Next Steps

DR. WISE: Mara.

MS. ASPINALL: I would agree. I'm trying to think about [this] timing-wise [and] whether that is a real time issue or that is a between-meeting issue. But I think it would be helpful and will have to be done anyway to move forward so we are not repeating things unnecessarily.

I guess I'm going to go back to the comments about time sensitivity. How do we want to deal with that issue to, as we have heard a lot of times, take advantage given some challenges, but to be able to prioritize some of these issues separate from what we have done in the past.

What I have heard from this discussion maybe, then, is two key things. One is reviving in some way what we have done in the past to ensure that it continues to be a priority with the next administration in an action-oriented way and not just for the sake of listing it.

Secondly, the potential of fasttracking a couple of issues so that when the administration is coming in and maybe immediately post the December meeting, hence work between now and December, that we have some prioritization of issues that can go to the administration. Given that may have to happen right after the December meeting, I think we need to discuss it today so that we can do the work between the meetings and get it approved by this group so it is ready in December.

DR. WISE: Comments or suggestions on what Mara is proposing? Really it is part of Next Steps.

MS. ASPINALL: It is basically an additional next step that would be required between meetings. To me, it doesn't change the fundamentals of the processes you outlined, which I think are the right ones for our long-term priorities, but ensuring that as a group we hit the ground running with the new administration on summarizing the existing issues and prioritizing one, two, or three new issues.

I have heard a lot of consensus about that, but I just want to clarify that. Whether it is the Evaluation Taskforce or another taskforce, there is some additional work to be done that can be presented in more specifics at this meeting in December.

DR. WISE: Kevin.

DR. FITZGERALD: Just to build onto that some of the issues that Paul brought up, again, when we identify the things that we have already addressed, perhaps with some comprehension, it might be helpful to also identify, if we can, why we think these things have perhaps not yet been fulfilled or our recommendations have not yet received the kind of traction we thought they should.

Maybe then [we could] come up with further specific recommendations to say on this issue, then, we recommend in addition XYZ. That, I think, could be done in a relatively succinct way without perhaps having to garner a great deal more information or expert opinion, although we probably have to make sure there is public consultation.

DR. WISE: Other comments, questions, or concerns? I should just remind everybody that the last time the Committee went through the priority setting process I believe there were 12 issue briefs created. So in fact, we have identified a smaller number of candidate issue briefs right from the get go. It may be, given that we have two standing taskforces already up and running, that, clearly, one would have direct relevance to some of these topics. [As to] the other, it would be more engagement with the taskforce to identify specifically which of these arenas it might capture.

But there is an infrastructure already in place that could fasttrack some of these issues to move it forward more quickly as opposed to relying strictly on creating a new structure. So I think we are well situated to respond to what Mara is suggesting.

Sarah, do you want to make any comments on fasttracking certain selected issues that we can identify here today?

MS. CARR: I think that is a decision for the Committee to make. If the consensus is that you want to do that, we want to honor this process but not to the point where you are not comfortable with the process and you think there are some things that need to take precedence. So I think we should be open to that.

DR. WISE: Other comments?

DR. EVANS: I think we should do that. What is the available time during this meeting to hammer out what we would think should be fasttracked?

DR. TEUTSCH: We have time until 11:30 today, but then we have time again tomorrow to have further discussion. What I would suggest is that, without talking about exactly what we are going to do or what the priorities are, we get some consensus that these are the right clusters. If we can get there now, I think we will have gotten part of this done.

We can delegate back to the Priorities Taskforce exactly what these issue briefs look like, and they don't have to look the same for everything. If it is on reimbursement and coverage it probably is more of an update of what is going on. As Kevin says, what would it take to move us to the next step. Others might have to be more elaborate because they are new.

Then, tomorrow we can deal with the issue that I think Paul Billings brought up and I have heard now coming up in other places: are there some things that we can move forward now that are at the top of the list that we really want to focus on so we can move more aggressively on them.

Particularly, if there is a topic or two that fit in with what we call the Evaluation Taskforce that we can say we actually want to move on even more quickly or move into the Education group, then I think we might be able to meet most of the needs that I have heard here today.

DR. WISE: Paul.

MR. MILLER: Along those lines, maybe I will something concrete. I would recommend that on the cluster issue called informed consent for genomic data sharing, following up on Kevin's point, I would broaden the title of that. One way of doing that is to add a couple of commas. You might say "Informed consent, privacy, and discrimination." Maybe throw discrimination in there, maybe not. But, to broaden that out to that family of issues that go around genomic data sharing.

I think that would more appropriately describe the kinds of issues that that cluster would sift through and do.

DR. WISE: Jim.

DR. EVANS: I would agree with that. I think it addresses the one thing that seemed lacking. I think that is a great general cluster. I think one thing that is lacking at least in any kind of explicit way are two of the issues that were in the top 20 regarding the electronic medical record. It could be the perfect place for that.

The other thing that I would suggest as far as these broad categories is, [instead of] "consumer access to genomic information" perhaps "implications of genetic information as a commodity" or "as a consumer commodity," something along those lines. I'm not sure what is meant by "consumer access to genomic information." We need a different header for what was addressed by the priorities there.

MS. ASPINALL: Maybe, given the broad issues there, it is consumer issues with future access to genomic information. It is this afternoon and tomorrow.

I didn't want to get into implications, but just what are the issues. The deliverable here may be identifying the myriad of issues firsthand. The second level may be what do we want to do with them. So we are, again, trying to be action-oriented and specific.

DR. WISE: That is really helpful and clearly would fit easily. Gurvaneet.

DR. RANDHAWA: This is just a comment, and I'm sure this can be done when we work on the issues briefs. But on the first one, genetics and healthcare reform, it just seems so broad and daunting. The two things that are discrete within that, which are the electronic medical records and getting the genomic data integrated in that, and then the clinical work flow issues and clinical decision support, are fairly discrete items to work on while this topic by itself is a fairly broad topic. But that could be done in the issues brief.

DR. WISE: Julio.

DR. LICINIO: When I looked at this I thought that healthcare reform is a very political topic and not within the scope that I have to decide if there is going to be healthcare reform and how to put genetics there. If we put "genetics and healthcare reform," then we have to talk about healthcare reform. Are we the best group of people to be discussing healthcare reform.

DR. EVANS: I think that the issue rose because of the specific implications that the rise of genetic medicine has for healthcare delivery and the structure of health care, which of course has a big impact on healthcare reform. My personal feeling is that that is a reasonable thing to have on there.

Now, it is very broad and whether it is something that should be triaged to a high position or not I don't really have an opinion on at this point, but I do think there are very specific aspects of genetic medicine that have a big impact on healthcare delivery.

DR. LICINIO: Why don't we put healthcare delivery in the title? If it's not on the political agenda to do healthcare reform right away, then the whole thing dies.

MR. MILLER: I would suggest that we do healthcare delivery. Healthcare reform may come with a connotation implied within it that we as a Committee might or might not, or appropriately or not, want to say. Really, what we are talking about is whether we reform the healthcare system or not. We are really talking about the issue of genetics and healthcare delivery or the healthcare system, regardless of whether it stays the same or is reformed.

MS. ASPINALL: I agree. I think "reform" has political implications. I just think about the future of health care. I like "system" more than "delivery" because it may be broader than delivery. It is everything from products to structure to the fundamentals of it. So I would go with system or future. I know I wrote one of those, and what I meant is not necessarily somebody's capital letters, "Healthcare Reform," but rather how health care will be reformed and will be changed by genetics. So, "system" or "future."

DR. EVANS: I vote for "system." "Future" sounds subtle.

MS. ASPINALL: Too big.

DR. EVANS: Yes.

DR. WISE: Steve?

DR. TEUTSCH: I only want to comment that within the write-up were issues of the implications of the innovations in the healthcare system. So much of it is about innovation and the economics, some of which will probably fall to Mara's Evaluation group anyway, that are embodied within this.

DR. WILLIAMS: Can I get in here? This is Marc.

DR. WISE: Hi, Marc.

DR. WILLIAMS: Part of me says the discussion that has gone before is relevant to this idea of healthcare reform. This is a huge topic. Obviously, there are going to be a lot of variables. But I think there is one very specific thing that is very relevant to genetics and genetic testing and the Department of Health and Human Services, and that is how Medicare is going to define this in respect to their preventive medicine exclusion. That is something that is, to some degree at least, under the purview of the Secretary.

I would think that working to try and understand how CMS is going to be interpreting these tests as relates to their preventive medicine exclusion would be extremely important and actually would be doable in a relatively short time frame.

DR. WISE: Thank you, Marc.

DR. TELFAIR: What is not up there, and maybe this is a next step, is what I think has run through the discussion most of the morning. Of these clusters and of the subgroupings within these clusters, what have we already addressed, first of all. Second of all, some recommendations were made when you look at the individual, broad groupings under each one of these. You made recommendations specifically to retooling these as well. Maybe that is the next step, as opposed to what we are doing now.

DR. WISE: Yes, that would be included in the information for the issue brief so that the decisions about priority setting could be made on the basis not only on the importance of the issue and its nature but also its strategic role in this Committee ultimately taking effective action. Have we done it before, are other groups doing it, what is left to be done, what continues to be undone in the real world.

DR. TELFAIR: I guess my point is that we are walking through agreeing or not agreeing on whether or not these clusters make sense and we want to follow that through, but it seems to me that part of the information is missing from what we have already discussed. We need to include that in this because we will repeat this process again once we follow through with that.

That is the point I'm making. Should we go back to some of that information that we have already agreed to and come back and look at this because it sheds a different light on the list, to me, if we take this other information we have already discussed. Which are the categories, which are the recommendations, and that sort of thing. That is the point I'm trying to make.

DR. WISE: Can you give an example of what you mean?

DR. TELFAIR: Yes. For example, it was brought up earlier, public health applications and genomic research. One of the points that was brought up was also within public health is that several of these categories -- for example the education and health professionals, consumer access to genetics, the whole issue of genetics and healthcare within the system -- all actually fall under the broad category of public health applications.

DR. WISE: It does fall under it, but it is not coincident. It is not the same thing. There may be other aspects of public health that do not fall under the other categories. The issue brief will try to identify what those are, including occupational and some other things that came up, to see if it should be renamed, if it should raise issues that we haven't yet discussed here, for deliberation by the Committee. If it is felt it just doesn't cut it, then it falls to the wayside.

If the question is, is there sufficient utility in that category as it relates to moving forward with an issue brief, nothing more than that, that is where I would hesitate just chucking the whole thing on the basis of what we have got so far.

DR. TELFAIR: You just made my point. It is not so much chucking the whole thing, it is restructuring it based on the discussion we have had. You just restructured it and said we need to look at it. That is actually the point I'm making.

DR. WISE: Great.

DR. FITZGERALD: Just for clarification to try and avoid some of what Joe is hinting at here, or clarifying, one of the things we have run into before is this distinction between genetics and genomics. If you look up there, sometimes we say genetics and sometimes we say genomics. I think we just have to be careful when we determine our clustering exactly what we are talking about with regard to that.

Then, to respond to Barb's question before about the minorities and healthcare disparities, one of the issues we ran into was the fact that there isn't good evidence as to the potential exacerbations or the potential positive contributions that genetics and genomics can make to addressing those issues.

So again, that would be an example of a concrete suggestion or recommendation we could make to the Secretary. I think we have actually addressed that in some of the reports perhaps more tangentially, but to say in order to get at this somebody has to come up with this data, not that it is going to be easy to do.

DR. TEUTSCH: Let me see if I can pull some of this together. What I have heard here is that these general topics, and we have heard a lot of suggestions about how they can be somewhat reconfigured, whether they are stand-alone, whether they are cross-cutting. I have not heard a lot of suggestions about topics that have been missing from here. We have gotten a lot of advice about how we can recraft the names, how we can move around some of the subtopics, but people are generally okay with this set of issues.

Before we break, because we have 2.5 minutes, can we get agreement that this is a reasonable set of issues?

DR. EVANS: As long as you get the electronic medical record, since that is such a big topic.

DR. TEUTSCH: It was one of the issues within this that Paul showed us. We have a lot of specific suggestions about what needs to be tweaked and what are likely to be priorities or issues that need highlighting, but I got the sense this is a reasonable set of issues.

MS. ASPINALL: Yes.

DR. FITZGERALD: I think it shows that, perhaps contrary to past precedent, we voted with some logic.

[Laughter.]

DR. WISE: Don't get carried away. We have to vote again.

DR. TEUTSCH: I got the sense that Eharmony works. There are things like that, too. But we have to be careful.

[Laughter.]

DR. TEUTSCH: Any dissent, though, to that set of issues?

[No response.]

DR. TEUTSCH: If not, then what we will do tomorrow is we have an hour. What I would like to do is deal with some of the things that we heard earlier. Are there things that perhaps aren't even worth our time at this point that we should drop off, and are there a couple of issues that we should highlight that one of our existing committees [could take up], or other kinds of things that we should take up with a greater sense of urgency over the next five months before we reconvene and actually vote on a priority.

Is that a reasonable agenda for tomorrow?

With that, then, first let me thank Paul for his enormous amount of work.

[Applause.]

DR. TEUTSCH: And to the staff for pulling all of this together. It was an enormous effort. We are most appreciative to you, Paul, for leading us through this discussion.

We are going to wrap it up, and we are going to now depart for the Reagan Trade Center. There is a bus that is outside the building on Second Street. For those of you that have lunches, you can pick them up here. For those of you who didn't, you can get them over at the Reagan Building.