effort. She has a group of people that have already been identified. But that work is now beginning, as opposed to the education one, which has already moved nicely along.

DR. WISE: Thanks, Steve. The issue briefs being developed can reject elements that came up high on the list or include others or other things that come up over the course of the conversation and the discussion. The voting to date on these issue items are to provide general guidance to the development of these issue briefs.

These issue briefs will then be distributed to the Committee for review, and we will vote on these issue briefs and ultimately select the priority issues for subsequent action steps. Thanks.

So I expect that my presentation may have generated some questions or points for discussion. We now have some time to explore through open discussion any issues that you may want to raise.