

Genetics Education and Training Taskforce Progress

Barbara Burns McGrath, R.N., Ph.D.

[PowerPoint presentation.]

DR. McGRATH: Thank you. As Steve said, our level of activity has been steadily increasing, so you will be seeing more of us over the next couple meetings. I will just launch into this one today. Today is one of the more brief ones, I think.

We have a couple goals. I will give a report about where we are in the progress. The bulk of the time we will be spending this morning on the update on the data-gathering activities. Each of the leads of the workgroups will be talking about their specific activities.

Then, we have saved about 20 or so minutes at the end to discuss workgroup policy directions. Let me explain that a little bit. We have not completed all of our data-gathering activities. You will hear where we are in that process. Clearly, we are not at a point to have any final policy directions or recommendations, but we have some thoughts on these things and we will be presenting those to you today. What we are asking from you is to give us some feedback and perhaps guidance on a conceptual level.

Our next step is to draft these guidelines to draft form. However, we are not looking to fine-tune our recommendations at this point. There will be a chance for that in future meetings. I'm asking us to think big picture still with us on this, to make sure we are covering all of our bases.

Having said that, on the other hand, we are past the point of really wanting to brainstorm and bring in all ideas and all comers. We are at that middle point of looking for feedback and guidance from you, not fine-tuning but not brainstorming. I think that will be clear as we go further.

Here is our roster. Each group will describe who is on their committee. As you can see, it is pretty big. I think we are in pretty good competition with the Oversight Committee. I'm not sure. I'm not counting one for one, but I think we have a pretty robust group.

The other people that need to be added on this, of course, are the staff. Kathy Camp has been leading our efforts. You have met Brian Haugen and Alex Lynch, the two people who have been with us this summer. They have been helping a ton on this.

As you know, we have organized ourselves around core concepts. One is the Consumer group that Vence Bonham is the lead on. The Health Care Provider group Greg has been leading, and David Dale now is taking over as the incoming chair. Joseph Telfair continues to be the chair of the Public Health Provider group. Although he has rotated off the Committee he has been very involved, and I appreciate the fact that he is staying involved. Today Kate Reed, who has also been very involved in the committee, will be presenting their report.

I'm not going to go over all of our charges again. All of that is in your book. At the last meeting, we went through how we came to be formed as a committee and each workgroup gave a bit of an overview of their activities.

As we have been developing our plan for how to proceed over the last year or so, we have been guided by three things. I wanted to point those out to you. When possible in this report, we have been looking for comparative data so that we could look at trends across time. We have tried to find data sets that we could replicate. So, think of that.

Another big goal or principle of ours is that we would like to shed light on the needs of vulnerable and underserved populations. We have tried to hone in on those issues as much as we could.

Finally, we would like our recommendations to end up ones that are measurable, so that the next taskforce that comes along in five years has an easier time looking at this than we have been having.

As you are listening to the reports from the three groups, perhaps you could think of those things and give us advice so we can perhaps achieve these goals that we have.

In today's meeting we will be talking about these policy directions, conceptual recommendations, and looking for feedback, if you have any, and specific questions about methodology. Our data collection isn't complete. We are nearly finished, and we will try to tie it up by June 30th, which gives us a little more time to take some new directions or make corrections, if we come up with suggestions today.

The data analysis has been ongoing, and we expect to complete it by the end of the summer. At that point,

the final draft should be finalized. That is also being written as we are collecting data, so we are fairly along the way with that.

On September 15th, or around mid September, you all will receive a draft report of the task force. We would like you to read it in preparation for the October 8th and 9th meeting. That is the meeting where we will really roll up our sleeves and look at the report and recommendations. At the end of that we will be asking for approval from you.

Around November it will be released for the 60-day public comment period. We anticipate getting all those comments back, analyzed, and integrated into the final report sometime in the spring. So, around the March meeting we should have the final report. Then, in June it gets transmitted to the Secretary.

That is our timeline. We are actually, I think, pretty much on it. I think we have stayed on it all the way because we have such great people pushing this forward.

The next thing is, each task group will talk about what they have been doing in their research activities, and present some data. I love it when we can

present data at these meetings. Each group has some very interesting things. We will have a discussion at the end. You may have specific questions about methodology or ideas for different groups that you think should be surveyed or ideas about recommendations. I will ask you to hold all of that. We will have one big discussion at the end and you can direct it to each person, so we can move through the whole report. Some of your questions may be answered by other people speaking.

I'm going to step aside. The first person is Vence, talking about Consumer and Patients.

Consumer and Patient Workgroup

Vence Bonham, Jr., J.D.

[PowerPoint presentation.]

MR. BONHAM: Good morning. What I would like to do is to start by thanking the workgroup. They have been working very hard over the last few months.

Many of the members of the workgroup are here today. I encourage you to talk to them individually with regard to any suggestions, guidance, directions, or concerns that you may have as to how we have approached our job with regards to helping to identify recommendations for

the Committee with regard to the needs of consumers and patients. Again, I appreciate their work and their commitment to provide the best advice to the Committee.

I want to take a second and think about this question of the public, patients, and consumers. When you think about the diversity of this country and the types of individuals that may need and seek genetic information, how do you make a decision of how you describe patients and consumers.

We have made a decision as a workgroup that our focus has really been on those individuals that are seeking information. When you think about those consumers that are seeking information through direct-to-consumer genetic testing or other approaches, and patients that are seeking information through their providers and through various websites, we are focusing on those individuals. We are not thinking about the general public that may not be thinking about the questions of what their needs are with regard to genetics education and genetic needs, but those that are seeking out information. I think that is important as we think about the context of the work that the workgroup has been doing.

The specific charge that we have is to provide recommendations that address the genetics education needs of consumers and patients. Again, this is focused on those that are seeking out information.

What I want to do is really talk about the design of our collection of data process. I'm the only workgroup that doesn't have data to present today. We decided not to present any data but really wanted to focus with you on our design to collect information to help us analyze and make the recommendations that we will ultimately make.

We have really focused our work with regards to looking at a variety of things. First is the reports on federal agencies' and organizations' activities regarding genetics education for consumers and patients. We will be collecting information across the different agencies on what activities are going on so that we have a sense of the activities. There is a lot going on at this point in time focused on the needs of consumers and patients.

We want to provide recommendations as to how, what, where, and when to communicate genetics information to public and patients, and to review best approaches to consumer- and patient-level genetics education. We will

come back to that as we talk about one of the methods that we are using to collect data.

We want to provide an appendix of consumer and patient education resources so that this can be of guidance and assistance to the agency and to the Secretary.

I would like to focus on our specific data-gathering methods and the four ideas that we have identified. The first is basically an environmental scan that we have done of a broad array of topic areas to gather information. We have actually conducted some qualitative work here. We have done 11 interviews, that I would describe as semi-structured interviews, with experts in these specific topic areas. Each of these were telephone interviews, but they were transcribed.

They were set up so that there was either one or two individuals that were being interviewed at a time. We found some real advantage to actually having two individuals from the same expertise area on the phone answering the questions because they were able to bounce off of each other and to add information and really make the data quite rich for what we received. The majority of the interviews were done with two individuals at a time.

I want to identify specifically the individuals that we had an opportunity to talk to. They all provided a great wealth of information. You see they are coming from different expertise areas and backgrounds. We had individuals who are actually experts around health communication and genetics education. They provided us a perspective on both their own research and work of others related to education of the public. We had those that really are experts in genetics and science education. We focused on having a better understanding of what are some of the needs from that perception. We also talked to clinicians, individuals who are caring for patients at different levels, about their experiences and the guidance that they provide.

We also had national advocates from several organizations that have not typically been involved in the genetics organizations or communities, the traditional group of advocates that we reach out to, but clearly were of importance. These were recommended by the Advisory Committee, and so we had the opportunity to hear their voices and perspectives, which you will see in our recommendations ultimately.

We did reach out to the industry to try to get a perspective from those individuals who are reaching out directly and working with consumers and seeking to provide them services and information. We wanted to get their perspectives with regard to the needs of the public, particularly consumers of genetic testing.

Finally, we focused on the policy perspectives and some of the things that are being learned here. Dr. Hudson, who I know has been in front of this committee many times, had an opportunity to share her perspective related to the needs of the public and patients.

The second area is an area where we have collected quantitative data. This process is going on. Some of you may even have actually received this through the various ways we have sought to distribute the Web-based survey. This is a survey that the workgroup developed with input from others. It was sent out through the Genetic Alliance to their 1,000 affiliates, as well as to 71 organizations which are primarily health care advocacy organizations that are not focused on genetics but that are dealing with specific disease areas or broader health concerns and issues.

I want to highlight one thing because of the importance of really thinking about the questions of underserved communities and issues of disparities related to the work of this taskforce. We oversampled for organizations representing minority and underserved communities. We really sought to make sure that the voices of those organizations are part of what we are learning with regard to the needs of education for patients and consumers.

We really used this process to get additional information from the experts. As of June 9th, we had 301 responses to the survey and 29 partially completed. So there was a drop-off, but we will be able to use their data. So, at this point we have 330 responses to the survey that we will be analyzing.

The second area of data collection that we are going to use is with regard to a national survey that was done by COGENT, which is a marketing survey company. They provided us permission to use their 2008 report. They did a national random sample of 1,000 individuals across the country. So, from a perspective of having a national view, we do have national data around issues of genetics and the

perceptions of the public.

Clearly, many of their questions are very important and relevant to the work of thinking about education. We have access to that data, and that data will be incorporated into our analysis and our recommendations.

The third area is some work that is also going on at the National Institutes of Health. I think at the last meeting Larry Thompson presented to the Committee some of the work that was going on at NIH. This is related to that work. NIH has commissioned the Academy of Education Development, AED, to prepare a very thorough literature review report with regard to the scientific literature as well as what is in the public, such as newspapers and magazines, with regard to issues of genetics and the public.

It will provide us greatly detailed information about what studies have been done around genetics education for the public, the perceptions, commentaries, and various viewpoints. We have the opportunity to actually use the literature from work that has been done by others to help to inform the work of our workgroup.

This work has been completed by AED. We will now

be using that as one of our strategies in coming up with our recommendations.

The work that we have done has been to really try to reach out in various ways to collect information. We are actually collecting new information through the qualitative interviews and the empirical survey method that we have used with the workgroup, but are also gathering information from other groups, like the COGENT survey and the literature review that is being done by NIH. We are using various strategies to collect information so that we can really move forward to provide you the best information with regards to the needs of the public.

Next steps and policy directions. As Barbara stated, we are early with regard to making recommendations, so these are just directions to give you some sense with regard to what are some of the themes that we are seeing across the data that we think are extremely important.

One area, is providing patients and consumers with tools to identify knowledgeable health care providers. This goes to the question of seeking out credible experts when they are trying to make decisions with regards to genetic testing or understanding genetic information.

Another, is to develop models to enhance genetic health literacy for the public. This is the question of can we develop different kinds of models, recognizing that different communities may need different strategies with regard to the dissemination of information.

How do we enhance K-12 science education and content on the role of genetics and health and the issue of probabilities and risk; how do we provide that information; how do we educate the public in understanding risk, which is a major issue. It was a common theme in our qualitative interviews that we had.

Then there is the issue of understanding the role of genetics and environment so that people do not perceive that genetics plays more of a role than it really does. The public needs to understand how the interactions of both environment and genetics play a role in health and disease.

Our next steps are to complete the data analysis, to identify gaps and barriers to successful genetics education efforts, and refine proposed recommendations for the draft. Thank you.

Health Care Providers Workgroup

Greg Feero, M.D., Ph.D.

[PowerPoint presentation.]

DR. FEERO: Thanks, Vence. That was beautifully done. I think, with the Health Care Providers Workgroup, you may see a somewhat more pragmatic and less elegant approach to data gathering, but I think you will find it valuable, as well.

I would also like to thank the Health Care Provider Workgroup members. They played an integral role in developing the initial surveys for health professionals. The federal survey that I will talk about in a minute here was already largely developed, although they helped in the process of paring it down, and then again in reviewing the data for presentation today.

You can see up there that there are a diverse number of groups represented and types of health care providers, including nursing, genetics specialists, as well as practicing clinicians like myself and Ph.D. researchers. Marc also is a practicing clinician.

Today I will be presenting only a portion of the information-gathering process that our group is undergoing. There is a literature review that is ongoing that I will not talk about. Also, Judith has been working particularly

on genetics health work force issues for the report, which is separate from what I will be speaking about.

Just briefly, what were the goals of our workgroup activities. As you will see in a minute, we are duplicating a federal survey that was done in 2004 to inform this group around federal activities for health professions education in the hopes that we can compare and contrast those results to gain some insights on what the trends have been over the last five years, particularly given the explosion of potential clinical applications in genetics and genomics.

We would also, with the activities that I'm going to be talking about today, like to get a snapshot in time of what the health professional groups are thinking about genetics and genomics education. There is, admittedly, in our ascertainment a slight bias to physician primary care because I think, in general, the workgroup felt that that is one of the areas where the need potentially is the greatest, given the volume of care that is delivered in the United States through that particular set of provider types.

From querying those groups, we would like to gain

a sense of what their future plans are in this area in order to help enable, hopefully through multiple pathways, their goals.

I won't spend a lot of time on the federal survey. I put a lot of information into your slides. I think you have already heard this. It essentially duplicated the survey that was done in 2004, and targeted groups that have SACGHS ex officios. It had a combination of open-ended questions and some more closed-ended questions about budgets, et cetera.

We attempted to make it less onerous than the last survey. I heard multiple folks say that the last survey was just incredibly difficult for the agencies to complete, so we cut out some of the materials that made things more challenging, e.g. an accounting over the last five years of what you spent on various projects, which was very hard to complete.

We distributed it in early 2009, and sent out Email reminders. We had about an 85 percent response rate, however only a 45 percent completed survey rate. So, a number of these agencies responded back saying that they really didn't have much to report.

We had six agencies in common between 2004 and 2009. They are some of the more prominent agencies that you would expect to be invested in this area, which is good. We should be able to do some comparisons back and forth.

Three agencies had no reply in 2009, despite Email reminders. One reported activities but was unable to complete the survey.

So, what did we get back. We got about 295 pages of PDF documents. We are in the process of looking this over from a qualitative standpoint. Brian is working on a database to compile this information to make it somewhat more accessible for the Committee.

I think that at the end a meaningful, quantitative analysis is probably unlikely, e.g. a comparison of what was being spent overall in 2004 to 2005 is going to be very challenging. We will get to a couple of comments that point this out. There are some selected excerpts.

The first comment up there essentially says that the CDC is not able to fully develop this area, e.g. education for health professionals, due to a lack of

resources, et cetera. HRSA, on the other hand, felt that they were able to fulfill their role in health professions education adequately at this time.

NIH's response was quite interesting. The individual institutes responded separately. There was also an overall response. Actually, I am not speaking at all for the NIH or the NHGRI today. I'm speaking for the workgroup. I think one of the challenges in looking at this is extracting what we perceive to be core health professions education activity from other activities.

For example, included in the accounting from the NIH was a very large award for the National Center for Integrated Biomedical Informatics to basically train informaticians to use health-related data. The Committee, I guess, and the workgroup will have to make a determination whether that really represents the kind of education that we are talking about.

Likewise, there was a neurodevelopmental toxicology grant included in there. Again, I think it is really a qualitative decision as to whether that counts or doesn't count towards health professions education.

So again, these are tentative, possible policy

directions. This is, I think, quite vanilla, but I think it is one we could start a discussion from. The Secretary of HHS should establish, empower, and fund health professional genomics education activities within HHS.

It is interesting to note that there is such a diversity of perceptions of what health professions education activities are across the various agencies. I think that that is an interesting challenge moving forward when trying to decide is there coordinated movement in one direction in terms of bolstering this area.

A little about the health professions survey. We elected to target a diversity of health professions organizations. We, again, had a bent towards primary care. In what way do I mean that. For example, we surveyed the AMA, the American Academy of Family Physicians, and the American College of Physicians, but we didn't go to the American College of Cardiology and a lot of the more specialty-oriented organizations in the physician world. That just gives you an idea of the kind of honing down that we did. The committee played an active role in that process.

We created the survey within the committee and

piloted it with the board of NCHPEG. That is a group of individuals that represents a diversity of different types of health professionals. We got their results back. The survey was reviewed by a survey methodologist in the fall of 2008 for reasonableness, although I would argue that this survey is not as elegantly put together as Vence's.

In early 2009, the survey was distributed. Email and phone call follow-up occurred, and the survey targeted eight genetics organizations, eight health profession education organizations, those that particularly focus on the educational aspects of health professions, and then 28 overall organizations that provide advocacy, et cetera, for health professionals, and then three of the federal advisory committees.

The response rate was 58 percent. All the genetics organizations responded, 39 percent of the education organizations responded, 57 percent of the overarching organizations responded, and 67 percent of the advisory committees responded. I think there is actually interesting information right there in terms of the level of interest in the survey amongst the different types of groups.

We acquired about 329 pages of PDF documents from this group. Qualitative and quantitative analyses are planned and underway. There is also a database being created of this information. I think we will be able to do some meaningful quantitative analysis.

I would like to just walk you through the results of some of the questions that were asked and what we found. This first question looks at, overall, what level of importance does the organization put on educational activities in general. I will draw your attention over here. This is a Likert Scale, where a one is not much importance at all, five is a lot of importance. Whether they were a general professional organization, a genetic-specific organization, or an education organization for health professionals, essentially, all of them ranked education as a very high priority.

If you then move to the question, "What importance do you place on education specifically related to genetics and genomics?" you see immediately a spread in the priorities. The overall scores are still quite high, but suddenly, in the general professional organizations, there is this trend down, with some folks responding one.

Again, here you can see in the education organizations several responses of two and three, so it is a relatively low priority to teach or to focus on genetics education for their groups.

The next question -- and I cut out some of the actual raw data here -- was, "What overall priority does genetics have in the other priorities facing your organization?" You can see for the general professional organizations -- and this is essentially what you would predict -- that it is just on the horizon. It is there but it is certainly not a high priority for them to deal with, whereas the genetics folks felt it was a high priority. I think this starts to point at what we might be able to do to change this.

The question was, "How proficient and comfortable would you say your organization's leadership is with genetics and genomics education?" What you can see here is the median scores. The general professional organizations and the professional education organizations gave relatively low scores about how proficient they thought their leadership was in this topic area. That might point out a direction of targeting leadership for some education

to get them thinking more about the topic area, rather than immediately going out to the rank and file.

Likewise, this question, I think, is pretty telling. "To what extent is your organization's membership satisfied with the organization's current emphasis on genetics and genomics education?" What you can see is, among the professional organizations, they would say in general that they are moderately satisfied. I think there may be a little ray of hope here that there may be some dissatisfaction, that there is not enough going on in the education organizations, and that we could ramp up the activities and not meet with blank stares.

What are the barriers they identified. I thought this was actually quite interesting because I expected the health professions education organizations and the professional education organizations to really harp on this issue. It is one that comes up a lot, the evidence for effectiveness. As you will see in the next slide, neither organization type really ranked this highly. It really had a lot to do for both of them with competing priorities in their minds and, in some cases, lack of educational resources.

This popped up here, but again, competing priorities is clearly the task at hand as to how to get this up in the queue for things that need to be done.

Possible workgroup direction from this. The Secretary of HHS should facilitate the development of public-private partnerships with health professional organizations to develop and implement a core data strategy for genomics education in the United States. I think that would be a fairly reasonable starting point for discussion.

The last thing I would like to report on is a meeting that just happened on Monday and Tuesday of this week. This was something that NHGRI had in the works and very nicely folded into, I think, this evidence-gathering process.

We brought together, with some other federal co-sponsors and one of the other advisory committees to the Secretary, a group of leaders from a diversity of primary care organizations, including both the overarching organizations that provide advocacy for the communities as well as those that are directly related to education of the rank-and-file primary care doctors. The goal of bringing them together was really to engage them in a discussion of

genomics education for the next five years, to really draw out what they thought should happen rather than impressing upon them from the genetics perspective what should be happening in the next five years.

I think overall the meeting went quite well. No one stormed out of the room. They all got along nicely. I would point out to you that I don't really believe that this type of meeting with this diversity of physician groups for genomics has happened. There may have been something around the Genetics and Primary Care Initiative similar to this, but I'm not entirely sure that there has been a similar meeting. Others may be able to comment on that.

Again, this is very preliminary. We had the meeting captured by a transcriptionist. There was a meeting writing there from the other advisory committee. They will be producing a report on the maternal and child health issues that were covered. I put down some of the general themes that came out this that I think you might find interesting.

There was substantial accord on several topics. It was pretty plain from everyone there that they did not

think that genetics and genomics education for health professionals would fly as a separate, distinct add-on to the education process as it stands. Really, genetics and genomics need to be integrated throughout existing infrastructure, e.g. if you are teaching about cardiovascular disease, you make sure that when you talk about cardiovascular disease you talk about the genetic components of risk, pharmacology, pharmacogenomics that might be relevant to the topic, et cetera.

They felt that there was a great need for better coordination between the physician groups and, in fact, allied health. We had some folks from the nursing communities present on their educational activities, as well as some folks from the physician assistant community present to these physician groups. I think there was a recognition that the similarities of lack of knowledge might overcome the differences between the groups in some respects in terms of their educational needs.

There was broad consensus that family history should be a major focal point for both care and education around genetics and genomics, but a number of folks expressed dismay that it was very difficult to capture

family history in the tools that they use on a day-to-day basis to provide care, the electronic health records.

There was a general agreement that the pipeline for genetic specialists needs to be expanded. There was a lot of discussion about who do we turn to in our environments when we begin to tackle a genetic or genomic issue and then run into something that is extremely complex. Many of them expressed concern that in the more far-flung areas of the United States there may not be well-trained genetics professionals readily available.

They particularly thought the transitions in care were important to genomic medicine, particularly in the preconceptional, prenatal, post-natal, and newborn screening periods, and also around the transition from pediatric to adult care. They thought a team-based approach using the patient's medical home, a topic which came up a number of times, really would help to alleviate that. Again, it is going to require that coordinated activity between the different team members of the medical home to make it happen.

There was a clear discussion around the clinical utility issue and how important that is to getting folks to

adopt genetics and genomics education. If they don't think that there is a clear benefit to their patients from doing so, they are not likely to pay much attention to the educational activity.

It was indicated that everyone felt that the RRCs, the residency review committees, and the CME approval processes are really key points of influence that could be approached in the near term to improve genomics integration -- I think the term that was used yesterday was "insinuation" -- throughout the primary care education infrastructure.

There was a consensus that they would like to get back together again in six months to a year to review progress in their organizations and do some additional planning for future activities. I think that is the end of my presentation.

Public Health Providers Workgroup

Kate Reed, M.P.H., Sc.M., C.G.C.

[PowerPoint presentation.]

MS. REED: Last but not least, I am going to present where we are with the Public Health Providers Workgroup. I think we lie somewhere in between the other

two groups. I have some preliminary data to present, but it is very preliminary. We are still collecting a lot of data. One of the things that we are going to ask for from the Committee is ideas of other groups that we may be able to survey or include in the survey to collect the real data that we need here.

First, as with the others, this group has come together quite well and is quite representative of different areas in public health. Joseph has really been a great force to keep us moving.

I will talk about this in more detail, but one of the major challenges with this group is to define our population. If you look at the IOM reports, to paraphrase the definition of what a public health professional is, it is anyone interested in health at the population level. That gives us a very broad audience that we are trying to capture and get information from, and that has been one of our challenges. Joseph has really been great in helping focus our efforts here.

I will say that I came into this midway through, so any mistakes that I make in this presentation are mine alone. Thank you to both Barbara and Kathy for helping me

get up to speed on where we are right now.

What we have done at this point is, there has been an online survey developed. The group focused on looking at competencies. Specifically, we are looking at competencies because competencies are applied skills and knowledge that enable members of the public health work force to effectively practice public health.

These have been developed by a number of groups. As you can see, we were looking at five overall to see what competencies have already been developed, and then trying to use an iterative process to figure out what is common between those various competencies that have been produced. So, what is the core set of competencies that different groups have come together and said this is what public health professionals need, as opposed to starting from the beginning and coming up with our own new list of competencies.

The purpose of competencies in the public health field, as it is with health professionals and other fields that use competencies, is really to structure educational programs and to define what public health professionals should be doing in terms of knowledge and skills.

The other thing that I just want to comment on is that we have had significant discussions about genetics versus genomics competencies. Really, for most of the 12 competencies that we came up with we used this combined term, the reason being we didn't want the terminology to be a barrier for people to be able to answer the questions appropriately. There are some of the competencies that deal specifically with genetic health services that we only used the term "genetics." So, we have had that full discussion, and I just wanted to let the group know.

I also want to mention here that there have been other efforts to survey the public health professionals to determine what activities are ongoing, how important genetics is in public health, how it has been integrated, what some of the challenges are. The latest ones that we have been able to find were really completed in 2001 and 2002. They have been done with numerous groups. Again, one of the requests for input from you will be, what is the appropriate group for us to be serving here and have we captured them in the groups that we have already done.

The groups that we have already sent out our survey to are, as you can see, the state genetics

coordinators. These are individuals in state departments of health who are responsible for whatever the state defines as genomic activities. It is not necessarily a 100 percent job. Actually, Sylvia was in charge of that survey in 2002. I think it was the publication looking at who is doing what and to what level. We do have some data on that.

The APHA state affiliates are independently established, and they are responsible for participating, implementing, and advocating on behalf of various public health issues related to the priorities of APHA.

We also sampled 366 members of the Genomics Forum from APHA. This is a recently formed group. It is a group of individuals who are generally involved in public health. They are not necessarily APHA members. They are involved in public health, they are interested in genomics, and that is what we know about them.

Those are the main groups that we have preliminary data from. Recently, on June 9th, as you can see, we sent the survey to the Association of State and Territorial Health Officers list as well, with the instructions that we would like the health officers to

answer the survey and then distribute it to other individuals within their organizations who are not specifically involved with genetics or genomics. We gave them examples of state genetics coordinators or maternal and child health because we do want to get a broad audience.

As you can see, we have received 133 full responses. This comes up to a response rate of about 26 percent. Again, looking at past surveys of public health professionals, it is within the range.

Our survey has three main parts: one, your role in public health; second, the importance of public health within your setting; and then the competencies. We will talk through, again, the very preliminary results for each of these.

One of the first things we are trying to get our head around is at what level of public health do you work. As you can see here, something to note is that 31 percent of the sample that we have currently collected is academic, as opposed to 49 percent federal or state. This is something that is going to be important to keep in mind as we analyze the data further because those two groups in

particular, as well as some of the others, are going to have different priorities and resources that we need to take into account as we look at things like importance, competencies, and things like that. Again, this doesn't include the recent mailings.

We asked an open-ended question, "What is your job title?" For those of you that have not seen these word clouds before, the larger the font, the more responses were given with those words involved. So this is just a very quick visual to exemplify the diversity of individuals who are involved in public health and who are answering the survey.

It is also very important to keep in mind that the groups that we have surveyed so far are more likely to be involved in genetics. The fact that genetics got nine occurrences out of our group is probably higher than we would see in a general public health sample because most people are not going to have "genetics" in their job title. So, the idea and the scope will likely change as we continue to broaden the population that we are sampling.

Part two of the survey was to look at the importance of genetics and genomics in your institution's

leadership. The first question was, "Does your senior administrator think that genetics/genomics is important to, first, your job responsibilities, and then their job responsibilities?" Looking at the responders' job responsibilities, if you add it all up, 75 percent think genetics and genomics is important to the responders' job responsibilities. To their own responsibilities, it is 61 percent.

This also will be very important to look at based on what role they have within public health, not only if they are working at a state or federal level but also if they are working in academics or other settings.

A 2001 survey that was done looked at a very similar question but sent it to six distinct groups within public health. They sent slightly different surveys to maternal and child health individuals, lab directors, health officers, and chronic disease. That doesn't come up to six but those are the four I have written down, so we will go with that.

What they found is, in terms of job responsibilities and what we would expect, is that there are different senses of how important genetics and genomics

is to each of those depending on what your responsibility is. So, again, as we would expect, responders in maternal and child are going to see genetics and genomics as a higher level of importance because that is where newborn screening lies. Lab directors is the next down, health officers next down, with chronic disease at the end. As we move forward with this analysis we won't be able to directly compare the data, but it will be interesting to see generally, given job title, whether this falls out in a similar distribution of importance.

We also asked, "How adequate are your resources for implementing genetic and genomic competencies into your work or role?" As you can see, 74 percent responded that the results were at some level of adequacy. Again, it is interesting when we go back to other data available. Earlier data said one of the major concerns was the lack of funding.

So, the fact that people are perceiving that resources are available and are at somewhat of an adequate level is a positive thing. Maybe awareness is growing. We need to note this, and then we may need to figure out exactly, again, as we add more people to this survey, if

this still falls out to be true.

The third part was to look at the competencies specifically and ask individually how important each competency is, how confident are you in demonstrating this competency, and how frequently do you apply this competency, all answered on a Likert Scale. We don't have any analysis yet available, but the point of this is to do a couple of things. One, we wanted to get a sense of, are these competencies things that we should be asking about, are these truly the core competencies, and where do they fall. How is genetics and genomics being incorporated currently into public health on a day-to-day level.

Given that very preliminary data, what we have tried to do is come up with some very general ideas about the policy direction. Again, these are based on what we know from the literature as well as this preliminary data. It is not hard to fall out that likely the policy directions are going to be in two areas. One is, who is being trained right now and how do we increase or improve the education and the integration in current trainees, and then, how do we begin to educate the current work force.

There are a couple of things that I think will be

important to keep in mind that I have already mentioned. One is the diverse nature of this group. Doing general education programs for public health professionals may or may not be useful given the different uses of genetics and genomics in each of the roles within public health. We need to look at targeted programs that help us to do that.

We had a conversation with Muin Khoury, who also emphasized the idea of translation. How do we educate not just about the knowledge base of genetics and genomics but the actual translation aspects of genetics research, and how do we use that to almost bolster the need for education within this group.

There are some current activities going on. Dr. Khoury is working with people at the NCI to look at what current educational activities are ongoing and how those map to this translational highway from basic research to clinical integration. They are looking at what activities are currently ongoing. That is something that may be informative in creating policy directions, as well. Thank you.

Committee Discussion

DR. McGRATH: Thank you. I think it is obvious

that this is a really many-headed beast that we are dealing with. One of the challenges is that we could go all over the landscape and talk about education and training needs. The danger of that is that we would cover everybody but it would be on such a superficial level it would be meaningless.

The other direction would be to narrow in and lose track of some of the important players in this, and that is a challenge we have been dealing with since we started. I think the three presentations show where we have decided to focus, but you may have some suggestions about groups that you think are particularly important to pull back in. We have some capability to do that. That would be good feedback to hear.

I think we will put up some of the recommendations. We have about 15 minutes to open it up to discussions. Our next task is to sit and put pen to paper and start writing recommendations and finalize the data collection activities. I would just very much welcome, as we all would, any suggestions from anyone on any of the three taskforces about either methodology or helping us as we craft these recommendations. Marc.

DR. WILLIAMS: I'm going to represent my parochial interest as a member of the group. Perhaps it has been missed from the surveys or we need to think about it a little bit more, but what is missing is the idea of the movement towards point-of-care, just-in-time education within the electronic health record environment, at least from the provider perspective.

I didn't necessarily identify individuals or groups within the survey that were asked about genetics relating to that. Now, that may just be because this is an amorphous group and there is not a real go-to place, but I just want to make sure that we don't lose that. I think there are many of us who believe that is going to be critical in terms of the ongoing post-graduate education for health care providers and particularly is going to be essential relating to actual on-the-ground translation.

DR. FEERO: It was not specifically in the surveys. It did come up in the physician meeting the past several days. It was thought to be most relevant to the practicing clinician and how to reach the practicing clinician, as opposed to relevant in the medical school and resident training processes. It was definitely a point

that will come out in our summary from that.

DR. TEUTSCH: My sense of all of this is there is obviously a large differential set of needs from all of these different groups, as you have alluded to. I wonder if they reflected anything about the timing of their needs, particularly the primary care practitioners or some of the people who have less direct involvement at the moment and who don't see a lot of immediate applications that are germane to them.

In terms of our recommendations and how we would roll these things out over a period of time, and I know that you will get to a different level of detail, specificity, and actionability, I wonder if people talked at all about when they think they are going to be ready for this across these different constituencies.

MR. BONHAM: That is something we need to try to address from the data that we have gathered with regard to time, because I do think that there is different timing. We made some conscious decisions from the perspective of the patients and consumers to focus on those that are already seeking information. So, we have a level where timing has already been recognized from that perspective,

but I think that there may be some things in the data that may be of value.

DR. FEERO: I think implicit in the issues that were reflected in the health professions survey around barriers and their priorities of genetics relative to their overall education priorities, you see some of what you are getting at. Right now it is not really on the horizon in the primary care groups.

However, there was also that question about how facile do you feel your leadership is with this area. It is a little hard to decide, given how rapidly this field is evolving, if the issue is that they understand it and it is not a priority, or at this point in time they don't have enough knowledge to fully appreciate whether they should be making it a priority or not.

I think what you saw in the two-day meeting was that a number of the folks that came were people who weren't already thinking about this quite a bit. They came in, listened to some of what was said, and realized in pharmacogenomics there are a lot of labels out there that we need to be thinking about. People have been prescribing drugs like Carbamazepine for 30 years and are not aware

that the FDA has changed the labeling and there is a potential liability issue. Maybe there is a bit more urgency, particularly in pharmacogenomics and cancer genetics topic areas, than they would think otherwise.

MS. ASPINALL: That was my question. It is a little hard on the phone. Is it okay to interrupt?

DR. TEUTSCH: Go ahead, Mara.

MS. ASPINALL: Maybe you answered it with that, but maybe systematically as we go forward, are there any areas of critical need, regardless of our process and the Secretary's process, for which there is the potential or actuality of harm without some additional information and that in some way we need to accelerate knowledge of that critical need?

DR. FEERO: I would say, coming out of the physician meeting, PGX was definitely an area. Another was the direct-to-consumer movement and concerns about how to and should they deal with that information.

Also, cancer genetics, and one that I guess I have a personal conflict of interest with is family history. I don't have a financial conflict of interest, but I'm just so immersed in it. That really did come out

as being an area that they felt is vastly under-utilized. The systems that are getting put into place now for delivering care, the electronic health record systems, are not well built to capture it.

There needs to be some thought given to, are we going to lose a whole bunch of our ability to provide genetic risk assessment if we can't capture family history information, and the role of health IT.

MS. ASPINALL: It doesn't sound like there is one type of physician group or one particular test that is so egregious that emergency action needs to be happening but it is more broadly getting this information to folks.

DR. DALE: I was just going to comment that, as I listened to the consumer side, I was thinking about Consumer Reports, the magazine. If you are buying a car or a refrigerator, you look for it in there, and if you are not, you don't, but you are glad it is there because it is a relatively unbiased review of almost all the common things you might ever want. We need something like that, and I think the public does but not every day. That is, in a sense, at least a way of conceptualizing what might be a target.

MR. BONHAM: I think a representative from Consumer Reports presented here, correct? Maybe I'm mixing meetings up.

MS. ASPINALL: Yes, two meetings ago.

MR. BONHAM: I don't know; maybe at some point we need to reach out to them and find out exactly where they are going. One of the questions that came up in our discussion with the industry was to get some sense of the kinds of information that they are providing that is more general education and not targeted toward their marketing of their services. Clearly, many of the companies are now thinking about issues of what general information needs to be provided to the public to help them as they make decisions with regards to genetic services.

DR. McGRATH: Just from looking at the public health competencies and the rest of the data, one area that is a really thorny one is, how do we move toward looking at complex diseases and the role of the environment. That is a more difficult concept, I think, to grapple with. I think it is going to show up in public health. Those folks could be the ones to help us move forward to a greater understanding and a greater communication about the role of

the environment. So, I would put that on the hot list.

DR. BILLINGS: I have two responses. One is, I don't think, as a committee, it is a wise idea for us to get too deeply involved in the tension between the specialists and the primary care doctors and who manages what. It is pretty clear historically that most of the genetic information that we want to see education improved upon is probably best embedded in specialty care. While many patients are treated in primary care settings, most of the hard information and the best evidence is probably in specialty care. So, it would seem to me that we don't want to lose sight of that.

The other thing I was struck by in all these presentations is that we obviously want to see improvements in education about genetics. There is ample evidence, and there continues to be ample evidence in all groups, that we could do better. On the other hand, we don't want to get ahead of ourselves at some level. I was struck by that tension between the down side of being too aggressive about educational efforts and under-emphasizing the environment and the causation of disease, and so forth and so on.

MS. WALCOFF: In terms of recommendations to the

Secretary, I would be really interested to know in terms of your discussions with clinicians and physicians that were aware of some of this labeling and were thinking about this, is the labeling that is being provided by FDA useful to them? Is it something that they find that is actually helping them understand, particularly with pharmacogenomics, what they need to do with that product and how it should be incorporated into their practice?

DR. FEERO: I would say that I probably don't have the depth of survey, survey not in the sense of a survey on a piece of paper, but the depth of enough discussions with enough different clinicians to really comment on that except superficially. People are concerned about it. They feel like the information is there but they don't really have a good handle on what the next steps are and what the implications are for following or not following.

There has been label information about pharmacogenomics for a number of drugs for a long time, but it seems like in the last year or two the profile of the labeling has been raised. So there is some confusion as to what does that mean, what do I do, am I at liability if I

don't do something, et cetera.

MS. WALCOFF: Exactly. I think, as we go forward, that would be something very useful for the Secretary to actually work on in terms of working with FDA.

DR. EVANS: I just wanted to amplify on what Paul said. I think we do have to be very careful that we don't inappropriately push genetics education. As somebody who does do some degree of general medicine, those competing interests that these providers have are extraordinarily valid. Oftentimes, they should outcompete genetics education.

I think that the way to deal with that is by getting to prioritization, to really prioritize our educational effort. Those priorities should be contingent upon evidence of how it affects health outcomes. Where those aren't present and where those are lacking, we really shouldn't try to argue too strongly for education.

I agree with Paul. I'm not sure if we should just assume that the place of focus is the specialist. When I think about where the most bang for the buck is with genetics, I think that Greg's focus on family history is most appropriately in who people see for the most part,

which is, at least at first, generalists. We don't want to neglect the generalists, who are the wide end of that funnel that eventually funnels people into areas where genetic knowledge is necessary.

DR. WILLIAMS: I would like to just follow up on what Jim said there. I think the other point that I would make relating to that is, while I do agree that we need to focus on the things that we have evidence around, one of the things that I was struck by as I was going through the materials in preparation for the meeting relates to at least the current way that we train health care providers and physicians, particularly the modified apprentice model of internship and residency.

We clearly have a huge gap in terms of mentoring how genetics and genomics can be integrated into care at the bedside. I think it is an extremely thorny problem, and the solutions are not obvious in terms of how to address that. It is also clear that attitudes about whether or not this is really critically important in day-to-day practice are really developed in that venue.

If we don't somehow step up to the plate and say, how can we actually get this mentoring to take place within

that post-medical school but pre-graduate setting, I think we are going to have a much greater problem down the road.

MS. DARIEN: Just to build on some of the comments before and also to put on my consumer and educator hats, I think one of the most important things to do when you are talking about education is to figure out how to put it into context. Genetics has to be put in a context of how it relates to the environment and how it relates to all the other decision-making.

I think that one of the things that is missing, particularly with consumers, is that you look at all the genetics testing and you look at what is going on in the education but you don't necessarily know how that relates to other things. I think of it from the consumer viewpoint, but I also think that there is a provider viewpoint about where this relates and where it doesn't relate, and where the genetic information has some value because you can make decisions based on it and where it has no evidence or no value.

DR. FEERO: Just going along with Marc's comment, I think one of the other issues that is related to this mentorship approach to education is the confluence of that

and the fact that this field changes so rapidly. How do you balance this issue of an evidence base, which takes years and years to generate, and the fact that there are things that are coming out that occasionally have such amazing face value that it is hard to not say that you probably ought to be thinking about them. I think that is something in the report that really needs to be emphasized.

DR. EVANS: I completely agree. It is not an easy matter to prioritize. I think that some of the things are pretty obvious, like pharmacogenomics relabeling of drugs. I think other things may rise to the level where we would want to emphasize education based precisely on a looming impact. I think, for example, of multiplex analysis in the direct-to-consumer arena, et cetera.

Those are going to take some judgment around the table to figure out. I just want to get my bid in for taking a nuanced approach to what we emphasize so that we aren't perceived as just evangelists.

DR. WILLIAMS: The very specific thing that I want to add related to providers is, have we had engagement with the pharmacy R&D community relating to that? I think it is going to be absolutely critical to get engagement

with that group. As I envision how pharmacogenomics is going to evolve, I think that much of that is going to fall within their bailiwick because they are really best prepared to deal with a lot of the information. They already have the content expertise in terms of pharmacogenetics and that type of thing.

DR. FEERO: Actually, I could relatively easily, with your approval, reach out more to that community. I was in a meeting about two months ago where pharmacist leaders were talking about this. They actually are chomping at the bit to really become more involved. They say, metabolism of drugs is our business. Genes define metabolism, to a large degree, so we would really like to get more involved in this. I think we could relatively easily bring that perspective into the report.

DR. McGRATH: In response to a lot of the tone here, I think the report will give the landscape of where, since this is a committee about the needs of society, society gets a lot of its genetics information.

We all know the statistics. A lot of people would like confirmation by their physicians, clinicians, or health care providers at point of care, but a lot of steps

happen before they ever make that step. I think one thing we will be able to contribute is to talk about those multiple steps in the community and the role of public health officials, and broaden it a little bit so it doesn't look like point of care in the clinic is the first place that people start hearing about things.

DR. AMOS: Have you talked to the MEDCO people? Andrea and I were at a personalized medicine conference a couple months ago in Baltimore. The MEDCO pharmacy people have implemented pharmacogenomic testing for their prescribing practice. They are the largest provider of those pharmaceutical services to the insurance companies. I just wondered if you had talked to those folks.

DR. BILLINGS: Russell T. Garden is the guy who runs it.

DR. FEERO: In believe, I believe he presented, or one of his near folks in the hierarchy presented, at believe it was a meeting hosted by APHA several months ago here in D.C. MEDCO was definitely there and presented. They are playing a huge role in this process. In fact, I think just in the past week a study that MEDCO is doing on Tamoxifen closed. We should be getting some interesting

results from their work.

DR. TEUTSCH: Rob Epstein, of course, presented to us last time.

DR. NUSSBAUM: What is very impressive is not only your work but the stunning gaps that exist in all arenas. I just wonder if the taskforce stepped back and said, let's look at what has happened with preventive services, with chronic illness, and even with those educational programs where we still have 50 percent translational gaps in knowledge, and whether there is a way of leapfrogging. The leapfrogging could be in personal health records and other types of information services.

I just wondered, given the tempo, the rapid advances that we expect in the years ahead, whether we could use this information to give us a new model or paradigm for how consumers, doctors, and other health professionals can be guided to new evidence and optimal care.

What you have shared with us is wonderful, but it is very, very traditional, isn't it? I just wonder if there is a breakthrough way of thinking. We have so many new electronic information tools available to consumers,

and we also know that health professionals need lifelong learning. This is just an area that will even be accelerated.

DR. McGRATH: That is a great charge. Thank you.

DR. NUSSBAUM: One suggestion is the concept of all of us having personal health records. Those health records would contain a tremendous amount of demographic information, preventive services, and preventive needs. We could then embed decision support for the physician, be it specialist or primary care physician, be it other health professional. As we gain new information, whether it be pharmacogenomic information, that could be fed into that process.

Looking at preventive services or common chronic illness today, if we miss the mark half the time, just think, with the gaps that we have that you have so well identified and the opportunities, where we will be in the genetic arena.

DR. EVANS: That really gets to something that Marc has brought up time and time again about just-in-time education, et cetera. It really fits with the rest of our session today about health care reform because it is all

part and parcel of trying to motivate people.

DR. RANDHAWA: I have a couple of suggestions. If we will be reaching out to the pharmacology and the pharmacy communities, there is a fairly rich history of drug-drug interactions. There is a lot that can be learned from the entire field in terms of FDA labeling, the information on how that is used, how the evidence base was created to come up with these clinical decision support tools, and the alerts that are often turned off at the point of care because they are not very useful. I think there are many things there that can be helpful as we think about making it more actionable information.

The second point is, it might be useful to separate out general information from actionable information. If we don't do that, then I think we are conflating issues that are hard to tease apart.

DR. FERREIRA-GONZALEZ: I was wondering if you have also reached out to the laboratory community.

DR. FEERO: Herein lies the issue of expanding the net. As soon as the pharmacists and the laboratorians are involved, then you end up with this wider and wider net. We grappled with this in the workgroup on health

professions education. Where is going to be the most likely bang for our buck.

Just speaking to the specialty communities, the feeling was that there are a lot of applications. ASCO has guidelines. There is already a fair amount of effort directed towards them and getting them up to speed, whereas for primary care folks there may not be. There was also a feeling that the laboratorian community is probably better off, at least right now, than primary care.

I think you have to think carefully -- and, actually, you probably should be talking to him because he is taking over as chair of the workgroup -- about how wide you want to cast this net and how much time you want to take in trying to cast it.

DR. FERREIRA-GONZALEZ: Yes, but I think in talking about the pharmacists or the laboratorians, these are individuals that are interacting with all the different specialties all the time and have been educated and are continuously educated. I cannot tell you how many times they call me to see what results mean. Then you go over some education at that point.

The laboratories have a very active role in

educating primary care physicians and even specialists in genetic information. We need to make sure that the laboratory community is also on board with genetics. We have certain communities that are really on board, but we have to have the whole laboratorian community. That, I think, is a critical component that could play a very active role in the education of the health care providers.

MS. REED: One of the things that I'm hearing is that there is a lot of overlap between these groups. Is there any utility in thinking about educational efforts on multiple levels.

The health providers are also consumers. If there is general education that everybody needs, can it be left to the consumer group. Can we assume that that will help get health providers up to a certain level and that we then need to add on whatever extra level that they need. Laboratorians are a combination of health providers and public health. Is there any utility in thinking of it in a step-wise fashion, if that is not what we are already doing.

DR. TEUTSCH: Barbara, thank you to you and all of you on the panel for all the work that you have done and

are going to do. I know that directionally you have already indicated where you are headed. Obviously, next time we are going to be looking at things at a lot more specific level and the kind of things that are likely to be actionable that we can, as you said, measure and monitor going forward.

We look forward to that discussion. We appreciate everybody's comments, thoughts, and input. Hopefully that will be helpful.

At our next meeting we will have this report, which, as Barbara said, you will have seen in advance. We will be marching through it, systematically looking at each of those recommendations and getting everybody's input, so it will be ready for seeking public input. Thank you very much.