

Break-Out Sessions

May 15, 1998

1:15 – 4:30 PM

Session A.: Privacy and Confidentiality

(1:15 and 3:00 sessions combined)

Facilitators: Sonia Suter, JD, MS (Kennedy Institute of Ethics, Georgetown University)
Lawrence Gostin, JD (Law, Georgetown University)

Transcriber: Stephen Modell, MD, MS (Research Associate – Health Management and Policy,
University of Michigan)

Sonia Suter: The relevant areas discussed by the communities were disclosure of genetic information to third parties, access to genetic information, discrimination, and autonomy / liberty interests. The community responses were:

1.
 - a. Strong opposition to legislation that would require disclosure of genetic information.
 - b. Support for legal rights not to disclose genetic information.
 - c. Support for professional policies encouraging patients to disclose to relatives.
 - d. Support for enforcement mechanisms to protect against disclosure (with protections for professionals in some circumstances).
2. Overwhelming support for legislation that would prevent insurer access to and discrimination based on genetic information.
3. Support for legislation intended to prevent general employer access to genetic information, with public health as the exception.
4. Strong support for legislation protecting autonomy and liberty interests.
 - a. Strong opposition to mandatory genetic testing of adults (not newborns).
 - b. Strong support and belief in the value of informed consent and genetic counseling.
 - c. Ambivalence when counseling would infringe on individual liberty, e.g., mandating genetic counseling. Counseling to be made available, not forced (participants were divided on this).

Also in the broader document are the general policy recommendations Ed Goldman addressed this morning. The recommendations involve balancing protection of privacy and autonomy with research interests and clinical care. They also cover disclosure and discrimination. There are four main areas:

1. Disclosure of Genetic Information

- a. Strong support for legislation not mandating disclosure of genetic information to third parties, including spouses or potentially affected relatives. This is consistent with existing and pending legislation.
- b. Health care professionals should have no legal duty to disclose genetic information to third parties without consent. In emerging case law there is a duty to at least warn the patient that relatives are at risk. But in another case we looked at, it is unclear whether the duty would go further and require contacting the relative.

- c. That there definitely is a required duty to disclose to at-risk third parties has not been stated by the courts yet. We recommend professional policies requiring directiveness to encourage patients to disclose information to affected relatives as part of their moral responsibility.
- d. Serious consideration should be given to requiring health-care professionals to disclose to at-risk third parties in narrow situations (and to shielding them from liability) when:
 - i the individual faces a serious, preventable risk
 - ii the patient is unyielding in their refusal to inform the individual
 - iii the risk is avertable
 - iv no other effective alternatives exist to prevent the potential harm
 - v efforts to obtain the patient's informed consent are unsuccessful

These criteria were not part of the community dialogues. The communities do believe there are public health risks to be protected against and that professionals are to set policy in this area rather than the legislature. The communities considered the notion of “serious risk” vague, which is the drawback of a flexible policy.

2. Insurance Discrimination

- a. Overwhelming support existed for legislation that would prevent insurer access to and discrimination based on genetic information. We recommended legislation prohibiting insurance discrimination based on genetic information, including actuarial fairness.
- b. We recommend that legislation look at health and other kinds of insurance (life, disability) differently with respect to issues of discrimination.
- c. We question the wisdom of prohibiting discrimination with respect to genetic conditions only. Legislation should seriously consider whether there should be a difference in underwriting based on genetics compared to general medical conditions—there was general opposition to underwriting of any sort.
- d. In general, legislators should address issues of insurance discrimination in the context of the access question - the problem of the lack of access to health care and insurance.

3. Employment Discrimination

- a. There was strong support for legislation preventing employers access to genetic information.
- b. The communities supported exceptions where there is a benefit to public safety or employee safety. The caveat is that care must be taken to ensure a legitimate basis for such exceptions – there must really be a benefit to the public. That is, don't test all pilots for Huntington's disease.
- c. The policy team recommended that legislation should not require employers to conduct genetic testing to protect public safety. There was some community division on this. Perhaps the communities did not distinguish genetic information from other information employers need to protect the public.
- d. It is appropriate for employers to offer genetic testing to employees who are interested in knowing their workplace susceptibility. The focus should be on making the workplace safer.
- e. The communities support anti-discrimination legislation in the workplace.

4. Privacy / Autonomy Interests

- a. Any state involvement should preserve reproductive and general liberty.
- b. Legislation should emphasize that genetic testing of adults should be voluntary.
- c. Governmental programs should not impose restrictions on childbearing.

- d. Policies should allow individuals to decide whether to receive genetic test results.
- e. Informed consent must be required, but legislatures should avoid articulating specific elements of it.
- f. Professional policies should insure that genetic counseling is a part of professional policies. This leads to the further question of whether genetic counseling should simply be made available or whether it should be legally required?

Lawrence Gostin: I would like to cover genetic information in the context of the broader health information infrastructure in the U.S. The basic system exists to collect / store / and use genetic information, and to support the category of services including genetic testing and counseling. According to the Institute of Medicine, there are three aspects:

1. The Electronic Patient Record

This is longitudinal, stretching from a pre-birth health stick to post-death records. More information is available about us before we are even born. The system can collect your medical information for your entire lifespan. After death there is no privacy due to autopsies. Take the tomb of the unknown soldier which is being re-opened, or Abraham Lincoln's grave, which has also been opened to demonstrate whether he had Marfan's Syndrome.

2. The Direct Collection of DNA

e.g., with stored tissue samples as held by NIH, CDC (the National Institutes of Health and Centers for Disease Control), and federal agencies. These are "inchoate" genetic databases (as termed by Phil Collins). The future use is unclear to both the person being tested and the researcher. Guthrie cards for newborns are the classic example. These are kept by all fifty states.

3. Longitudinal Research

The CDC-led NHANES-IV national survey will include genetic testing.

What are we to do about all this material, e.g., a drop of blood in tissue? The costs will come down. Industry, managed care, pharmaceutical companies will want this information. An issue that arises is, "How much should society encourage the collection? How much should society restrict the proliferation of genetic information?" This points out the confusion between security and privacy. Trade-offs exist between individual privacy and the public good—we can't have it both ways. There is activity in this area. I chaired a Task Force the CDC commissioned through the Carter Presidential Center which yielded proposals in the area of health information and privacy. Right now the CDC is hosting the first Annual Conference on Public Health Genetics. Attendees are looking at privacy concerns, the communal groups desiring the genetic information, and various proposals.

Summary of Participant Responses

[bracketed numbers refer to pages in the "Community Dialogues" and "Policy Approaches" sections of the Policy Approaches / Recommendations Report]

Several persons touched on the role of government in genetic liberty. One participant suggested universal testing (i.e., government-promoted screening) for genetic predispositions, cancer for example, as a way to solve ethical dilemmas. Since few people are without some type of genetically-associated predisposition, this person felt that such a system would make people more inclined to share

genetic information, getting around the confidentiality problem. Another person felt that such programs were only worthy of turning into legislation if a form of prevention or treatment for the condition exists and the condition has definable boundaries. Though the criticism of loss of personal autonomy under mandatory testing did not come up, another participant felt the public could become disenchanted with genetic screening if it were marketed as a public health program. [pp. 47-9, 62, 68]

The feeling was that we should not move too quickly on legislation that stands a chance of impairing research through limiting access to needed materials and records. [p. 61] Individual autonomy was viewed as being most important, while at the same time people recognized that policies should be adopted that would not damage the research enterprise. These policies could include anonymization of data used in research through stripping of identifiers, as well as comprehensive privacy statutes. It was noted that anonymization of data could have counterproductive effects for some public health and health services research. [pp. 72-4]

The government was viewed as responsible for the guaranteeing of privacy. [pp. 50-1, 62] However, there was some consternation with the slowing of anti-discrimination legislation in some states. The inclusion of terminology about privacy rights on the samples used in research was noted as an obstacle both to the passage of this legislation and to making it compatible with research. [p. 73]

Participants wrestling with the idea of legislation protecting professionals from disclosing genetic information to third parties in certain situations came to several conclusions: there should be a distinction between professional duty to disclose and professional privilege to disclose in needy situations (the latter allowing professional judgment); disclosure of genetic information should generally not be viewed as similar to the infectious disease model of disclosure; properly handled, information about biological parents could justifiably be made available to adoptees. [pp. 58, 68-9]

There was disagreement on whether rates should continue to be based on traditional actuarial analysis and whether those with a positive genetic test should be penalized against in terms of their rates. One person thought the system was not yet ready for a change, versus several people opting for "a flat rate for everybody." Reasons given were that we don't want to be punished for family history, people have no control over whether they have a genetic condition, and we all have genes which predispose us towards illness. Two participants suggested intermediary solutions with legislation establishing minimum packages for different risk pools.

Participants concurred that genetic information should be treated like other medical information (contra "genetic exceptionalism"), with both types deserving protection from discrimination. [pp. 61, 76] This was true both in terms of insurance rating and freedom from the excesses of required testing, e.g., in the workplace. Participants acknowledged that instances of genetic discrimination might not be that abundant in the workplace, but feared that the perception of increasing costs with testing could cause some companies to alter their policies. [pp. 50, 75] Uncertainty existed in how genetic and other medical information could be placed under the same roof insurance-wise. The suggestion was made that we should start with genetics, not all medical information, then move towards a more general separation of insurance plans from underwriting. [p. 76]

There was general support for reasonable access to health care insurance. People seemed willing to pay more in premiums, with several participants inclined to community rating for genetic testing as a way

of spreading costs and risks. [p. 55-6, 76] The sentiment was that other areas such as infertility treatment and advanced reproductive technologies were less appropriate for community rating systems, though. Another concern was that even if access to health insurance were guaranteed, there would still be communities not enjoying availability of genetic and genetics-related reproductive services. [p. 77]

Participants agreed on the importance of educating the public on genetic matters, but disagreed on the source of the education. Shortcomings were cited in professional training in genetics and the time providers have available to instruct patients, but it was argued nonetheless that professionals have more understanding on what needs to be done to educate people than do legislators. [pp. 59, 64, 66, 77-78]

Break-Out Session B.: Access to Genetic Services

(1:15 and 3:00 sessions combined)

Facilitators: Dean Smith, Ph.D. (Health Management and Policy, University of Michigan)

Dan Brock, Ph.D. (Philosophy and Biomedical Ethics, Brown University)

Transcriber: Cathryn Bock (Graduate Assistant – Health Behavior / Health Education, University of Michigan)

Dean Smith: In this session we want to ask, “Where would one take a policy like this if we were actually planning to implement it?” We will be discussing briefly how access issues were framed in the policy deliberations, the types of questions that were asked of the groups, and recommendations that came forth. We want to look at the meaning of these policies and the feasibility of taking steps to translate them into action.

A. Access - Dimensions and Definitions

This session is on access to genetic services, but “access” is a very broad term. I will start with some definitions from health management and policy. Access is the “fit” between patients and providers along five dimensions. The five A's are:

- *Availability* - the volume (supply) of services relative to patient needs. Basically, this means that there is someone present who actually can provide the service.
- *Accessibility* - the location of services relative to patient locations and transportation opportunities. Not only do the services exist, but people can get to them. Transportation is amenable and the services are made available to people in a way they can understand.
- *Accommodation* - the organization of the service system and its ability to accept / admit patients (including hours of service, appointments). There is a process for admitting people with adequate hours of service and times they can make appointments.
- *Affordability* - the price of services relative to patient ability to pay (including issues of insurance coverage). The price that people have to pay relative to their ability to pay is such that they can still have the services.

- *Acceptability* - the relationship between patient attitudes about provider personal and practice characteristics (and providers' attitudes about patients). There is a relationship between the people providing the service and those receiving it such that they can communicate with one another and are willing to work together. In the academic setting where physicians are involved in research and constantly dealing with grants, this often suffers.

One can imagine policies involving all of the A's of access, although discussions deal mostly with availability of services - there being an adequate supply of trained counselors and testing sites - and affordability. As economists say, "At the right price, anything is accessible."

B. High Level Access Issues

The high-level access issues that were brought up in the dialogue questions can be stated as principles:

- Assuring appropriate access to genetic services will require the coordination of professionals, government agencies, insurers and other organizations.
- Genetic services can be expensive. Defining *appropriate* access will not be easy and will be a continuous process as we learn more about the genome and as more services become available.

C. Policy Recommendations

We also had a number of policy approaches that came up from discussions. There were no areas in which acceptance of approaches or recommendations was unanimous. The access-related policy recommendations that did emerge can be summarized with five statements:

- It is recommended that policy makers consider mandating the *availability or offer* of genetic counseling.
- It is recommended that policy makers explore mechanisms to increase the number of professionals who can provide adequate genetic counseling. This second principle is implied in the first one.
- If policy makers consider making genetic counseling available, they should develop mechanisms to allow for payment of such services.
- If counseling can't be made available for all tests, it is recommended that counseling be made available for those that have the greatest need, especially genetic tests that raise complex psychosocial and reproductive issues.
- It is recommended that newborn screening programs ensure that there is follow-up and treatment without regard to ability to pay.

It is one thing to have tests made available to find out if there is a genetic predisposition to a condition, another thing to make policy available to help people decide what to do with it, and a further issue what to do once you know. In Michigan we had a screening program for breast cancer in women in which there was a half million dollars to spend and we had to decide how to spend it. Those involved decided all the money would go towards free screening, with no money left over for treatment. These

are tough decisions to make. Do we only test, treat, follow-up, and find a cure for a select population, or do we treat everyone?

Dan Brock: I will summarize what I see as some of the main policy issues in the access area:

- **Access for the Uninsured**

We have over 40 million Americans without health insurance, which raises special issues of access. What public priority should genetic services have given other important services that are not available to the uninsured? Some genetic testing can be important in preventing serious harms, and in some cases it is cost-effective to do testing and follow-up. That might be a reason for giving special priority to these services, but the problem of access for the uninsured still remains.

- **Genetics Coverage for the Insured**

To what extent should genetic services be covered as standard benefits for the insured? A typical condition for the termination of most benefit and managed care plans is the notion of medical necessity. This notion is a little trickier to apply in the genetics area. We may need to think in a different way about what criteria should be used for inclusion or exclusion.

- **Coverage of Genetically-Related Reproductive Services**

Should these services be mandated for insurance plans as coverage of specific reproductive technologies? If it is simply optional, then coverage will exist in some plans and not others, and these services, which are expensive, will not be available to persons lacking coverage in their insurance plans. This brings up the issue of whether that is unjust or unfair.

- **Spreading Risks**

Is it the purpose of health insurance to spread risks as broadly as possible across the population? If so, this would seem to imply some kind of national health insurance, though this does not seem to be in the offing for the near term. But we can still talk about mandating community rating for insurance if we think this is appropriate. This relates to our broader understandings of the purposes of insurance.

- **Underwriting Genetic Risk**

Is it morally acceptable to underwrite insurance in the area of genetics if the purpose is to spread risks across the population? A number of people have argued that given our increasing ability to test for more and more conditions or risk factors, continuing to underwrite will in effect undermine the purpose of health insurance, which is to spread risk. The more you underwrite, the more you avoid spreading risks across the population since you are actually trying to gear premiums to the risks. That is implied in the notion of actuarial fairness.

- **Actuarial Fairness**

Two different conceptions of fairness are at work here. One is our conception that one shouldn't have to pay higher insurance costs for health risks that are no fault of one's own. The other is the notion of "actuarial fairness" that insurers use, which Thomas Murray talked about this morning. What is the appropriate conception of fairness for health insurance?

- **Health Insurance vs. Life and Disability Insurance**

Should health insurance be treated differently from life or disability insurance? The community dialogues report cited two reasons for possibly doing so. One was the idea that health insurance is more of a necessity. Second, there is a serious problem of adverse selection with regard to both life and disability insurance. It is not part of our notion of fairness that if a person develops a life-threatening condition, they have the right to buy huge amounts of life insurance when the insurance company doesn't know of that condition. There are moral differences involved which could justify policy differences.

- **Genetics Exceptionalism**

As discussed by Thomas Murray, is "genetics exceptionalism" (treating genetic conditions differently from other "non-genetic" conditions, e.g., with respect to health insurance) justified and feasible?

- **Economic Incentives**

Should we have economic incentives to get people to use genetic services? This would be more than simply offering funding. Related issues are "What services can be applied for?" and "Who should be paying for them?"

- **Access to Genetic Counseling**

What genetic counseling should people have access to in addition to genetic testing? This can involve issues of pretest counseling, posttest counseling, and who gets counseling - everyone who has had the test, or only those who have had positive results? Expenses will increase as we gain the ability to do a lot more tests. There also are not enough genetic counselors to do systematic genetic counseling for the tests we have now, much less those we will have in the future. It is estimated that if we had a population-wide cystic fibrosis screening program, it would exhaust the ranks and still leave us with a shortage of all the genetic counselors that exist today.

- **Prohibiting Employer Access to Genetic Information and its Exceptions**

Should employers be prohibited from using their employees' genetic information? The dialogues report notes strong opposition to employers being able to use that information, but two exceptions exist: a. public health reasons, e.g., testing airline pilots if they have a history of Huntington's disease; b. for the benefit of the employee - to determine whether they might have special susceptibilities to particular workplace conditions. (Employers have also invoked this reason in non-genetic cases.)

- **Feasibility of Prohibiting Employer and Insurer Access to Genetic Information**

There will be some record of genetic testing if it is done. How feasible is it and how would it be possible to keep the information from employers or insurers, and if they do get such information, to guarantee that they don't use it in decision making? For example, insurers have found all kinds of strategies to avoid getting high cost patients in their plans once they have the applicant's information, not just denying them admission.

- **Nonfinancial Barriers to Access of Genetic Services**

Nonfinancial barriers to health care - geographic, cultural, ethnic, and educational - do exist and have important consequences. Will there be comparable nonfinancial barriers for genetic services? What strategies are necessary to try to deal with such barriers?

- **Effect of Employer or Insurer Access on Test Taking**

Will the very possibility that personal genetic information might get to employers and insurers and be used by them in decisions affecting potential employees or enrollees be a significant barrier to individuals undergoing the tests, when they otherwise would do so? They could be reluctant to undergo testing for fear it will be used adversely against them.

- **Abortion and Policy Making**

Regarding the politically charged issue of abortion: this can lead to irrational policy decisions to cover some things but not others in ways that don't make sense.

- **Right Not to Know / Disclose Personal Genetic Information**

Should there be a legally protected right not to impose or disclose medical information? Here again we have the issue of whether health insurance is similar to life and disability insurance.

- **Who Should Decide?**

Given the very strong consensus in the dialogues that some law and regulation is desirable in this area, the question arises: "Who should it come from?" There are various pluses and minuses to the different alternatives.

These are the main policy issues as I see them. For me many of the issues are moral ones which have a policy import.

Summary of Participant Responses

[bracketed numbers refer to pages in the "Community Dialogues" and "Policy Approaches" sections of the Policy Approaches / Recommendations Report]

Participants discussed the merits of covering the costs of genetic services. One person felt they should be treated no differently than other medical procedures, and that genetic as well as non-genetic services are part of one continuum. Participants tended to argue against genetic exceptionalism from the coverage standpoint. [p. 76] Several saw genetic testing as costly, possibly placing employers in the position of having to pay unwanted larger amounts for employee insurance. One professional in the group remarked that payers (insurance companies, managed care) might not be adverse to across-the-board mandates where organizations are affected equally, a suggestion also made at the March 1997 Genome Policy Conference. One person relayed from the community dialogues she participated in that there are other health needs which are equally deserving, such as mental health and substance abuse. Three participants felt that access to and coverage of (through insurance, Medicare, Medicaid) a particular kind of genetic testing should be based on general need, though one person cited the importance of leaving open the door for less tangible, more personalized factors. There was also mention of prenatal testing services not getting to those most in need of them. [pp. 54-6, 62]

Though examples of general medical procedures not requiring counseling were brought up, people felt that genetic testing poses an additional layer of complexity requiring counseling, with one person stating that it would be unethical to offer genetic testing without counseling. This was not a simple equation, though. There was some feeling that counseling was more imperative in the case of prenatal testing than adult predictive testing, e.g., cancer testing. The distinction was once again made between

the offering of counseling and the requiring of counseling, with the former drawing more interest. It was felt that this was matter for professional standards rather than law or legislation. [pp. 52-3, 64-6, 77]

People felt it is important for counseling to be available, but the source of the counseling encountered heavy argument in both sessions. The general feeling was that those offering the counseling would need a practical appreciation of the values of non-directiveness and informed consent, though it was recognized that there may be situations in genetics when a more directive approach is needed. [pp. 57-8, 64, 67-9] While some felt the responsibility for genetic counseling should belong to professionally trained genetic counselors, there was general concern that the demand would outstrip their availability. The fact that insurance companies do not independently reimburse for genetic counseling was also cited as a limitation. [pp. 66-7] As more and more genetic tests come up, many felt counseling duties would need to also be a part of physician responsibilities, with intensity of the counseling depending on the specific situation. However, there was concern for lack of availability of physician time to conduct the counseling. One person suggested bringing more of the health care team, such as social workers, into the picture.

People in both sessions agreed that support for newborn screening should continue, regardless of ability to pay. [pp. 55-6, 71] Participants generally gave their support for coverage of the current varieties of genetic testing dealing with inherited conditions of earlier onset. Participants emphasized there should not be a blanket policy of coverage for all genetic tests—the nature of the condition mattered, from both a practical and an ethical standpoint. There was the feeling that more and more tests would be developed to check for genes associated with conditions of later onset and concern that a system needs to be in place to avoid costs arising from more ubiquitous testing. Some people felt that insurances tested for late-onset conditions with an environmental component should be held responsible for and bear / be rewarded the increased or decreased costs stemming from their own health behaviors. The ethical issue of people not wanting to relay health information to their doctors for fear of being held responsible was cited but not resolved.

The issue of health services research concerned with genetic testing came up. People felt that such research could be valuable in determining the cost-effectiveness of genetic services. There were more people in favor of some form of consent for access to personal genetic information for research than there were against the idea. The discussion did not touch on the components of cost-effectiveness or the possibility of anonymizing data. [pp. 72-3]

Three people mentioned the need to have in place protections against disclosure of personal genetic information and consequent genetic discrimination. These concern related to employer and insurance discrimination as well as to group participation in research protocols. [pp. 49-51, 61, 74-6]

There was also the feeling that appropriate education was important for those delivering genetic testing and genetic counseling. Members stated there should be more genetic training for doctors as well as an attempt to train and produce more genetic counselors. [pp. 77-8] How this could be accomplished was not spelled out. One participant admitted, “There should be protocols for education - elementary schools through professional training, but funding/acceptance is low.” One person suggested interactive computer models as an innovative solution. Licensing for conducting genetic testing and

counseling was viewed favorably though it was also recognized that adequate systems may not be in place at this time. [p. 59]

Break-Out Session C.: Reproductive Technologies

(1:15 and 3:00 sessions combined)

Facilitators: Elizabeth Petty, MD (Human Genetics and Internal Medicine, University of Michigan)
Richard King, MD, PhD (Medicine and Pediatrics, Division of Genetics and Metabolism, University of Minnesota)

Transcriber: Aaron Kalinowski (Graduate Assistant – Hospital and Molecular Epidemiology, University of Michigan)

Elizabeth Petty: We will be talking about some of the policy approaches that came out of the dialogue sessions, focusing on specific genetic testing and reproductive technologies. These issues are very real, actual concerns that apply to people and families, touching all of us in some way at some point in our lives. During the past week in my adult genetics clinic, I have seen two different individuals who help to illustrate the various problems and issues that come up.

- 1. Recently I saw a family where the husband has an autosomal dominant genetic condition. It is disfiguring; he has had multiple surgeries and medical problems associated with it. He and his wife are very concerned about the risk of having a child with the same condition because of all the problems he went through as a child. They are interested in knowing the actual risk to their children. The child would have a 50 / 50 chance of having the condition. The gene is known and there is actually genetic testing for it. We talked about the condition and what is available for genetic testing and prenatal diagnosis. The husband and wife took in the information but left the clinic saying, “Thank you. That’s helpful information. We’re going to take our chances. We appreciate all the education but do not want genetic testing.” The patient left without any genetic testing, and decided to proceed with family planning. The couple will hope for the best and deal with whatever the outcome may be.*
- 2. In another family, both parents, though unaffected, are carriers of a genetic condition. They have a 25% chance of having a child with cystic fibrosis, for which specific genetic testing is also available. This family doesn’t feel they can go through prenatal diagnosis and abortion because it is against their own moral values and principles, but they do have the financial means to look at other assisted reproductive technologies. They are actually very interested in doing in-vitro fertilization with preimplantation diagnosis. This option is what is most comfortable for them and their family given their available resources.*

These two cases illustrate the different choices that families may have to make. Both couples are concerned about having children with a specific genetic disorder. In both cases we, as geneticists and genetic counselors, listen to their concerns and try to support whatever decisions they want to make. The case scenarios we are talking about are not necessarily futuristic, although they will continue to evolve and scientists will have even greater abilities in the future. The related questions will apply to everybody in the room or to our families in some fashion, requiring us all to think about them and deal with them.

At present there is very little legislation dealing with genetic testing specifically in terms of reproductive technology. Legislation exists and is being further explored for medical privacy and discrimination, but there are not a lot of specifics concerning regulation of genetic testing and reproductive technology. There is a large gap between what we are currently able to do in terms of testing, and the treatment that exists in the prenatal arena. We have a lot of knowledge, but in most cases at present we are not able to intervene in-utero to change or significantly alter the course of disease.

There are some difficult options that individuals often must face, one being termination of a pregnancy. These issues, which are tied into moral considerations about abortion, revolve around when conception starts and human life begins. People have a wide array of different opinions, and often times these opinions get in the way of talking about the other issues, including those connected with genetic testing and reproductive technologies. We have been very fortunate in the community dialogues to have had very rational, calm discussion of these issues, which often can be quite volatile. These are very important human values we can't ignore and which have to be kept in mind.

Currently, there is very little overall support for financial backing of or widespread access to complex assisted reproductive technology. Oftentimes, it is not easily available unless you are in the upper middle class, and have the financial means and the educational background to know about and specifically ask about it. But discoveries rapidly continue and it will be important that all individuals are aware of their options regarding reproductive decision-making.

Some of the broad questions we want to address in this session are:

- Do individuals have a moral responsibility for good reproductive decision making?
This is a very subjective question. What is "responsible reproductive decision making?"
- Who is responsible for making "good reproductive choices?" If individuals or their families do or do not have a moral responsibility, does the government have the right to say what the "good choice" to be made is? Do health professionals and professional societies have a right or an obligation to say, "This is the right choice and this is the wrong choice?" Who should be making these policies - the individual, scientists, doctors, the marketplace? Right now reproductive technology is market-driven. There is a dearth of specific laws and guidelines. In genetics generally we follow a non-directive counseling approach; we are taught to support the decisions that individuals and families make based on their own values. We shouldn't influence them with our own particular values and beliefs; our job is to educate, inform, and support individuals as they confront difficult choices.
- Which new technologies should be given public or governmental support to make sure they are available for everybody wanting them? The list potentially includes in-vitro fertilization where the egg and sperm are put together outside the uterus, then put back into the body to develop into a human being; preimplantation genetic diagnosis; in-utero gene therapy (future trials are conceivable but it is not currently being done on a clinical basis); cloning; and new reproductive technologies that right now we cannot yet imagine.

The Community Dialogues went over several different areas designed to address these issues:

- reproductive responsibility

- the use of genetic counseling
- genetic education
- use of assisted reproductive technologies
- new research efforts

Some general policies we came up with taking into account the Community Dialogues were:

- Standards of genetic policy, especially those relating to the use of reproductive technologies (less so for genetic privacy and confidentiality), should be left to professionals rather than governmental regulation. This came up over and over: “Less governmental regulation / more professional regulation over professional standards.” Input from the public, ethicists, sociologists, and others is needed on how to regulate the professional standards, insure adequate participation in the process, and discipline in cases where the standards are not followed.
- Legislators should proceed slowly and cautiously with any legislation related to genetic testing and reproductive technology. Genetic discoveries are advancing at a rapid pace. It will be extremely difficult for legislators to appropriately keep up with these developments. Care should be taken in the language and definitions used, and to knee-jerk responses that could be detrimental to policy.
- More public and professional genetics education is needed. The more the public knows, the more informed people will be in making their own choices with assisted reproductive technologies and genetic testing.
- Policy-makers should support and look into specific concerns the public and the media raise about new genetic and reproductive technologies. What should we really be concerned about? Cloning twenty Michael Jordans is probably not something that should engage political debate at this point! We have to tease out the valid concerns from those which are sensationalistic as presented in the media.

Specific policy recommendations focusing on genetic and reproductive technology we came up with were:

- There is no strong support for the government to regulate what reproductive technologies should be available. This includes preconception, preimplantation, and prenatal genetic testing. There was no consensus for government mandates citing what technology should and should not be used. The government does have a role in looking after the welfare of citizens, especially children.
- Development of specific policies mandating any form of prenatal, preconceptual, and preimplantation genetic testing is not suggested at this time. The community dialogues did outline some “broad brush strokes” of public opinion and added to the canvas largely from other policies already in place by drawing from case law and professional standards. People do want to preserve reproductive freedom and liberty so that they and those around them can make their own reproductive choices.
- There was strong consensus that genetic counseling should be made available to anybody who is undergoing or considering genetic testing. The nuances of how it should be made available, issues of access, who should provide the genetic counseling and how it should be provided were not fully fleshed out but clearly need to be addressed.

- It is important to think about appropriate education for genetic counseling, both related to the professionals conducting it and to their patients.
- There was a lot of caution related to forming quick judgments regarding limits to be placed on fetal genetic testing and reproductive technology, especially with respect to late-onset disorders. We should proceed slowly in this area; more information is clearly needed. Professionals should solicit and evaluate input from others including ethicists and the public when developing standards.
- There was general consensus that informed consent is necessary for genetic testing. People should know who is looking at their DNA and why, and what are the limitations of testing. Professionals who have expertise in the area, together with input from other professional groups and the public, rather than government, should develop the specific elements that need to be included in informed consent.
- There was a consensus that there are times when a serious genetic disorder exists and professionals may need the ability to disclose the genetic information to a person other than the individual with whom they are working, despite the importance of privacy and confidentiality. We need to think about the advisability of protections for professionals in these instances.
- Government needs to go slowly with legislation that would prohibit any types of research. There is not unanimity on what technologies should be developed or banned, even with technologies like germ-line gene therapy and cloning. We did not reach clear consensus on appropriate policies that could be established for the banning of technologies. We need to avoid knee-jerk responses which could potentially lead to curtailing of research beneficial to human health.
- Policy makers should devise mechanisms to enhance public and medical education on genetics and reproductive issues. Without education, people don't have the means to ask the right to make informed choices, and to give informed consent.

These policies were shaped with major attention given to the discussions and results of the community dialogues.

Richard King: I will be addressing a few of the questions that have come out of these discussions. First, what goes on during prenatal and preimplantation diagnosis? Prenatal diagnosis has been widely available for some time now. In preimplantation genetic diagnosis, eggs are harvested from a female, they undergo in-vitro fertilization in a petri dish, at an early stage - 8 or 16 cells - one of the removed cells is tested to check whether it carries a specific disease gene known to run in the family. If the disease gene is present, then the couple has a choice of whether to implant the early embryo or not. Preimplantation diagnosis is much more limited in its availability, usefulness, and probably in its success than prenatal diagnosis. It is also quite expensive. Prenatal diagnosis has become the norm. If it is at least not offered, this often presents a real liability problem for physicians dealing with at-risk pregnancies. Four issues that came up with discussion of these two forms of testing were:

- Should there be mandatory preconception or prenatal genetic testing as there is with newborn screening? Currently, mandatory testing is limited to newborn screening. Three states have no

exceptions. Many states have provisions for parental objections and other reasons for not undergoing screening. Newborn screening is used to test for diseases in which early intervention is useful and treatment exists, e.g., phenylketonuria, certain inborn errors of metabolism, and genetically-related thyroid disorders. The diseases screened vary from state to state, and are somewhat dependent on the population of the state. Many states screen for sickle cell although we don't have the same type of effective therapy for it as we have for a disease like phenylketonuria. The screening is still mandatory, though. Most of the screening is for diseases which are fairly common, the severity poses a public health problem, and treatment is available. Could we apply these terms to mandatory preconception or prenatal genetic testing? At what level? Early newborns, childhood? For example, would we test newborns for mutations of a breast cancer gene, a gene responsible for hypercholesterolemia (dangerously elevated cholesterol levels), or a gene leading to Alzheimer's disease? In California, all physicians are required to offer maternal serum alpha-fetoprotein (MSAFP) screening to check for risk of having a child with Down's syndrome or neural tube abnormalities. The law makes the offering of MSAFP screening to all women almost mandatory. Not offering it could make the provider liable. Should there be mandatory preconception or prenatal genetic testing? (Other than MSAFP screening, this does not presently occur.)

- Who will make the decision as to whether there should be mandatory prenatal testing? The Genome Technology and Reproduction Project used the approach of rational democratic deliberation to develop policy recommendations. The question exists: Is that the appropriate way to make policy? Should policy be set by professionals, or the community, and if by the former, then which professionals should set policy? Does the American College of Medical Genetics have suitable mechanisms for developing testing policies and for monitoring compliance?
- Should there be mandatory prenatal testing for diseases with an adult onset? With most genetic diseases, genetic susceptibility and environmental factors are involved. Do they really represent a public health risk in the same way as congenital absence of thyroid hormone or PKU, which can lead to retardation? The frequency of women genetically susceptible to breast cancer is much higher than the frequency of children with PKU, but is the former of sufficient public health risk to mandate testing? The professional community generally agrees that testing minors for genetic disease should be performed when it is therapeutically or diagnostically beneficial. Should prenatal testing be conducted for diseases that will have their onset at the ages of forty, fifty, or sixty? This needs to be addressed.
- Should genetic counseling be a mandatory part of preimplantation and prenatal diagnosis? While you might think this would be a given, most states in fact provide support for genetic screening and counseling, but they do not support prenatal testing, abortion, and genetic counseling for any type of prenatal diagnosis. Prenatal diagnosis can be done without counseling. Thus, the question of whether counseling should be mandated arises. There is also the additional question, if genetic counseling is mandated, of who or what organization should set the policy?

These are the main issues related to prenatal and preimplantation genetic diagnosis. Artificial insemination and in-vitro fertilization (IVF) raise an additional set of issues:

- Should there be insurance coverage or public support for artificial insemination and IVF? Should they be provided for every couple? Is it the right of every couple to have a child? Does this right merit insurance coverage or public support?
- Should these technologies be used for, and should support be granted for reducing a couple's risk of having a child with a genetic disease such as cystic fibrosis, or in the extreme, having a child of a particular sex (sex preselection)?

There are many future methods of assisting in human reproduction. The most important one discussed at this conference is human cloning. Those of the minority opinion, like myself, believe human cloning will occur in the not too distant future - not to reproduce oneself, but to provide organs and tissues for human health. It's similar to cases used in genetics classes where couples come in with a child who has a particular type of leukemia and they need an HLA-matched sibling for bone marrow transplant. The question is: Should the couple be allowed to try and reproduce until they get the right HLA-matched sibling, terminating those pregnancies which are not HLA-matched? Is that a reasonable use of prenatal diagnosis? This has actually been done and the questions asked! Human cloning is another step beyond that.

All of these questions are related to the conduct of genetic professionals, how they should set policies, how they should enforce them, and how they will educate themselves, physicians at large, and the community. Will they take up licensing and have incentives and disincentives for the following of guidelines on mandatory actions and the use of reproductive technologies?

Summary of Participant Responses

[bracketed numbers refer to pages in the "Community Dialogues" and "Policy Approaches" sections of the Policy Approaches / Recommendations Report]

Professional standards of care were deemed to be the best policy to follow in the offering and financial coverage of specific types of genetic testing. [p. 52] Public willingness to subsidize a technology, such as in-vitro fertilization, was also viewed as important in deciding whether the technology should be covered by insurance. Assisted reproductive technologies might not be covered under these criteria. [p. 55]

One person brought up the issue of reproductive liberty in relation to people of color and those of lower socioeconomic status. These persons have lacked choice in the past; making choices available for all persons including the underserved was viewed as an important first step to preserving reproductive liberty. [pp. 47-9, 54-5, 61-2]

The question of whether testing should be mandated under certain circumstances, as is MSAFP screening, thus depends on the professional standard of care. However, there was uncertainty about whether the MSAFP model should be applied to more recently developed genetic tests. Several participants felt that promotion or restriction of testing should be achieved through regulation of availability and financial coverage. Democratic input into this level of decision was viewed as important. There was concern over the idea of mandating use of reproductive technologies like IVF. [pp. 47-49, 54-5, 61-2]

In contrast to the mandating question, it was felt that government can play a welcome role in the protection of individuals. [61-2] The example of cloning was brought up. People should be the beneficiaries of such technology; government could see to it that people are not exploited. [pp. 53-4, 57]

Two participants, while recognizing the importance of personal freedom, also mentioned the utility of the public health viewpoint in certain situations. For example, the development of a viable treatment for a genetic condition could justify breach of privacy in some serious instances where one person's genetic information could help another. Policies need to take into account both the individual and "communitarian" or public viewpoints. [p. 68]

The question of prenatal testing for a late-onset disorder, Huntington's disease, was taken up. One person argued that even individual hospitals were unable to agree on this question. This result suggests once again that controversies regarding the boundaries of prenatal testing are not ready to be settled in the legislative arena. [p. 54, 70]

At various points during the discussion different people voiced ideological sensitivities over the use of genetic technologies, not just prenatal but also adult predictive testing. Disability, cultural, and religious viewpoints need to be taken into consideration, underscoring people's resistance to the notion of mandating genetic testing and reproductive technologies. People from different backgrounds can have entirely different opinions on whether a given type of testing should be performed or procedure used. From people's responses, individual choice seems paramount in these decisions. [See item # 24 of the Spring Community Dialogues Report]

Participants grappled with whether religious beliefs about the beginning of life should dictate use or nonuse of technologies like preimplantation genetic diagnosis (PGD). [p. 50] The upshot was that due to polarity of opinion, religious belief would probably not be able to yield a generalizable policy. [See item #'s 32-34 of the Spring Community Dialogues Report]

The question of "Who should make policy?" came up many times. The value of citizen input was stressed. [p. 79] There was some fear that the minority viewpoint could be drowned out. Professional members of the group clashed on the matter of to what degree public deliberation about policy would need to be informed by expert opinion, with one person stressing deliberation involving people's "gut level" viewpoints, several advocating deliberation informed by expert knowledge. The question of whether professional standards should be the sole responsibility of professional organizations and whether the organizations should be responsible for policing themselves was mentioned in the speaker presentations but not resolved in participant discussion. [pp. 59, 77]

Participants felt that making education on genetic matters widely available was important if genetic testing is itself to become widely available. [pp. 59, 77, 78] There were many distinctions made within the category of education. While there seemed to be no agreement on the degree to which public deliberation should be influenced by expert opinion in the process of forming genetic policy, there was consensus that professionals can be invaluable in providing information to patients so they can make their own individual medical decisions. Participants tended to distinguish education of children, high school students, college students, persons enrolled in continuing education, and adults. One person felt that teaching acceptance of personal differences could begin as early as the fifth grade. There was

some feeling that high schoolers already encounter a basic level of education in genetics, and uncertainty whether more should be added. Points of sensitivity arose. Two people criticized any educational focus on abortion. One person felt it would be very difficult to explain to people the ramifications of PGD. Another felt that dialoguing is a useful educational technique for coming to grips with advanced technologies. There was some uncertainty about how to communicate disability issues while at the same time not creating distortions in regards disease and disability. One member stressed that adult education ideally should be tailored to the recipients' educational levels and levels of understanding; audiences could vary widely.

Mini-dialogue Session: Genetic Liberty, Genetic Privacy, and the Bounds of Personal Responsibility

Facilitators: Leonard Fleck , PhD (Philosophy and Biomedical Ethics, Michigan State University)
Leonard Weber, PhD (Philosophy and Biomedical Ethics, University of Detroit-Mercy)
Transcriber: Anne Kelsey (Graduate Assistant – Health Behavior / Health Education, University of Michigan)

Number of Participants: 24

Participant Codes:

LF= Len Fleck
LW= Len Weber
DY= Daniel Yankelovich
B= Black
W= White
A= Asian
F= Female
M= Male
Example: 35 WM 1 = 35-year old white male #1

Voting Codes:

SA = Strongly agree
A = Agree
U = Uncertain
D= Disagree
SD = Strongly disagree

LF (community dialogues phase director): [Welcomed everyone and introduced Len Weber. He explained the key pad technology used during the dialogues. People use the key pads to vote their responses, from strongly agree to strongly disagree, to a series of questions. People vote then, hopefully, are willing to share their responses in order to have rational discussion with others. That was the aim of the dialogues.] Here is a sample question so that you can all practice using your key pads: “There should be a federal ban against research to develop the capacity to clone humans.”

Sample Question Votes

SA	A	U	D	SD
19	14	14	19	33%

[Len Fleck passed around the initial letter and readings that were sent to the dialogue participants so that conference participants could get an idea of what materials were used. He explained these materials defined certain terms that would be useful for dialogues. For example, he defined public interest as an interest that each and every one of us has but is unable to protect on our own, so we need to turn to the government to protect that interest (for example, clean air and water).]

LW (community dialogues facilitator): [Len Weber passed around a list of key pad questions to be used in the mini-dialogue.] These are questions related to genetic privacy.

35 WM 1: How did you come up with these questions?

LW: They were selected from a longer list of community dialogue questions.

LF: Originally, I developed the questions thinking about different perspectives and values that we may need to consider. This program is a demonstration process. The issues reflected in these questions are more complex than typical social science survey questions, but so is the real world.

35 WM 1: What about validity?

LF: We learned how the participants read these questions based on the dialogues. We changed the questions as seen fit based on the requests of participants.

DY (Conference Speaker & Panelist): Over the period of 6 sessions, you had how many questions?

LF: Approximately 50.

DY: Did some get more discussion than others?

LW: Five or six questions might fall under one broad topic. We spent most of the sessions discussing these broad topics / issues.

65 WM: You have assumptions in many of these questions, I see.

LW: Yes, absolutely, and we'll discuss them with each question. Let's go ahead with #1: "In a free society, such as our own, individuals should be free to find out information about their own genetic endowment to whatever extent they wish, in accord with what they judge to be their own best interests, uncoerced by law or public policy. That is, individuals should not be forced by law to know genetic facts about themselves they do not wish to know." Does anybody need clarification?

30 AF: If a patient refuses information, do other people get that info., like physicians or insurance companies?

LW: That is not part of this question. [No more comments. The vote is taken.]

Item #1 Votes

SA	A	U	D	SD
61	30	0	4	4%

This looks very similar to the Michigan dialogues. There's a clear consensus. O.K., onto #2: "Individuals should be free to divulge or withhold information about their own genetic endowment as they wish, in accord with what they judge to be their own best interests, unconstrained by law or public policy. That is, individuals should not be forced by law to reveal genetic facts about themselves that

they do not wish to reveal.” This question moves from receiving information to revealing it. Any clarification needed? [No comments. The vote is taken.]

Item #2 Votes

SA	A	U	D	SD
46	29	13	8	4%

LW: We’re noticing a change here. What’s the difference?

60 WM 1: If it said that blood at a crime scene shouldn’t be analyzed without the criminal’s permission, we’d disagree.

LW: You’re right. That is another way to consider it.

40 BF: The other side is that we shouldn’t use genetics as a blood hound.

LW: What we’re getting into is confidentiality. And while we generally agree with keeping confidentiality, we know there are some exceptions, which explains the reduction in agreement. Question #3 talks about public interest as opposed to individual interest: “There are circumstances in which public interests are at stake when it comes to genetic risks. If there are genetic disorders to which an individual is vulnerable and which might threaten public safety (e.g., early Huntington’s disease in an airline pilot), then we should have laws requiring genetic testing in those occupations for those specific disorders. This may be contrary to the interests of an individual, but the public interest is of overriding importance, and individuals are free to seek employment in other areas.”

50 WF 2: Are you talking about “vulnerable” or “expressed?” The individuals in question don’t necessarily have the condition.

LW: In effect, the statement says there may be some circumstances where it is appropriate to mandate genetic testing.

50 WF 2: You mean when the pilot, for example, is 50, not 20, right?

60 WM 1: Is testing for epilepsy genetic testing?

LW: I’m not sure.

30 BF 2: Seizures can be caused by many things, not just genetics.

LW: Again, we’re talking about genetic diseases that make someone dangerous.

55 WM: We have to believe that we have accurate tests to give us this type of information and that the laws can deal with it. We may be skeptical about both.

40 BF: We have to have confidence that the information will be used only for these purposes.

Item #3 Votes

SA	A	U	D	SD
0	9	27	32	32%

LW: In the dialogue groups, we had a greater split.

40 WF 3: Are we changing the outcome by discussing the question first?

LW: Yes, but it's the discussion that is important, not the results.

DY: I believe the discussion would make a difference.

55 BM: Yes, I was in a dialogue and the discussion definitely made a difference.

30 WM: In Saginaw, we considered which conditions might have a sudden onset, thus causing danger. And we couldn't come up with any. Most have symptoms that show up in time to address the problem before public safety is at risk.

30 BF 1: I have a problem with the issue of predisposition vs. actually having the disease. I feel that this question would be answered differently for these two.

DY: Let's have a quick vote when the question is read, then discuss and re-vote.

LW: O.K.

55 WM: Did you discuss moral issues with these questions?

LW: Yes, the first 6-week series was about ethics; the second series was about policy.

50 WF 2: You have to worry about the use and misuse of this information, especially since predisposition to a disease doesn't necessarily mean anything.

65 WM: Doesn't the word "should" imply a moral judgment?

LW: It is related to legislation here, not personal choices. O.K., onto #4: "A free society would not be worth living in if everyone were permitted to use their freedom irresponsibly, i.e., driving 100 mph down city streets, or dumping all sorts of chemicals into streams and lakes. That is why we have laws to constrain individual behavior in some circumstances. We should not allow our citizens to be free to be genetically irresponsible. At the very least, when individuals know, or have reason to believe on the basis of family history, that they are at risk for a serious genetic disorder, they should be legally required to undergo genetic tests that would inform them of the genetic risks to which they themselves might be vulnerable." Quick vote:

Item #4 Votes

SA	A	U	D	SD
0	11	0	26	63%

55 BM: It's so ambiguous. There are so many things to disagree with. How do you know if the person is competent to know the family history?

LW: Let's put it this way—are there any circumstances under which individuals should be forced to undergo testing? [Most say “no”.]

35 WM 1: I would say “yes” and I'm in the minority. So what does that mean for the dialogue process?

LW: It would be recognized that most people feel one way, but that there is some disagreement.

30 WM: It's most important to understand why and under what circumstances you disagree.

LW: Could you explain your position?

35 WM 1: There are some public health concerns. Individuals should have information to modify their own behavior so they reduce the risk to others.

LW: I picture question #4 as not having any interventions attached. I think #5 will help to further this consideration.

55 BM: He wasn't able to convince me to modify my stance.

DY: This statement suggests that an individual has the moral right to exercise his / her rights without regard to others and it has further implications than genetics.

40 WF 3: We need to remember that the one person could be the “right” person. There is no ethically “right” answer to these dialogue questions.

LF: We told the groups that the minority position was not necessarily the wrong one. Look at the initial advocates for civil rights. It's up to those individuals to share their views.

LW: Let's move onto #5. The difference is from self to future children: “A free society would not be worth living if everyone were permitted to use their freedom irresponsibly. We should not allow our citizens to be free to be genetically irresponsible. At the very least, when individuals know, or have reason to believe on the basis of family history, that they are at risk for a serious genetic disorder, they should be legally required to undergo genetic tests that would inform them of the genetic risks to which their future children might be vulnerable.”

Item #5 Votes

SA	A	U	D	SD
0	24	10	19	48%

LW: What happened here?

65 WM: Children are involved.

30 WM: It's about concern for others.

60 WM 2: It is an assault on personal dignity to force you to know your genetics because of the psychological impact on the rest of your life, and that holds true even when children are involved.

50 WF 2: We who disagree believe that we need to allow people to act irresponsibly when we live in a democratic society.

WM 55: What I worry about is who measures "reason to believe?" How is this carried out?

30 BF 1: Who wants a world of perfect children?

50 WF 2: And who is perfect?

35 WM 1: I agreed because it would give parents the resources to take responsible actions.

35 WM 1: [To person who was concerned about measuring knowledge] Is your only concern about accuracy? If there is an accurate measure in the future, how will you feel?

55 WM: I think we're dealing with things that are inherently imprecise.

LW: Let's talk about Tay-Sachs. If you know from your family history that there's a risk, should a law require you to test?

50 WF 2: But in some ways, the example is bad. Hard cases make bad law. What about Down Syndrome? The child has a quality of life, so it's different from Tay-Sachs. Reasonable people come down on either side.

40 WM 1: But I think maybe there should be a law for cases like Tay-Sachs and other extreme diseases.

45 WF: No matter what the case, voluntary testing based on education is better than mandatory testing.

30 BF 1: You always get down to questions of the value of life. Even if there is inevitable death, there can still be some good life.

40 WF 2: Did anyone in the dialogues wonder who the genetic police would be who oversee these laws?

30 WM and 55 BM: Yes, we were concerned.

LW: Yes, concern was very real. [No further discussion.] Time to move onto question #6] "If individuals are at risk for a serious genetic disorder that would significantly compromise their own length of life or quality of life, such as Huntington's or an earlier onset (age 60-70) form of

Alzheimer's, then they should be legally obligated to reveal such facts about themselves to potential marriage partners. This is a level of personal genetic responsibility that should be legally mandated."

Item #6 Votes

SA	A	U	D	SD
6	11	11	33	39%

55 BM: I'm surprised that many agree.

LW: This says nothing about genetic testing.

65 WM: I see an analogy with HIV, so I voted "Strongly agree."

LW: Let's look at the analogy. This doesn't put the partner at risk, like HIV does.

60 WM 2: This doesn't say one shouldn't tell the spouse. It's about a legal mandate.

30 WM: Questions 4, 5, and 6 seem to be about personal responsibility. How can we regulate genetic responsibility when we can't even regulate social responsibility, like paternity?

35 WM 1: What does "personal genetic responsibility" mean?

LF: It addresses the question of whether there are different responsibilities we have with our genetic information.

50 WF 2: I guess there's also a question of whether information means we have more control over our lives. I'm not sure it does.

55 WM: I tell my students that the new pick-up line in bars is "What is your genetic code?" [laughter]

LW: What about question #7? "It is too intrusive and restrictive with regard to individual liberty to require any form of genetic testing of adults by law. Instead, as we do with AIDS, we should legally require all couples who apply for a marriage license to undergo genetic counseling together. They would be informed of the various sorts of risks and benefits of revealing such information to one another. After that they would be free to do as they wish in these matters."

Item #7 Votes

SA	A	U	D	SD
16	5	21	26	32%

LW: Michigan groups were evenly split. Any comments?

30 WM: One of my concerns in the Michigan group was about coercive effects of genetic counseling that might exist.

50 WF 1: I think there are more important priorities we need to counsel people about before getting married — like parenting skills.

45 WF: In this world, marriage and childbearing aren't necessarily related. And I'm concerned about coercion.

LW: Do you think genetic counseling is coercive?

45 WF: Yes.

LW: Is HIV counseling coercive?

50 WF 2: One is more directly related to public health than the other is.

LW: What I understand is that before someone gets a marriage license, they'd have to be told about various tests that are available. Are you still opposed?

60 WM 2: Yes, it's an assault on psychological well-being. People getting married have other things to worry about.

35 WM 1: It's not a big thing to give up (fifteen minutes of counseling) for the right of marriage, which puts a burden on the state.

55 BM: I agreed. I'm in the minority, partly because of the ignorance factor. I find it difficult to find opposition to this.

40 WF 2: A point of clarification. There's nothing in here that says the counseling is used for procreative purposes. Could it refer to information on diseases that they may develop?

LW: This is a more generic statement.

40 BF: It may be better public health practice to have information on paper rather than insulting the intelligence by making them go to counseling.

60 WM 2: Individuals should not be obligated to hear information that they don't want to hear.

30 WM: I strongly agreed, assuming it is not coercive, because it provides information for them to think about genetic responsibility and discuss the issues with a counselor, and it may be the only chance to get to address these issues with someone who can answer their questions.

LW: What if we said this was part of a high school curriculum? [Many people agreed.]

50 WF 2: I would support this more than with a marriage license because of the resource allocation problem with requiring genetic counseling.

45 BM: I disagreed because of the quality of counseling and the bias of counselors. Would it be equal for all people, or would it differ by race or economic status?

LW: What we've discussed so far is laws regarding individual behavior. The next questions are related to the behavior of genetic counselors. Question #8: "There are circumstances in which it would be irresponsible for genetic counselors (or other health professionals in similar situations) to be casually non-directive. Individuals need to be told firmly and directly when the rights or interests of others (potential spouses / potential children) would be adversely affected by a refusal to divulge the results of a genetic test, or a refusal to have a test. That is, individuals need to be told by counselors or physicians that it would be irresponsible and inappropriate to withhold such information. Requirements for such directive counseling should be part of the professional policies of the relevant professional groups."

Item #8 Votes

SA	A	U	D	SD
24	24	12	12	29%

45 WF: This relates to a problem of what is the standard of responsible genetic behavior. I get nervous about professionals defining this.

LW: What we're talking about here is related to revealing information to family members.

50 WF 1: I think it's unfortunate that "casually" is in there.

LW: Let's strike it. We have two different models: the physician model of being directive, and counselors who come out of a different model - wanting to increase individuals' freedom to act on their values. Some say the counselor model needs to be modified to be more directive.

50 WF 2: The problem is the idea that the genetic counselor "knows the right answer." So genetic counselors can't really be directive. People have such different ideas about what is right when it comes to genetics.

LW: But we accept it when doctors tell pregnant women that smoking is dangerous. So, why is this different from telling them that not getting tested is a risk to the baby?

40 WF 2: Smoking is behavioral.

40 WF 3: We see from question #1 that we believe receiving information is very personal and private.

30 BF 2: Speaking as a genetic counselor, we're not directive, but we do more than just give information. We get them into dialogue to help them really think about decisions and take them through the decision-making process.

35 WM 1: This is an interesting question of power. Physicians have more power than genetic counselors.

LW: Let me begin to wrap this up. One thing you heard was that in the Michigan dialogues there was a general interest in having professionals, not legislators, make policy. I think our discussion today shows that even this issue is complicated.

LF: Thank you for participating. Feel free to bring your opinions to me, Len, Toby, etc.

COMMENTARY (Leonard Fleck): The dialogue experience at the conference was about as close as we realistically could come to duplicating what occurred in the seven dialogue communities. But there were some large differences. To summarize the similarities and differences:

- We had only 90 minutes for this session whereas we had at least two hours for each of the evening community dialogues.
- We used the very same items at this conference that we used with the community dialogue, and hence, Len Weber could instantly make comparative judgments.
- In the actual dialogues participants had reading material for each session at least a week in advance. Moreover, they also had a several-page "leader's guide" that raised a number of provocative issues, and that served as an issue agenda for the evening. We gave participants at the conference copies of such materials, but obviously this was not something they could read, much less absorb, as part of participating in this conference dialogue. We should also note that community dialogue participants had ample preparation for overall participation in the project. For conference participants we could only provide a dose of such preparation in the introductory lectures that I and Ed Goldman did earlier the first day.
- There was a cascading effect in the actual community dialogues; participants could build on what had been said in prior weeks for purposes of determining consistency of views / consistency of value commitments. We could not capture this part of the experience at the conference.
- Participants at the conference had two agendas, whereas dialogue participants had only a single agenda. That is, dialogue participants were engaged with discussing the substantive ethical and policy issues that were the focus of the project. Conference participants had that as a secondary agenda. Their primary agenda was really to learn how the dialogue process worked, whether it was seriously methodologically flawed, whether this was something that could be practically duplicated in their own communities, etc. That is, they were assessing the dialogue process as critical reflective "outsiders," not just participating in the conversation. In the summary of the session itself you see that reflected in comments and questions that were posed. Sometimes questions had a substantive focus; other times they reflected methodological concerns.
- In the final analysis there were fragments of rational democratic deliberation that sparkled through at the conference. Participants did speak to one another, and rationally addressed challenges that came from other participants. Consequently, participants could see where differences were deep and real, requiring much more discussion, as well as where differences were merely apparent, or else rationally resolvable. In short, participants got a good sense of the value of the process.

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