

CHAPTER 7

THE GENOMICS HEALTH POLICY PROCESS: A MODEL OF DELIBERATIVE DEMOCRACY

Dr. Greg Fowler

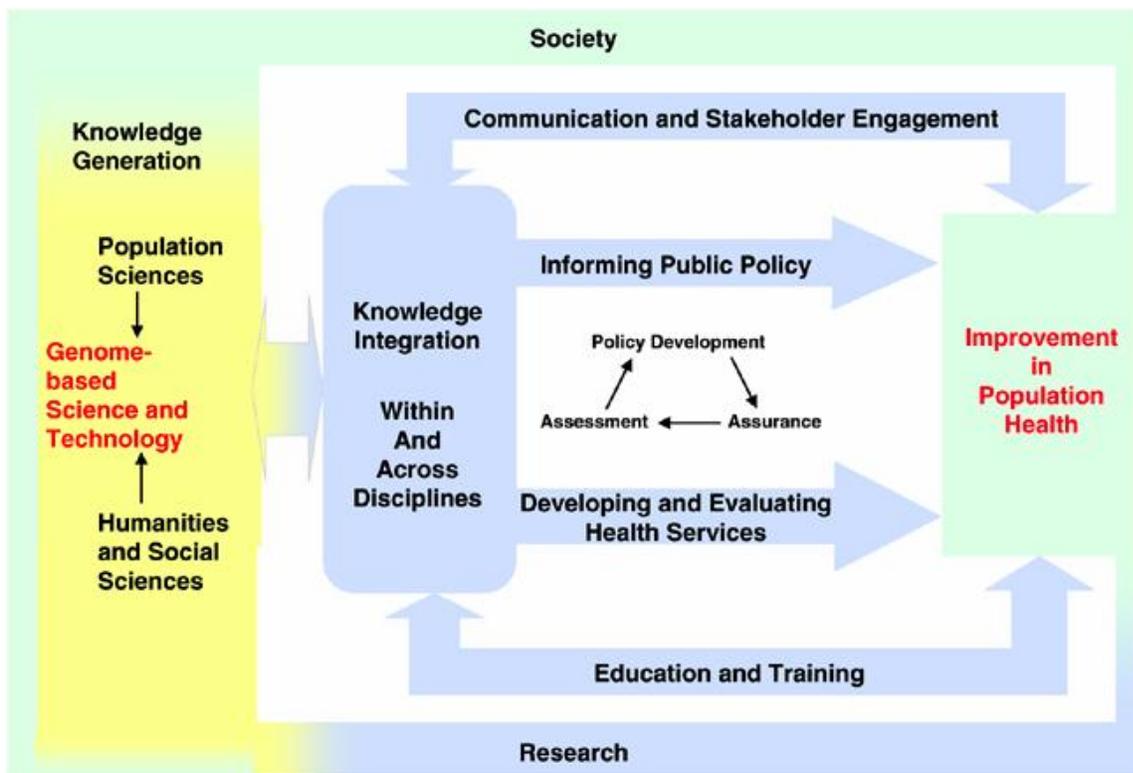
Why *Genomics* Health Policy?

The last eleven years has witnessed a breathtaking acceleration in genome science, the process of looking at hundreds, if not thousands, of genetic interactions simultaneously in order to understand the root causes of diseases and to better understand how an organism works. Genomics is a synthesis of many disparate and diverse fields, including biology, public health, engineering, computer science, and mathematics, all working to map the interactions between thousands of genes and their cellular and extracellular environment.

The social sciences and humanities are also integral components of the genomics revolution as ethicists and legislators create policies and laws that will guide the integration of genomics into scientific practice and health care. Today, genomics has yielded the richest source of [biological data](#) we have ever known.

Public mistrust of the scientific establishment tells us that attention must be paid to the way in which genomic knowledge and expertise is expressed, heard and acted upon. There is concern that new genomic technologies might be used in ethically and socially unacceptable ways with the public left powerless to resist their advance. On the other hand, advances in genomics offer the potential to transform health care. Such tensions at the intersection of core human values and technology, if unaddressed, impede research and reduce the ability of the scientific enterprise to serve society.

In April 2005, an international expert workshop convened in Bellagio, Italy to “translate genome-based science and technology into improvement in population health.” In their final report, the conferees recommended promoting a public policy development process that uses structured activities involving both the general public and scientific experts, an international and interdisciplinary partnership approach that “will offer unprecedented opportunities for improved disease prevention and therapy.”



Specifically, the key outcomes of this international forum for dialogue and collaboration are five-fold: 1) to promote relevant research; 2) to support the development of an integrated knowledge base; 3) to promote education and training; 4) to encourage communication and engagement with the public and other stakeholders; and 5) to inform public policy.

Why a *public policy* approach?

Policy makers who seek public input should understand the nature and limits of the information they seek. At different points in the policy development and decision making process, they will want to...

- Assess a spectrum of community values;
- Understand technical data about the options under consideration;
- Provide rational structure to the policy problem;
- Evaluate alternative policies under consideration; and
- Determine how the power forces in society are aligning on the issues being considered

Involving the general public in complex public policy issues works best when, as a matter of empirical fact, policy makers, the public, and technical experts engage with one another as *partners in a common endeavor*. All three are members of the same community. But they have different roles to play in serving the common good.

- The general public articulates community values.
- Experts identify relevant facts and probabilities.
- Policy makers combine community values and the best available data in choosing among various alternatives.

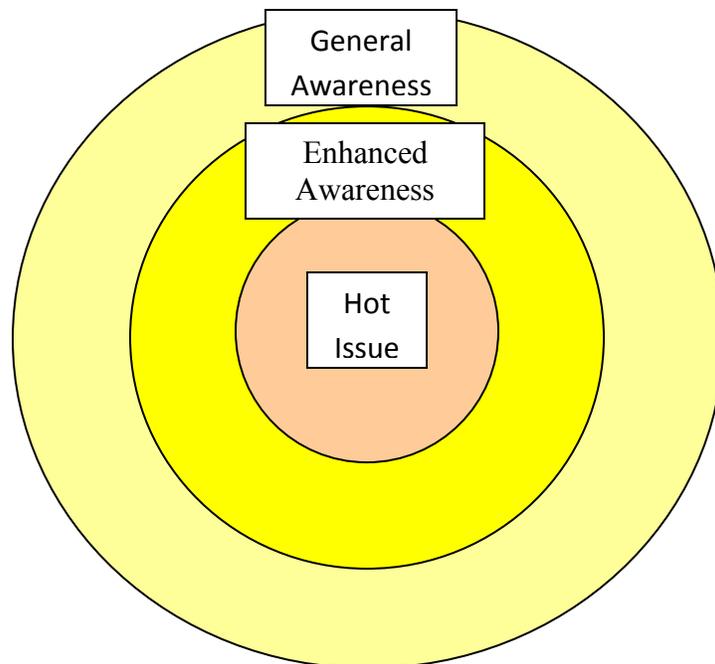
Specifically, citizen participation contributes to the realization of three important goals:

- The normative rationale of deliberation gives meaning to democracy in policy formation and implementation.
- Value input from a broad range of the public can get decision makers to think outside the box and enhance the quality of the decision process.

- Participation plays an important educational and psychological role in the social development of the individual citizen.

The lack of scientific knowledge amongst the general public often leads policy makers to rely solely upon expert input and omit or trivialize the ordinary citizen’s role in policy development. Indeed, public perceptions and beliefs that run counter to *de facto* expert knowledge are not acceptable justifications for public policies. However, citizens do not need sophisticated scientific knowledge about technical genomics in order to play a valuable consultative role in the policy process. Their role is to articulate the values that inform the common good of their community. Moreover, there is evidence that exclusive use of expert input can actually *exacerbate* public conflicts.

How might one think about “public engagement” (citizen input) in genomic (health) policy formation?



Health policy formation moves through a cyclic process. Most of the time, only minor policy issues are being worked on. This can be thought of as the “**General Awareness**” phase.

The effort to accomplish serious change creates the opportunity to structure a direct link between members of the public and policy leaders in the very process of designing, implementing, or evaluating a major new policy-rich arena of science and technology (e.g., genomics).

Community groups seeking to facilitate this interplay between the public and policy makers use conferences, community meetings, focus groups, surveys, and town hall events. These methods are designed to gather information for policy makers who actively seek input from the community relative to specific policy related questions.

Does Oregon have a history of *public* policy decision-making?

In Oregon, [GeneForum](#) and [Oregon Health Decisions](#) have acted in consulting roles with state policy makers to generate citizen input about values for public policy decision-making. In the process, both organizations (for 10 and 30 years, respectively) have explored the full continuum of possibilities for incorporating public value judgments into public policy decision making, from simply providing a list of values for stimulating decision makers to think outside the box to building a decision-analytic model for combining public values and expert value judgments to yield evaluations of policy alternatives.

We call it the “[Public Policy Partnership Model](#).” The essential feature of this model is the separation of value judgments from factual data. Deciding *what* is important—and *why* it is important--requires value judgments. Value judgments are necessary to construct the fundamental objectives of public policy.

Deciding how to achieve a higher-level objective requires factual knowledge. Expert knowledge of facts is critical for designing the means to achieve the valued outcome.

Both of these kinds of knowledge need to be used by the policy maker to fashion appropriate public policy in the common good.

How does the model work?

The model can be combined with various group process techniques, such as focus groups, town hall meetings, or community meetings.



These various approaches yield qualitative data to aid the policy maker's intuitive understanding of the values information relevant to the issue at hand. The model can also be combined with quantitative survey methods to assess the distribution and intensity of values held by members of a given community.

How does the policy maker get the ball rolling?

On the public side of the discourse, the process begins with the policy maker's desire to

understand the community values relevant to the particular policy issue at stake. The key to this discourse mode is the question, “What is important to you about X?” followed by “Why?” asked recursively to move from superficial preferences to more stable core values.

Properly designed meetings can generate public input that flows from questions that encourage wise discussion among a broad cross-section of the public.

For example, with regard to the many social and ethical issues emerging from the application of new discoveries in genomics--

- How private should genetic information be?
- Should it be exclusively under the control of the individual? The family? The human race? Pharmaceutical companies?
- Who should have access to information about a person’s genome? Private individuals or families? The State?

These are not factual matters to be decided by experts, but rather are matters related to the values held by the community.

Why is “expert input” a necessary part of the partnership model?

Expert information, on the other hand, is evidence-based data about issues. Technical discourse relies on established norms for determining the most plausible evidence. Here the policy maker needs to hear and understand the strength of the evidence that a given explanation of an issue is the best one available. It is a common practice for the policy maker to commission technical reports from appropriate expert consultants.

A difficult and critically important task of the policy maker is to guide the technical experts to focus on those specific aspects of their field of expertise relevant to the issue at hand and not

simply impose their own values in place of technical analysis.

In what sense is a policy maker a “receptor site”?

In this partnership model the policy maker is a “receptor site.” The policy decision maker—a committee, commission, legislature, board of directors, or negotiation team—must be committed to combine the public’s input about values with expert information about facts into a coherent policy. A well-prepared receptor site will optimize this outcome by--

- Involving the decision makers in the design of the information-gathering process, and--
- Coming to agreement with them on how they can best bring the information obtained to bear upon deciding among policy alternatives.



In Oregon, Geneforum has used the partnership process described above to work with the [Oregon Advisory Committee on Genetic Privacy and Research \(ACGPR\)](#), a permanent advisory committee of citizens, experts, and legislators charged with monitoring genetic research and privacy throughout the state.

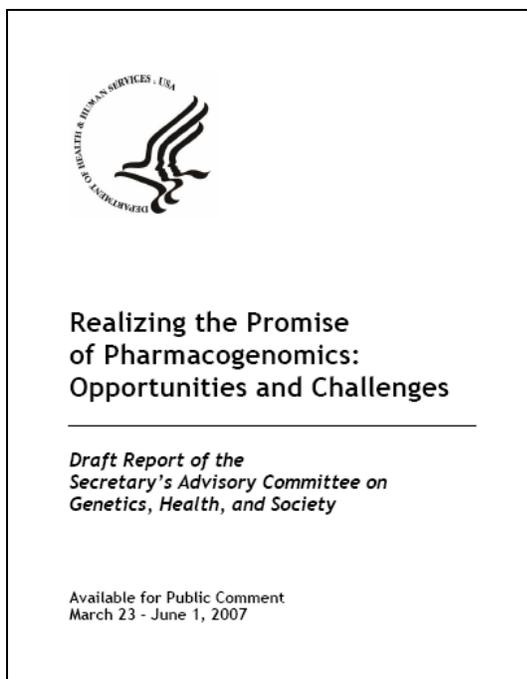
The ACGPR fits the definition of a “policy maker” in the public policy partnership model. Its current mandate includes the obligation “to create opportunities for public education and elicit public input on the scientific, legal, and ethical development within the fields of genetic privacy and research.”

Does the partnership model work?

Using focus group design and community meeting formats, qualitative data about the values held by Oregonians about genetic privacy and an assortment of related issues, has been incorporated into a number Oregon revised statutes (e.g., ORS 192.531-540; ORS 743.730) and administrative rules (e.g., OAR 333-025-0155 and OAR 333-025-0165).

In 2008, Oregon Health Decisions arranged meetings with more than 1,000 Oregonians in 15 communities around the state to hear what Oregonians think and value about health and health care. This notwithstanding, the public consultation process we see as a valuable response to an objective need has not become habitual among policy makers, in general, in particular outside of Oregon and at the Federal level. The most common approach is to consult with experts, select among policy options, and invite public comment on a near final draft of a policy statement.

As a case-in-point, in March 2007—and acting on its mandate—the [Secretary’s Advisory Committee on Genetics, Health and Society \(SACGHS\)](#) solicited public comments on its draft report on the promise, opportunities and challenges of pharmacogenomics, a branch of genetics which deals with the genetic variability in individual responses to drugs and drug metabolism



The committee received 58 comments: 53 from subject matter experts and only five from the public at large. While there may be many reasons for this disparity, the figures nonetheless suggest that U.S. policy decisions regarding genome-based research and applications reside distantly from the partnership advocated in Bellagio, and isolated still largely within the domain of experts.

More immediately, on June 21, 2011, the Centers for Disease Control of the Department of Health and Human Services issued a call for public comment on “Assessing the Current Research, Policy and Practice Environment in Public Health Genomics” with the purpose of assessing “the most important steps for public health genomics in the next five years “ (2012-2017) with public comments solicited through August 1, 2011.

The CDC established an Office of Public Health Genomics in 1997 to focus on:

“Conducting population-based genomic research, assessing the role of family health history in disease risk and prevention, supporting a systematic process for evaluating genetic tests, translating genomics into public health research and

programs, and strengthening capacity for public health genomics in disease prevention programs.”

The [order and scope of queries in the call for public comment](#) is characteristic:

- 1) Identifying the most important activities to be carried out by the public health system to apply genomic knowledge to public health goals;
- 2) Identifying public health-specific outcomes to be achieved by this;
- 3) Identifying policies needed to achieve these outcomes;
- 4) “What institutions, organizations, and agencies need to participate in achieving these outcomes and what roles should they play?” and
- 5) barriers anticipated to achieving those outcomes and how to overcome them.

Is anything missing in this approach?

While some public engagement initiatives have been funded by HHS, here engagement with “outside entities” (lay citizens notably *unmentioned*) is framed in terms of those entities being instruments of the already established goals, targeted outcomes, and policies.

In this regard, Oregon has been far ahead of HHS in seriously engaging— and more importantly—benefitting from the input of citizenry in considering genomic policy as a good for and of the public.

What is needed to insure equitable health care policy in the Age of Genomics?

Regularizing an alternative model of public consultation is critically needed, one in which citizens, experts, and policy makers are partnered in a coordinated process that can effectively implement 1) the appropriate impact of *expert* input; 2) the appropriate impact of *public* input, and 3) a process by which expert input, public input, and policy perspectives are combined to yield a choice among policy alternatives.

Achieving this three-pronged goal will be possible when the genomic policy process ensures that citizen input is reflective of the larger community, not simply the aspirations of vocal interests.

By using both public values and expert knowledge in an intentional, collaborative, open, and transparent environment, genomic scientists, the public, and policy makers can reasonably hope to create effective genomics policy in the future.

Good policy decisions will be crucial to reaping the benefits that should flow from the coming revelations about the genome by addressing important issues with prudence. These will include—

- Protection of individual and family privacy;
- Effective education of health-care providers and the public

Informed dialogue leads to better understanding, consensus building and a more stable environment for commerce.

Public policy decisions will result in better outcomes if they are based on both public values and technical knowledge.

Common citizens must become more involved in debating matters of great civic concern—as well as engaged in developing policies by which they are affected and governed.

Practicing genomics in the real world means thinking about the outcomes from the start, so that science and society can pull together to optimize the benefits of this new knowledge to human welfare and opportunity.

about genomic medicine; and—

- Appropriate health-care system reimbursement for the cost of validated preventive measures.

Genomics has had an exceptionally powerful facilitating role in biomedical advances over the past decade. Only time will tell how deep and how far that power potential will take us. With fair and equitable public policy decisions in place to help guide the translation of genomics discovery into the practice of genomic medicine and public health, the best is yet to come.

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Additional Readings

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