

## Summary Notes

### Genetic Services Policy Project Spring 2005 Advisory Committee Meeting April 8, 2005 10:00 a.m. to 4:00 p.m. Four Points Hotel Chicago O'Hare

The second advisory meeting for the Genetic Services Policy Project (GSPP) was held on Friday April 8<sup>th</sup>, 2005 at the Four Points Hotel Chicago O'Hare.

#### **Attendees**

##### Advisors/Consultants:

- Jean Anderson, International Society of Nursing Genetics
- Jeffrey Bauer, ACS Healthcare Solutions
- Meg Booth, Association of Maternal and Child Health Programs
- Amy Brin, American Academy of Pediatrics
- Daragh Conrad, National Society of Genetic Counselors
- Frank Gilliam, University of California Los Angeles
- Alissa Johnson, National Conference of State Legislatures
- Celia Kaye, Newborn Screening and Genetic Resource Center, University of Texas Health Science Center at San Antonio
- Don Kemper, Healthwise
- Ron Lankford, Healthcare Consultant to Payers
- Frances Margolin, Health Research and Educational Trust
- Joseph McInerney, National Coalition for Health Professional Education in Genetics
- Lawrence O'Connor, American Medical Association
- Inger Saphire-Bernstein, Blue Cross Blue Shield
- Peggy Stupca, Association of Genetic Technologists
- Leslie Wainwright, SG-2
- David Weismiller, American Academy of Family Physicians
- Mark Yarborough, University Colorado Health Sciences Center Center for Bioethics and Humanities

##### Project Investigators/Staff:

- Rick Carlson, University of Washington
- Penny Kyler, Department of Health and Human Services, Health Resources and Services Administration
- Amber Roche, Washington State Department of Health, Genetic Services Section
- Sherry Taylor, Washington State Department of Health, Genetic Services Section
- Grace Wang, University of Washington
- Cindy Watts, University of Washington
- Candi Wines, University of Washington

**Not in attendance:**

Advisors/Consultants:

- Bill Benedict, The Centers for Medicare and Medicaid Services, Region X
- Don Black, Child Health Corporation of America
- Carmella Bocchino, America's Health Insurance Plan
- Joanne Boughman, American Society of Human Genetics
- Brett Davis, IBM
- Patricia Deverka, Duke University
- Sarah Donta, The Council of State Governments
- Norman Kahn, American Academy of Family Physicians
- Trudi Matthews, The Council of State Governments
- Lee Newcomer, Ingenix
- Dan Perry, Alliance for Aging Research
- R.J. Ruff, The Centers for Medicare and Medicaid Services, Region X
- Priscilla Short, University of Chicago
- Barry Steinhardt, American Civil Liberties Union
- Sharon Terry, Genetic Alliance
- Michael Watson, American College of Medical Genetics

Project Investigators/Staff:

- Wylie Burke, University of Washington
- Kay Collins, University of Washington
- Debra Lochner Doyle, Washington State Department of Health
- Patricia Kuszler, University of Washington
- Michele Puryear, Department of Health and Human Services, Health Resources and Services Administration
- Scott Ramsey, University of Washington
- David Veenstra, University of Washington

The following represents a brief overview of the meeting and is not a detailed and complete transcript.

**I. Introductions, Update, and Discussion of Project Work**

Cindy Watts, PhD, Principal Investigator, Genetic Services Policy Project and Rick Carlson, JD, Investigator, Genetic Services Policy Project welcomed the Advisory Committee members and gave a brief overview of the goals for the three year Genetic Services Policy Project (GSPP). Year one will be complete in May 2005; the goals for this year were to collect information and begin to describe available genetic services.

The first product from this year's efforts is a cost effectiveness analysis literature review titled, "A Systematic Review of Economic Evaluations of Genetic Testing Technologies". GSPP investigators will present the literature review at two conferences: 1) International Society for Pharmacoeconomics and Outcomes Research, Washington, DC, May 2005; and 2) International Health Economics Association, Barcelona, Spain, July 2005. Genetics in Medicine has also accepted the literature review for publication.

The second product from Year 1 is a draft of eight state profiles describing genetic services by state. Staff chose seven of the states to represent the seven regional collaborations; Washington was included as the eighth state because of the staff's familiarity with services in Washington

State. The Advisory Committee received the draft document in order to provide comments. Copies were included in the meeting binders.

The goals of years two and three include completing case studies and disseminating information to trade and professional organizations. The GSPP will invite the Advisory Committee: 1) To participate in key informant interviews; 2) To provide guidance in the development of products for dissemination; and 3) To participate in workshops to present information.

Materials developed by GSPP are available for use by Advisory Committee members upon request to project staff.

#### Genetic Services Delivery

*Amber Roche, MPH, Washington State Department of Health, Genetic Services Section*

Ms. Roche presented data on the delivery of genetic services. Handouts of her slide presentation were included in the meeting binders. The discussion following the presentation included comments on the need to integrate genetics training in medical school curricula. Genetics is relevant to many specialties and should be taught as an integrated topic. The observation was made that medical doctors tend to choose other, more lucrative specialties over genetics. A suggestion was made to compare the number of specialists per capita that practice genetics to the number of other medical specialists per capita such as pediatricians, cardiologists, etc. It was noted that data on who receives genetic services are difficult to obtain. For example, databases using ICD-9 and CPT codes are not very informative because genetic services might not have unique codes. Instead, they may be lumped into general categories or codes as ‘other’ services. Results from the Genetic Alliance survey may be a good source of data about who receives services.

#### Genetic Activities in Public Programs: A Baseline Inventory

*Grace Wang, MPH, University of Washington*

Ms. Wang presented a summary of findings based on an inventory of genetic services provided or sponsored by state agencies. Her presentation included information on the types of services provided, how they are delivered, and who pays for them. Handouts of her slide presentation were included in the meeting binders.

Suggestions were made on where to obtain relevant data. For example, Maternal and Child Health block grant recipients report the incidence of specific genetic disorders detected through newborn screening programs; therefore each state program should have this information.

The group discussed the concept that everything has a genetic component. It was suggested that an appropriate question might be, “what is the role of genetics in a specific disease or in the spectrum of a disease?” The variability in gene expression, the number of genes that might influence a single disease, and gene-environment interaction affect the degree to which genes influence a disease process. It was noted that as more is revealed about the human genome, we are moving from identifying single gene disorders to trying to understand common diseases with complex genetic components. The group discussed the risks of ‘overselling’ the role of genetics and genetic exceptionalism.

The discussion also included comments about consumer perception and how it has the potential to drive the field. Consumer demand, or lack of it, can dictate the development and utilization of

genetic tests and services. If consumers believe that ‘genetics’ is the cause of their conditions, will they be willing to make behavior or environmental changes or will they expect a medical fix?

Other business:

Alissa Johnson made two announcements: 1) NCSL is developing a booklet for state legislatures on states’ roles in genetic programs and 2) NCSL is having its annual conference in Seattle on August 16-20, 2005 and is considering having an MCH roundtable discussion. Contact Alissa Johnson ([alissa.johnson@ncsl.org](mailto:alissa.johnson@ncsl.org)) for more information.

## **II. Genetics on the Radar Screen: Stakeholder Perspectives – Group Discussion**

The discussion continued with a question about whether payers emphasize or would expect to emphasize newborn screening. The group also considered actual risks for genetic discrimination versus perceived risks, and whether actual or perceived risks affect medical record-keeping.

Members of the committee noted that patients and providers are reluctant to report having a genetic test or the result of a genetic test. In addition, the lack of accurate ICD-9 and other billing codes limits the specificity of available information. This presents challenges for insurance companies, which use information about service utilization to develop benefit plans and set rates. Insurance companies often use proxy data if actual data are not available (e.g. family history).

The group noted a need for federal legislation to limit employment and insurance discrimination. Various drafts of legislation have been proposed at the federal level for the past several years; none of the bills have passed both houses.

In the future, genetic services may be used more for conditions such as cancer and rheumatoid arthritis to determine gene expression and tumor types rather than to detect and diagnose heritable conditions. This suggests that more patients will rely on specialists in other fields (e.g. oncology, rheumatology) than on geneticists. It also portends a need for a spectrum of genetic services over the course of a disease (e.g. screening, diagnosis, treatment, and monitoring).

The existing education system does not have the capacity to train health care providers for this type of care. There is a need for training that cross-cuts disciplines and relies on shared resources and joint curricula. The current education model is also influenced by licensing exam structures and requirements; there is an emphasis on “being an expert.” It was noted that both integrated and siloed training programs may be necessary; there will continue to be a need for experts and specialists.

Members shared some personal experiences with using integrated training models. Schools that advertise multidisciplinary programs have been shown to be more successful at recruiting students than schools that do not offer multidisciplinary programs. A program that trains laboratory technicians to work in multiple specialties is very successful. On the other hand, an effort to integrate genetics into basic nursing training curricula has been only minimally successful. Other countries may have education and training models that are better at producing cross-trained professionals.

### **III. Integrating Genetics into Consumer Information Products**

#### Information Therapy in the World of Genomics

*Donald W. Kemper, Chairman and CEO, Healthwise*

Mr. Kemper led a discussion on how consumer information products are developed and how their use is promoted by physicians, payers, and consumer groups. Copies of his slides were distributed at the meeting. He described the importance of “information therapy” (Ix) as a component of a patient’s care. Information therapy is the method of delivering the right information at the right time to help someone make the right decision. A critical element of the success of information therapy is having an electronic medical record.

One member asked how patients will manage risk information versus diagnostic information and be able to keep it private, yet share it with providers to receive the appropriate care. Testing for BRCA1/2 mutations was used to illustrate the impact of risk information on patient decision-making. A member noted a lack of both legal and financial support to treat risk rather than disease.

Payers were asked if they were developing policies that determine when and if they will cover certain procedures. Blue Cross/ Blue Shield plans use an evidence-based model to determine which services they cover. The procedure must show clinical validity and clinical utility.

Many clinical geneticists practice information therapy, but they are not compensated for the time and effort.

The risk of medicalizing everything or making genetics a part of everything and the possibility of losing the ability to change personal behaviors was discussed again in the context of this model. Some committee members noted that there are inadequate tools to study this phenomenon, especially in relation to genetics where the route from genotype to phenotype is not always well understood.

There were questions about how effective the information therapy model is and if the effectiveness depends on the education level of the patient. In general, studies are showing that this type of approach is effective. Studies of other interventions have shown that people will use information if it is offered, easy to get, and appropriately designed.

One of the biggest expenses involved in educating consumers is direct to consumer (DTC) marketing. An important factor in the success of DTC is whether a physician supports a product and its advertised message. The development, supply, and utilization of genetic technologies may be a “bottom-up movement” driven by consumer demand. Increases in discretionary spending combined with DTC marketing and the proliferation and movement of information are all factors that could contribute to a consumer-driven market for genetic services.

Something to consider: Are there circumstances under which a consumer should be prohibited from having information about his/her health?

#### **IV. Strategic Communication of Complex Social Issues**

##### Communicating Complex Social Issues: The Public Discourse about Early Child Development

*Dr. Franklin D. Gilliam Jr., University of California, Los Angeles*

Dr. Gilliam gave a presentation on how to construct messages and information to fit within a frame through which the public can relate and understand the message. He emphasized how to talk about the issue rather than focusing on the audience. Copies of his slides were included in the meeting binders.

Dr. Gilliam used an example of framing information about early child development. Other examples where this model has been successful include a children's oral health campaign, constructing messages about environmental health, and framing argument during the tobacco law suits.

The media play a substantial role in framing issues. It is difficult to combat the media's messages without the financial resources they have. One approach is to re-orient journalists, find out who their sources are and give them other sources that can deliver a different message.

#### **V. Wrap Up**

Dr. Watts solicited ideas for the next meeting. They included:

- 1) Bring a commercial testing perspective
- 2) Look broadly at educational issues
- 3) Invite ACMG and genetic counselor views on the future of genetic services, pressures of delivering genetic services, and how the genetic system needs to adapt.
- 4) Provide information about how tests are validated
- 5) Bring information or have a discussion about whether liability or malpractice change with the availability of more tests and information
- 6) Have a discussion about why public health may not want or be able to move beyond newborn screening
- 7) Discuss the licensure of genetic counselors and how it might change service delivery
- 8) Present information from the HRSA Personal Health Tools (PeHT) project on how the Internet affects health care
- 9) Discuss the role of the religious right in genetic issues
- 10) David Weismiller offered to give an update about the AAFP genetics year—education and uptake
- 11) Amy Brin offered to give an update on co-management