

Genetic Services Policy Project (GSPP) Advisory Panel Meeting
Meeting Minutes
September 24, 2004

The first meeting of the Genetic Services Policy Project Advisory Panel Meeting was held at the Churchill Hotel, Washington DC on September 24, 2004. Present were:

Advisors:

Jean Anderson
Meg Booth
Daragh Conrad
Brett Davis
Patricia Deverka
Sarah Donta
Donald Kemper
Joseph McInerney
Lee Newcomer
Lawrence O'Connor
Daniel Perry
Barry Steinhardt
Peggy Stupca
Sharon Terry
Brad Therrell
David Weismiller
Peter West
Mark Yarborough

Project Staff and Federal Partners:

Wylie Burke
Rick Carlson
Debra Lochner Doyle
Penny Kyler
Michele Lloyd-Puryear
Merle McPherson
Amber Roche
Sherry Taylor
Cindy Watts

Consultants:

Leslie Wainwright

The following represents a brief overview of discussions held and is not a detailed and complete transcript.

**Genetic Services Policy
Project Management
Introductions**

HRSA Introductions

Penny Kyler, HRSA Project Officer
Overview (see attached handouts) of where the project fits within Health Resources and Services Administration (HRSA). Maternal and Child Health Bureau, Division of Services for Children with Special Health Needs, Genetic Services Branch.

Genetic Service and Health Care Delivery, is also looking at the cross-cutting issues that are disease specific or systems specific and how they can come together.

The GSPP is nested within the concept of Translational Genetics. Also, within Translational Genetics HRSA is looking at the Public Policy Component as well as the educational component capacity for analysis and applied research projects.

Michele Lloyd-Puryear, HRSA Chief, Genetic Services Branch
These are two very important projects. Your work here will lay out HRSA's future work around providing national leadership for a broad population. HRSA is a service organization so the goals of these projects will be in the area of "services" and community based education. This Project is a cooperative agreement – a partnership between the project's staff and HRSA, where we both bring resources to the table.

Merle McPherson, Division Director, Office of Children with Special

Health Care Needs

The Genetics part of this initiative speaks to a huge emerging field that has wonderful new science to it. Much of the work there is that translational science.

The mandate we now have, is a family-centered comprehensive care approach. This portion is very much an implementation and sustainability. It is not a demonstration.

ACTION: none

Orientation Around the table introductions by Advisors.

ACTION: none

Discussion of Genetic Services Policy Project Elements

Wylie Burke

Overview (see attached handouts) of Genetics, Medicine, and Public Health. Diverse applications of genetics with diverse challenges in terms of bringing good services to people, in terms of the necessary professional and public education, and in terms ethical, legal, and social implications.

We face a number of questions: When does harm of a genetic label outweigh its benefit? Who decides when new tests and interventions are ready for use, and on what basis? And, how do we ensure access to all who can benefit?

Debra Lochner Doyle

The success of this project is determined by the experience shared by our diverse group of advisors, and the partnership between HRSA, the Washington State Department of Health, the University of Washington, and the Fred Hutchinson Cancer Research Center. It is very much a collaborative effort.

How are genetics services delivered, particularly in states with a poorer genetic services provider base. Are there alternative ways to deliver services in those areas, such as telemedicine, etc.

What types of educational materials might work best for your constituency groups, what information do they need or want, and how do they want that material disseminated?

Cindy Watts

Overview (see attached handouts) of the economics of the project in terms of who uses genetic services and why; who delivers the services and where; who pays for the services, and how do the providers get paid? Where do consumers and providers get their information about services? What is the government's role? What are the cultural, ethical and policy issues? What are alternative delivery models, and, what public policy changes do we need?

ACTION: none

Genetic Services Policy Project Elements

Rick Carlson

Overview (see attached handouts) of the changes coming in healthcare in the larger context. Genomics adds new knowledge every day. How do we deal with the new knowledge it provides? If we get into a consumer market, we will begin to see people make their own healthcare decisions and

medical services. If we give individuals that ability (to decide for themselves), we have to be prepared to have them make decisions that we (as healthcare providers) will think are wrong. We have to honor that decision unless it could result in great harm.

ACTION: none

Lunch Presentations Lee Newcomer – Vivius

Consumer involvement in self-payment in Healthcare and dramatically increasing the transparency of information to consumers they need to make more informed and better decisions.

Consumer choice is simply another name for cost shifting. Consumers are currently paying 48% of their out-of-pocket health care expenses.

Pilot program in Spokane to enable consumers to determine who their healthcare providers were, with their associated referring physicians. Premiums were set based on who the mix of physicians consisted of. Preconfigured packages of healthcare providers with its own unique price. These packages could be custom built to cover specific health-care needs, with its resultant price increase.

Insurance industry not interested in this model. Employers and consumers love this model. The close ratio was ~60%.

Brett Davis – IBM

Overview of information based medicine and why we see information technology as being so critical to the future of healthcare. Background of project with Mayo Clinic, at the cutting edge of IT within healthcare.

Dr.s today are diagnosing based on experience. At the genomics level you are not going to be able to memorize everything. It becomes critical to know how to access information to make diagnosis. We define Information-based medicine as the process of improving the existing pharmaceutical and medical practice and the knowledge generated from the integration of diverse clinical and medical data.

Lots of data are being captured electronically in silos throughout healthcare. More and more data is being generated as new technology comes on board and as new tests and research increase healthcare opportunities. There are volumes of environmental data out there that are also silo'd and often not integrated with genotypic and phenotypic information.

Data can be captured, integrated, and used in three different capacities. One being basic research, also in the clinical research and development, and finally in clinical delivery. Can revolutionize the way disease is diagnosed and treated.

Mayo Project takes clinical data and integrates it with the research data that has been generated at the Mayo Clinic, and also with external and public databases that exist in that have emerged in the last 10 or 15 years. (such as disease registries)

All the information about disease is out there, its just not easy to query. Phase I was integrated the data, over 4.4 million patient records, in a way that clinicians could query it. Prior to integration a query would take approximately 6 weeks with 4 people devoted full time to accessing various

databases for the data. After phase I the query took 6 seconds to answer. Pretty big impact on productivity. Being used in the research environment currently but expected to be used ultimately in the clinical setting with direct patient care.

ACTION: Phase II integrates the research data and allows unstructured text searches.
none

**Breakout Sessions
Group One Summary:**

We started off with a fairly lively discussion about how we might communicate with this group over the next year until we are able to meet again face-to-face. One of the things that we agreed upon was that the BLOG was the right way to do our routine communications. We will be parsimonious in our requests of you, we will make specific requests, we will not give solutions, but questions to take the most advantage of your expertise. We might also use web-casts and conference calls and not use list-serves to clog up your email. Also, we will be religious about giving you progress reports on the project.

Themes:

There are some cross-cutting issues that cut across all of the themes that kept reoccurring.

Its really important that we look at all of this from various perspectives, that we aren't always focusing on the provider perspective or the payer perspective or any other perspective. One of the strengths of this group is that we are going to look at all sorts of different perspectives and we need to keep that in mind. We need to stay cognizant of the regulatory context and the impact of existing regulations on service delivery and secondly we need to be aware of the different business models that different stakeholders have from which they operate.

The next theme was about information. This is clearly a very important theme throughout the project. Who gets it? Who controls it? How do we manage it? Does it matter who pays for it, in terms of the answers to any of those questions?

A related issue is value determination, and whose values count in making decisions about all of the above?

The last theme is the issue of consumer driven healthcare and its implications.

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Ideas for the Case studies to be developed:

- A case study around who would benefit from a specific drug.
- A case involving the criteria used to evaluate a new genetic service.
- A case in which the person being tested doesn't really expect to take action (predetermination of disease).
- A case study that involves the duty to warn and what constitutes adequate discharge of that duty; the issues around liability.
- A case study of a condition involving adult onset of a genetic disease where there were some primary prevention activities that could be taken in adolescence to prevent or mitigate the impact of the disorder.
- Newborn screening – What can we learn from the newborn screening experience that would translate to other areas?
- Coverage and Universal Coverage. It might be interesting to look at an international example in a country where there is universal coverage. Look at the interaction between universal coverage, the coverage and utilization of preventive services and genetic services in particular. When there is universal coverage, there is more emphasis on evidence based decision making, typically around benefits for a cohort rather than an individual.
- A case study that would have us deal with the practicality of genetic services provided in clinical offices where clinicians have limitations on their time and resources.
- Concept of beneficence, value determination. Whose values? Is it enough that this test will give the consumer information? Even if obsess/he doesn't behave differently, is there still value in the information? Who gets to decide? Perhaps the behavior change is not readily observable. Is the answer dependent on who pays for the test?
- Does testing affect the availability of insurance? Insurance companies are already making coverage decisions based on family history. One of the ways in which genetic information might actually increase a person's ability to get insurance coverage might be if a consumer has a family history of breast cancer (and so might be heavily underwritten), and then tests negative for the BRCA1 mutation.

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Group One Notes: Genetic information can make people more insurable (test vs family history). How providers and others manage huge volume of new information on all patients.

Ideas for the Case studies to be developed:

Who will benefit from drug, how to manage within complex system.

- affect patient?
- provider?
- manufacturer?
- overall economics?

Regulatory environment – some important information not observable – need to have hypothetical too.

Drug company will/may suppress information about value

Payer will define context within which reimbursable

Value determination

- who's values?

- informed by whom?

What criteria are used by various stakeholders to evaluate new genetic services?

Need to consider business models

Predetermination of disease when “consumer knows s/he won't act on information

Should payment for test be predicated on use of information?

Who pays for beneficence?

- family centered care – decision maker

- value of information – who's value?

Medical model vs family/broader model

Public health/private health

Duty to warn/ defensive medicine

JAMA OB Literature

Genetic test as defensive medicine

Trade association's policy on existing statements

What constitutes adequately discharging duty to warn?

Can we get providers and patients on same page around right information?

Primary prevention around adult onset genetic diseases (major chronic disease)

Create hypothetical that involves drug and treatment.

What is health? What is illness? The unpatient

What does genetic literacy mean (providers, patients)

Need different kinds of information for providers vs patients

Goal – health promotion – eliminate all sources of disease except genetic factors.

Genetics drives medicine information science of difference.

Difference between what is beneficial and what we can afford.

Bad at doing tech assessment

Consumer choice is ultimate of value?

Flow chart of d-m by different stakeholders.

Who should have control over information?

Individual medical record

Should information go only to medical home?

Does concept of medical home have legs outside newborn screening?

What we do to our infants is different from what we do to adults.

NBS system provides lots of experience with a specific context

Application of child IQ information/ HIV information

Case study on right to information – Lee's case information only

Does right to know attach to who pays?

Nothing about me without me

Patients see value in information

Payors see little value in inactionable information

Universal/single payer devalues personalized medicine

Case study: international example – is universal coverage compatible with preventive genetic information.

Case – what is practicality of genetic service with limits on clinician's time and money?

Education – evidence-based trend moves focus to cohort not individual

Not blasts of fragments, threaded discussions – on website or bulletin board

Boss can summarize and make specific requests and trigger response

Library of resources

Blog with passwords

NOT listserves

Make individual requests

Conference call/ webcast

Genetic Alliance is developing survey tool with immediate feedback and links

to more information.
Quarterly update on project – progress reports
One week response time
Come to us with questions vs solutions
Periodic sub-groups around specific issues
Distribute notes.

ACTION: - Sherry Taylor

**Breakout Sessions
Group Two Summary:**

We tried to distill it down at the end, to a couple of key take-aways as far as what we could talk through. The first is the enormity of what this project could be because there are so many stakeholder groups that could be involved and there is so much depth and breadth and variety of issues that affect all of these stakeholders. The more that we were talking the larger the issues became. But when we tried to come back as a group at the end of our time, we identified a couple of key take-aways.

One extraordinary opportunity that this group has is the idea of breaking some of those potentially negative themes/connotations around genetics and its implications and really challenge the idea that it is different than some other elements of the medical practice. How do we reframe genetics to the consumer away from the negative.

The second was building on the lessons learned. Because we have the history behind neonatal genetics, and in that process we have learned a variety of very important lessons. Where we are going in the future really builds upon that. We can use that as a guidepost, and we can build some case studies that reflect what we have learned, it really doesn't encompass where we are going because the disease categories are much larger and more complex. While they give us a history to build on, they might not always give us what we need to navigate the future.

Developing Case studies:

We built on the idea of both an antidepressant, possibly statins or gleevac, for a pharmacogenetics type of example.

We spent some time talking about the near-term/ far-term in the context of cancer because it's a diagnosed disease and thinking about some of the applications in genetics with a disease like that because the disease already exists, as opposed to some of the risk assessment type of applications where you are doing more prognostic type of work.

So the idea of potentially doing two different case studies, one in something that is more of a "here and now", such as a cancer example, and then something a little bit longer term, such as diabetes.

Definition of public health and the role of public health. The role the state potentially plays in initiatives like this and things that stakeholder groups would be interested in. And the role the state possibly plays in assuring that there are frameworks in place to get people up to speed on what they need to know.

We talked a little bit about revisiting the continuum of care and how since genetic information is going to be with you when you visit your primary care physician, if you happen to go to the ED, you need in-patient care, and making sure that whatever this turns into over time, there is a continuum of care. That the way we build lab testing modules for test reporting is

applicable to that continuum of care.

In the context of the laboratory we talked about the “must have” at some point of some ability to critically evaluate specificity of sensitivity parameters around tests that are coming up and when they are applicable in certain care paths to begin to frame some protocols as far as how they could be used.

Recognizing that there may not be enough genetic counselors to be able to satisfy all of the demand moving forward, nor enough competently trained laboratorians, how do we empower, either with IT tools, or other type of care decision matrix tools that the general provider audience can use to do a better job of being a deliverer of genetic information?

What type of education tools can be developed that we, as a team could develop, that we could then take back to our core constituents that they could then use. It was almost a teach-the-teacher, we didn't reach an exact resolution as far as what those exact tools would be other than the case studies would have extreme value across the board because each can potentially resonate and hit a chord at a slightly different level of those core groups.

Group Two Notes: Case studies:
Antidepressants
Statins
Gleevac
Walk-through system, look for points of change for policy-makers to look at impact of genomics
Newborn screening example – also consider issue of screening for adult onset disease, Icing carriers (ie CF)
Look for lessons learned

Information needed:
What is the most effective testing?
- protocols
- sensitivity
What is the role of public health
- agency
- generally
Professional education – when, how
What makes a provider qualified?
What continuing education is needed?
Education about what is an appropriate referral?
Importance of coordinated care after testing – who provides?
How are services being delivered?
Where do consumers want counseling provided? By whom?
What do consumers know/want to know about genetics?
IT tools to help providers
Barriers – stigma, fear of discrimination, perceived complexity – are they unique to genetics?
Is genetics different from general medicine?
Target different audiences with different educational approaches
Map out where genetic services are available
What restrictions are there on where genetic counselors can practice (ie licensing in California and Utah)
Diversity, cultural, language issues
Providers want cost effectiveness information, other facts.

Delivery of information:
Sent out to select members of organizations (beyond advisory group) for review.

Consumers:
Where in their state can they get information?
How will it impact the family unit?

ACTION: Distribute notes.
-*Sherry Taylor*

Feedback and Suggestions from Advisors: Kay Collins – please insert

ACTION: To be inserted by Kay Collins.

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Is the question of who pays for the test wrapped up in whether or not its okay for me to have that information even if I don't plan to act on it or there is nothing that can be done, as in the case of Huntingtons.

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Unknown

The issue of information having consequences for your ability to get insurance. Is that something you distribute like you distribute the costs of intervention?

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Unknown

but actually I'm one of the three out of four who won't.

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Unknown

If I DON'T have the genetic test I'm going to get denied coverage based on my family history. If I GET the test I can prove that I'm one of the three to four that won't. It's underwriting rather than coverage.

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Comments:

I hope that our cases could let us not worry about the status quo, but think about how do we make sure people use genetics counselors or advocacy groups or geneticists, but to ask, do we need genetics counselors? Do we need Advocacy groups, do we need geneticists? Strip it down and ask the basic questions. Here is how we currently deliver services, how could we do it differently?

Since so much of the focus is on delivery models, I think as we decide what the case studies ought to be, we want to make sure they're just not clinical examples that are individually removed from the delivery model questions. Fundamentally there are two delivery models, public and private. Public delivery models cannot take on this entire burden and private models have their limitations too.