POPULATION HEALTH MANAGEMENT
Volume 00, Number 00, 2011

DOI: 10.1089/pop.2011.0013

Community Engagement about Genetic Variation Research

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Abstract

The aim of this article is to describe the methods and effectiveness of the Public Engagement in Genetic Variation and Haplotype Mapping Issues (PEGV) Project, which engaged a community in policy discussion about genetic variation research. The project implemented a 6-stage community engagement model in New Rochelle, New York. First, researchers recruited community partners. Second, the project team created community oversight. Third, focus groups discussed concerns generated by genetic variation research. Fourth, community dialogue sessions addressed focus group findings and developed policy recommendations. Fifth, a conference was held to present these policy recommendations and to provide a forum for HapMap (haplotype mapping) researchers to dialogue directly with residents. Finally, findings were disseminated via presentations and papers to the participants and to the wider community beyond. The project generated a list of proposed guidelines for genetic variation research that addressed the concerns of New Rochelle residents. Project team members expressed satisfaction with the engagement model overall but expressed concerns about how well community groups were utilized and what segment of the community actually engaged in the project. The PEGV Project represents a model for researchers to engage the general public in policy development about genetic research. There are benefits of such a process beyond the desired genetic research. (*Population Health Management* 2012;15:xx–xx)

Introduction

Research on human genetic variation has been a focus of the current phase of the Human Genome Project.[1,2] An improved understanding of haplotypes—sets of genetic markers present on 1 chromosome that tend to be inherited together—has potential to accelerate identification of disease susceptibility genes, facilitate development of diagnostic tools, and expedite development of treatments.[3–5] The end result may revolutionize the way we understand, prevent, and fight disease.[3,6,7] The International HapMap Project, convened in October of 2002, is a high-profile partnership of scientists and funding agencies from Canada, China, Japan, the United Kingdom, and United States with a mission to discover and share information about haplotypes relating to disease and pharmaceutical response.[3,8]

Research of this kind raises many ethical and social concerns less salient in most genetic studies because it focuses on genetic similarities and differences between population groups in addition to individuals. Associations between diseases and gene sequences within population groups can lead to stereotyping[9–11]; connecting genetics with constructs such as race and ethnicity can undermine cultural identity;[12,13] and standard genetic research practices can be offensive to populations when cultural norms are ignored.[14] Researchers must be sensitive to these issues because fears about them have derailed prior attempts to catalog genetic diversity.[15]

Academics and ethicists consider community engagement a means to minimize risks associated with genetic research.[16–18] Indeed, HapMap (haplotype mapping) researchers actively addressed the ethical and social challenges of their research, including efforts to engage the local communities in many

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stages of the research enterprise.[4] Advisory boards of community members were established at each HapMap research site to provide ongoing oversight over access to DNA samples. These procedures are consistent with recommendations for increased community engagement in genetic research,[16,19,20] recommendations rooted in community-based participatory research (CBPR) principles that make community members stakeholders rather than mere subjects of research.[21,22]

HapMap organizers deliberately limited most engagement efforts, however. Researchers did not attempt to "seek lay input into the advisability, as a matter of science policy, of launching a project of this type."[23] Also, they focused engagement efforts only on the localities providing DNA to the project and omitted engagement of people from other areas.

The Public Engagement in Genetic Variation and Haplotype Mapping Issues (PEGV) Project was constructed to address these limitations: eliciting input from a community not providing DNA to the HapMap project. The project was conceptualized by researchers at the University of Michigan School of Public Health (UMSPH) in collaboration with Genetic Alliance (GA), a coalition of more than 600 disease advocacy organizations in 2005 (now numbering more than 1200 disease advocacy organizations). After honing a model of community engagement for policy development created in 2 prior efforts in Michigan,[24,25] UMSPH wanted to test it in a setting outside of Michigan. GA had almost 20 years of experience working with the public to understand their needs and to advocate for genetics policy, and had extensive associations with many communities nationwide. UMSPH and GA agreed to work together to implement the community engagement model to build upon exploratory HapMap educational and engagement activities GA had been conducting in New York State.

The main goals of the PEGV Project were to test a community engagement model, to document concerns about genetic variation research, and to make recommendations to address these concerns. We present the methodology of this project to provide guidance to genetic researchers and policy makers as they consider how to involve communities in research protocol development.

Methods

The PEGV Project was a 2-year effort that engaged a community in New York State in discussions about haplotype research. (We use "community" to refer to specific geographic locales in this manuscript, although we recognize that the term may be conceptualized in many different ways.)[26] Unlike all other HapMap engagement efforts, the PEGV Project solicited perspectives from a community that did not provide DNA for haplotyping.

UMSPH and GA worked together to draft the overall strategy and execute the initial steps of the PEGV Project. After community academics and organizations were brought in as partners, the overall strategy was revised per consensus of the expanded project team. The project process received institutional review board approval for all phases.

Setting

UMSPH and GA targeted New Rochelle as the site of the PEGV Project. New Rochelle was chosen for the PEGV Project primarily because it has a special relationship with the HapMap Project. Italian Americans in Westchester County, where New Rochelle is located, originally were slated to be one of the communities providing DNA for the HapMap Project. That plan to collect DNA was abandoned in favor of using individuals from Italy after extensive discussion by the International HapMap Project advisory committee, but much of the groundwork and relationships formed during preparation for DNA sampling facilitated the PEGV Project. In fact, the community had begun to be engaged around the DNA collection, and was very disappointed by the change in plans, so the project director (ST) undertook project planning and grant writing for community engagement.

New Rochelle is a diverse city north of New York City with nearly 75,000 residents; 68% of its residents self-identify as white only, 19% as black or African American, 20% as Hispanic or Latino (of any race), and 3% as Asian. More than 38% of New Rochelle's residents have a bachelor's degree or higher, and median household income is $55,500. Additional characteristics are provided in Table 1 to allow comparison to the demographics of the individuals recruited for focus groups.[27]

Overall strategy

The project director sought a proven model for community engagement, and engaged the principal investigator (TC) from the Genome Technology and Reproduction Values Project and the Communities of Color and Genetics Policy Project.[24] These projects tested models of community engagement for developing policy recommendations related to genetic advances and reproductive issues and related to genetic research and its applications in communities of color, respectively. This provided the structure that would allow the community to engage around the HapMap issue.

As shown in Figure 1, the PEGV Project had 6 main stages:

1. Identify community-based organizations that would be partners on the project;
2. Establish community oversight and advisory boards;
3. Convene focus groups to develop an initial list of genetics issues;
4. Convene the community-based dialogue groups to select issues of concern and carry out a series of dialogue sessions;
5. Hold a 1-day community conference;
6. Disseminate findings.

In a final phase, a brief survey of oversight and advisory board members was conducted at the end of the project as an informal process evaluation. Methods for the first 5 phases follow.

Identifying partners

Communities such as New Rochelle, with higher average incomes and education than the general US public, may not benefit from empowerment projects such as this one as much as less affluent communities. With this in mind, PEGV planners put particular effort into trying to engage voices typically quiet in genetics research and policy development.

To establish a community partnership, the project director met with colleagues at Iona College, (KD and PJM) a liberal arts college in New Rochelle, with whom she had a prior relationship, to discuss collaboration on the PEGV Project

Table 1. Priority Ranking of Consensus Items from Focus Groups

	Raw Score	*Total Score*	*Median*
Spanish Speaking			
Moral/ethical codes	1,4,4,5,5,5	24	4.50
Latino participation	1,2,3,5,5	16	3.00
Privacy	1,3,4,4	12	3.50
Government mistrust	3,4,5	12	4.00
Why do this study?	3,4,5	12	4.00
Education	1,1,3,4	9	2.00
Discrimination	3,3	6	3.00
Classification of groups—issues of identity	1,4	5	2.50
Limitations in genetic advances	1,2	3	1.50
Genetic stereotypes	5	5	
Concerns for those who are handicapped	3	3	
Genetic engineering	2	2	
Religion vs. science	2	2	
Youth			
Scientific accuracy	1,1,1,2,4,4,5,5,5,5,5	37	5.00
Playing god/control/funding	2,3,3,4,4,4,5,5	30	4.00
Privacy/confidentially	1,2,3,4,4	25	3.00
Disparities/access	1,1,1,2,2,2,4,4,5	25	2.00
Identity	2,5,5,5	17	3.50
Enhancement vs. health issues	1,2,2,2,3,3,4	17	2.50
Faith/belief/religion	2,3,5	10	3.00
International issues	2,2,3,3	10	2.50
Environment	1,3,4	8	3.00
Variation	1,1,3	5	1.00
Professional			
Who decides who controls information?	2,4,4,4,5,5,5,5	34	4.50
Who will benefit—all populations should have access?	1,2,2,4,4,5,5,5	28	4.50
Will this info stigmatize? Discrimination/prejudice	3,3,3,3,3,4,4,5	28	3.00
Concern about profit motive, patents, intentions	1,1,3,3,3,3,4	18	3.00
Enhancement vs. treatment	2,4,5,5	16	4.50
How will this change history, diversity—genocide	2,2,2,4,5	15	2.00
Environmental issues	1,1,2,3,4	11	2.00
Regulation vs. encouraging research	1,1,3,4	9	2.50
Lack of trust in government	1,1,2	4	1.00
Religious issues	1,1,2	4	1.00
Definitions of community identity	2	2	
Clients			
Priority over poverty and health care?	1,5,5	11	5.00
Drug companies use a profit motive and hurt people even more?	2,4,5	11	4.00
Lack of access—poor/disenfranchised	1,4,4	9	4.00
Consider quality of life?	1,2,5	8	2.00
Will this benefit privileged and powerful and men over women?	3,3	6	3.00
Will this create more ways to treat the disadvantaged unfairly?	2,2	4	2.00
What if information falls into the hands of sick scientists, government/terrorists?	4	4	
How will this change decision making?	3	3	
Will genocide occur based on this information?	3	3	
Fear of misuse of information	1	1	
Privacy and confidentiality		0	
This will make classes and classes divide		0	
Will classes put me in a box and stereotype me? Labels		0	
Will HapMap consider the environment?		0	
Will this create new definitions of what race and ethnicity mean?		0	

and to contribute to the college's Women's History Week celebration with a presentation on the achievement of women in genetics. The Iona faculty, including the provost and department chairs from biology, social work, and theology, were most concerned with ensuring that knowledge generation benefited community members and researchers alike,[21] and met with the project director and the principal investigator to plan the ELSI (Ethical, Legal, and Social Implications) grant application for the community engagement. Faculty at the college recommended the project director work with the Village Team Project (VTP) to establish wide community involvement. The VTP is a group of New Rochelle service organizations that collaborate to improve the lives of families living in New Rochelle through programs and initiatives that raise awareness of issues such as literacy, health care, education, support services, mental health, and

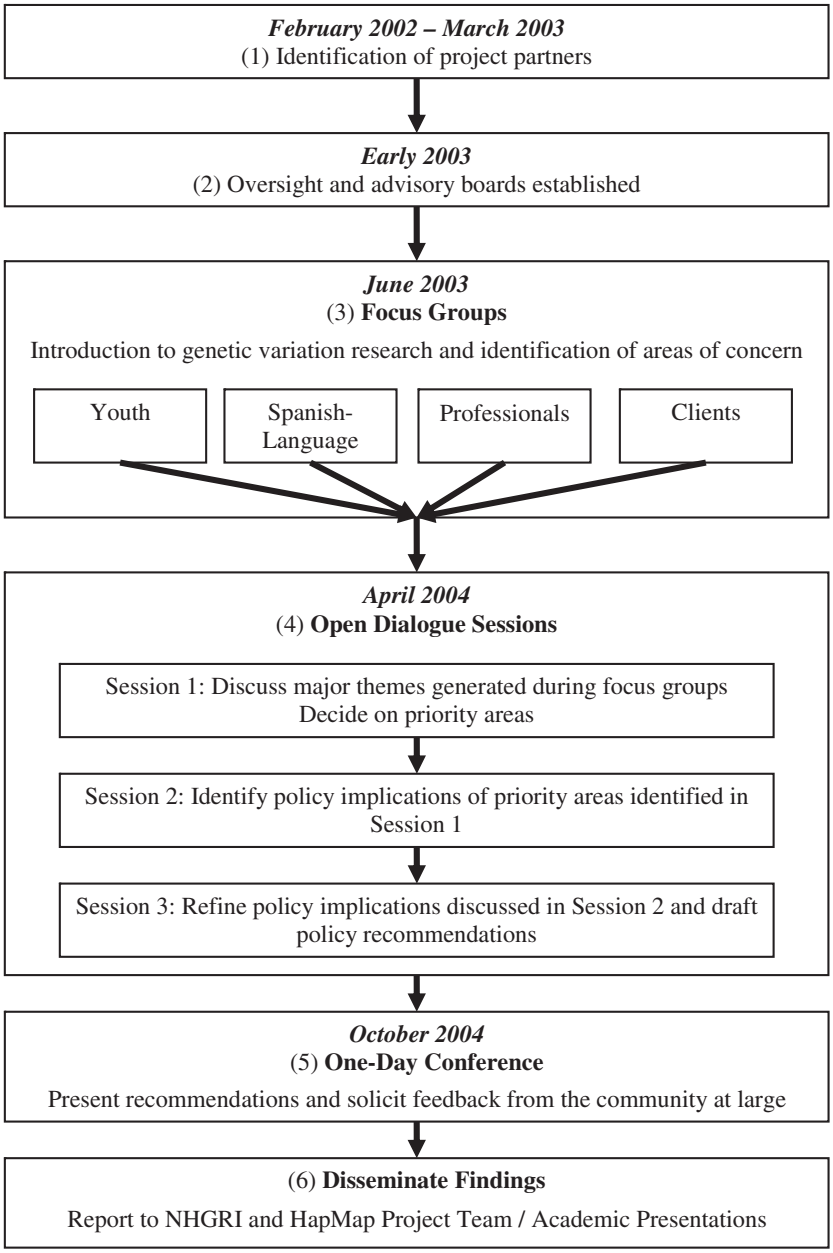

FIG. 1. Overview of project stages and timing. NHGRI, National Human Genome Research Institute.

violence prevention. Examples of Village Team members are New Rochelle's police, fire, and school departments, members of various religious communities, drug rehab centers, and health care professionals. They meet monthly.

An optimal engagement process starts with a project team becoming familiar with the community, getting to know formal and informal leaders, recognizing the diversity of perspectives among residents, and becoming an active participant in community activities.[28] Establishing connections with multiple perspectives within a community may be particularly important in genetics research, considering that characteristics such as race, age, and education often have strong associations with knowledge and attitudes about genetics.[29,30] Yet, time limitations, due to budget-year constraints, enforced by the project officers at the National Human Genome Research Institute (NHGRI), necessitated taking advantage of existing relationships in the VTP. Invitations were extended to the VTP to become partners in the PEGV Project because of VTP's extensive history of working with Iona College researchers on collaborative projects and its relationships with populations that typically are difficult to reach.

Oversight and advisory boards

Collective leadership and distributed influence are common features of effective community-based partnerships.[31] To ensure equitable sharing of power, 2 bodies were established to plan, coordinate, and oversee project activities: a Community Advisory Committee (CAC) and a Professional Advisory Committee (PAC). The final organizational structure is presented in Table 2.

Table 2. Project Organizational Structure and Roles

Entity	*Constituents*	*Role*
Project team	• Univ. of MI School of Public Health • Genetic Alliance • Iona College (community partner) • Village Team (community partner)	• Conceptualized project ◦ Secured funding ◦ Developed overall project protocol
Community Advisory Committee (CAC)	• Seven members of Village Team organizations	• Provided project oversight ◦ Developed research questions ◦ Developed protocol for each stage • Assisted in recruiting participants
Professional Advisory Committee (PAC)	• CAC members • Key members of the project team (principal investigator, project director, and on-site coordinator) • Two outside academics	• Addressed problems as they arose

Community Advisory Committee. The project director described and discussed the project during 2 of the regularly scheduled VTP meetings. The leadership of these social service and municipal organizations then determined through discussion that a 7-seat CAC, comprised of VTP members and some other non-VTP community members, would be best to represent the community. The VTP chose to invite individuals they felt represented the community because they were formal and informal leaders of various subcommunities within the city; for example, an evangelical church elder and a Latina breast cancer support group leader were chosen. Seven invitations were issued and all 7 individuals agreed to serve. CAC members developed research questions, synthesized community perspectives garnered from their collective experience, and provided guidance to the project team on engaging the community at large. Specific efforts included honing procedures for the focus groups, recruiting participants, cohosting the series of dialogue sessions, and helping to plan and execute the 1-day conference to present findings to the community. The CAC met approximately 6 times per year and CAC members received a $400 per year stipend to defray the cost of participation and to enhance the potential of success of CBPR efforts.[32]

Professional Advisory Committee. A 12-member PAC was formed to advise on major issues and problems as they arose. This committee consisted of the 7 CAC members, the study's principal investigator (TC), the project director (ST), the on-site coordinator (KD), and 2 outside academics with expertise in community engagement and genetics. This group met in person twice and by teleconference 3 times.

Focus groups

The first major engagement component of the project was 2-hour focus groups with community residents. The purpose of the focus groups was to generate an expansive list of concerns about genetic variation research and to identify the most pressing and common issues. Ideally, multiple focus groups would have been conducted until no new themes emerged,[33] but to ensure that the PEGV Project would be completed within the project funding period, the number of focus groups was limited.

The most critical criteria in determining the composition of the focus groups was the requirement that they elicit input from diverse community members, and that the voices of underserved individuals be heard. Researchers often recommend minimizing cultural diversity within focus groups because differences in norms of discussion can lead to situations in which conversation is dominated by a few aggressive individuals.[34,35] With this in mind, the CAC thought it would be important to oversample underserved communities, specifically African Americans and Latinos, so that other more dominant groups within the community would not overpower their voices. Of note was a deliberate decision to forgo a separate focus group comprising only African Americans. Some members of the CAC originally thought that it would be important to have such a group because nearly 20% of New Rochelle identify as African American and because African Americans often have different attitudes toward genetic services than whites.[36–38] In the final discussion, CAC members, including African American members, felt strongly that Westchester County residents are very accustomed to racial diversity, and so would be more comfortable participating in groups divided by language rather than skin color. African American leaders throughout the VTP concurred with this opinion. Thus, the Latino group, refocused and named Spanish-language group, would remain.

In addition to these 2 groups, there was consensus that individuals who receive social services from needle exchange programs, mental health facilities, and homeless shelters also were underserved and rarely had a voice in policy discussions. Therefore, a "clients" group was added to the list. Finally, given the topic, it was thought that youth and professionals from the community would be interested and would have meaningful input.

Thus, 4 groups were recruited; the focus groups ultimately were held at Iona College because of its central location, access via public transportation, and free meeting facilities. Focus group participants were recruited through invitations (that briefly described the project and provided meeting specifics) posted by CAC members at their respective organizations' facilities and distributed to their constituents directly. Each of the member organizations of the VTP and Iona College modified the invitation by placing it on their

letterhead, naming a local contact person, and distributing it. Recruits were offered a $20 stipend for participation.

CAC members set an enrollment target of 8 to 10 participants for each focus group, although those restrictions were relaxed based on interest. The youth group targeted individuals between the ages of 18 and 22. The Spanish-language group targeted individuals for whom Spanish was the first language. A professionals group targeted individuals who work in white-collar jobs in the community, most commonly as professors at Iona or medical professionals at an area medical center. Last, a clients group targeted individuals who used the social service agencies of the Village Team. Participants could attend only one focus group, even if they qualified for multiple groups, and the project team determined who would attend which focus group. CAC members felt these groups represented some of the most important dimensions of diversity within New Rochelle, an approach that allows researchers to best identify common themes and discordant perspectives.[39] The CAC accepted enrollment in the groups on a first-come, first-served basis. All of the participants consented through a written process explained to them at length. Their confidentiality, beyond being known to the focus group leader, was assured.

Thirty-eight people participated in the 4 focus groups, representing a wide array of ages, ethnicities and races, and incomes. Demographics of focus group participants are summarized in Table 3. They varied substantially across the 4 focus groups. Ages ranged from 18 to 102 years old; median age was close to the median age for New Rochelle. Race/ethnicity was fairly evenly divided with one third each of African Americans, Latinos, and whites; thus, our set of focus groups was oversampled for African Americans and Latinos compared to census data for New Rochelle. Almost three quarters of the participants were female; thus, females were overrepresented. Dialogue sessions had even better attendance, drawing between 30 and 53 participants apiece. More than 200 people, primarily from Westchester County, attended the closing conference.

Focus group sessions lasted approximately 2 hours each. To prepare focus group participants to discuss the HapMap Project, each focus group started with an educational session that lasted approximately 30 minutes. The educational sessions were led by the project director (or by a bilingual moderator in the case of the Spanish-language group) and focused on issues relevant to genetic diversity research. The focus groups (*a*) identified and discussed perspectives of their own "community(ies)," and societal concerns, apprehensions, and implications about genomic haplotype mapping; (*b*) explored how members think about research on genetic variation issues, including attitudes, beliefs, and behaviors; (*c*) discussed what factors each brings to bear in interpreting HapMap information; (*d*) described how these factors lead to attributions about benefits and consequences personally, as a member of community(ies), and society; (*e*) shared individual concerns, hopes, and other reactions with respect to genomic variation and health, identity, and illness; and (*f*) identified useful and understandable language and knowledge in terms of genomic variation, identity, and populations.

First, the project director explained DNA, chromosomes, and genes, in simple language, followed by an explanation of

Table 3. Demographic Information about Focus Group Participants and 2000 Census Characteristics of New Rochelle[28] (Numbers presented are in thousands)

	Youth	*Clients*[1]	*Spanish language*	*Professional*	*Total*	2000 Census*
n	12	5	9	12	38	
Male (%)	4 (23%)	1 (20%)	3 (23%)	2 (17%)	10 (28%)	34 (47.5%)
Female (%)	8 (67%)	4 (80%)	6 (67%)	10 (83%)	28 (72%)	38 (52.5%)
Age Range (median)	18–23 (20)	22–59 (40)	32–102 (51)	39–82 (52)	18–102 (39)	(37.6)
Self-identified race/ethnicity (%)[2]						
White	2 (17%)	2 (40%)	0	9 (75%)	13 (33%)	49 (67.9%)
African American	8 (67%)	1 (20%)	1 (11%)	3 (25%)	13 (33%)	14 (19.2%)
Asian	0	0	0	0	0	2 (3.2%)
Latino	5 (42%)	1 (20%)	9 (100%)	0	15 (38%)	14 (20.1%)
Currently married (%)	0	1 (20%)	5 (56%)	5 (42%)	11 (28%)	
Education (%)						
High school graduate or GED	3 (25%)	1 (25%)	1 (11%)	0	5 (14%)	
Some college	7 (58%)	0	0	0	7 (19%)	
College graduate	1 (8%)	3 (75%)	6 (67%)	5 (42%)	15 (41%)	19 (38.3%)**
Graduate school	1 (8%)	0	2 (22%)	7 (58%)	10 (27%)	
Income level (%)						$55.5***
<$15,000	4 (33%)	2 (50%)	1 (11%)	0	7 (19%)	
$15,000–$30,000	4 (33%)	0	0	1 (8%)	5 (14%)	
$30,000–$45,000	2 (17%)	0	3 (33%)	4 (33%)	9 (24%)	
$45,000–$60,000	1 (8%)	0	0	3 (25%)	4 (11%)	
$60,000+	1 (8%)	2 (50%)	5 (56%)	4 (33%)	12 (32%)	

[1]Sums in some categories are less than 5 because 1 participant submitted an incomplete demographic form.
[2]Participants were allowed to identify more than 1 category, so sums may be greater than 100%.
*2000 Census characteristics of New Rochelle.[28] US Census Bureau. (2000). New Rochelle City, New York. Numbers presented are in thousands.
**Includes graduate school.
***Median household income in the thousands.

gene expression and gene segregation patterns. With this foundation established, the focus shifted to the contribution of genetics to disease, particularly complex conditions, and the ways genes and environment both play important and interacting roles for most diseases. The education portion then shifted focus to population-level genetics. The project director described how some diseases have increased prevalence in certain populations because of descent from common geographical ancestors and then described how a specific single nucleotide polymorphism (SNP) can give important information about its surrounding DNA sequence. She then described how these blocks of DNA—haplotypes—could help scientists understand how genetics contribute to disease and how to develop effective treatments.

During the second half of each focus group, a script written by the principal investigator and the project director guided discussions. The focus groups were moderated by a bilingual law school professor who had extensive experience moderating focus groups. She was recruited not only for her familiarity with the methodology, but also because her previous experiences as a nurse, a lawyer, and a health care advocate in Central America were a good match for the project's focus on genetic variation between population groups. This moderator led participants to identify and discuss their perspectives on genetic variation and related research, personal concerns and hopes about such research, and what they saw as the societal implications of haplotype mapping. Throughout the session, the project director took notes and compiled a comprehensive list of participants' concerns. This list was presented on newsprint at the conclusion of the session and participants were asked to rank their 5 greatest concerns in order of priority (see the English and Spanish lists in Table 1). Focus group participants also were invited to participate in the subsequent dialogue sessions and community-wide conference.

Dialogue sessions

A community dialogue consisting of 3 successive sessions was convened in April 2004 to expand upon themes generated during the focus group discussions. Each of these sessions built upon the prior session. Dialogue session participants, who may not have attended the focus group session, were recruited through fliers at VTP agencies and Iona College. The number of participants was not limited. Attendees were encouraged to participate in all 3 dialogue sessions, although participants were not barred if they could not commit to all 3. Approximately 90% of the attendees participated in all 3 sessions, with some attrition in the 10% because of other personal commitments.

At the start of the first session, the project director gave a brief overview of genes, genetic variation, and the HapMap project. She also presented the issues, in rank order, on which the focus groups had come to consensus. These were used as the basis for the community dialogue. Sessions were co-led by community members who had expressed interest in leading the dialogue and the project director. Deliberation about the major issues distinguished value judgments that are public concerns from those that have a place only in the personal lives of individuals or distinct groups of individuals. Participants of the dialogue sessions were tasked with summarizing what they saw as implications of genetic variation and drafting potential policy responses. In the first session and each subsequent session, participants received background journal and popular press articles, with a wide range of literacy levels from about 6th grade up, about the HapMap project and genetic variation research and viewed a short presentation on topics discussed during focus group sessions. Participants then prioritized which topics necessitated policy recommendations by first having an open discussion, then listing all topics, then voting on the topics. This resulted in 4 main areas of concern: (1) access to HapMap data and therapies that result from it; (2) regulation of HapMap and biomedical research; (3) potential misuse of HapMap data; and (4) issues particular to race. In the second session, attendees broke into smaller working groups led by community members and thoroughly discussed the 4 main areas of concern identified in the prior session. In the final session, attendees again broke into groups, refined their statements about the policy implications of genetic variation research, and made actual policy recommendations. Sessions lasted 1.5 hours and were structured to be cumulative, with the beginning of the second and third dialogue sessions dedicated to collectively reviewing results from the prior session and taking up the discussion at that point.

Final conference

Iona College hosted a 1-day conference in October 2004 to facilitate broad public comment on project findings and to provide input on proposed recommendations to the National Institutes of Health about genetic variation research and the HapMap Project. The CAC, joined by some of the individuals who had participated in the focus and dialogue groups, as well as additional members of the Iona College faculty, created a conference planning committee. This committee coordinated advertisements about the conference for the community at large through e-mailed announcements to Village Team, Iona College, and GA listservs and newsletters. Flyers also were distributed through all of the Village Team organizations, and in a variety of community centers, clinics, churches, and temples. Conference planners also provided opportunities for individuals from underserved and underrepresented communities to receive scholarships and stipends to cover conference costs. More than 200 individuals attended. Of these, approximately one-third were from underserved communities as defined by the social services agencies of the Village Team. These approximately 70 individuals received a waiver of the $20 registration fee for the conference.

Segments of the conference were dedicated to educational overviews of basic genetics and genetic variation research. Attendees also participated in their choice of 2 of 5 breakout sessions based on major themes identified during the dialogue sessions. Each track was copresented by an expert from the local community, a member of the CAC, and an expert from outside the project team such as researchers from the NHGRI or the University of Michigan. The conference concluded with a town hall where attendees critiqued policy recommendations developed through the dialogue sessions, asked questions, and made final comments directly to International HapMap Consortium investigators.

Results

The protocol implemented in the PEGV Project accomplished its goal of engaging some New Rochelle residents in discussions about genetic variation research. An increasing number of residents participated at each stage. The PEGV Project was able to sustain interest among a segment of New Rochelle residents over the 2 years of the project.

Some flexibility in structure was necessary to meet the expectations and desires of the New Rochelle participants. Originally, each dialogue session was to occur in 2 portions. PAC members decided that the first portion on a given day would be conducted in English, followed by a second portion covering the same topics but conducted in Spanish. At the initial community dialogue, though, no one came to the Spanish-language portion. People from the Spanish-language focus groups attended the English portion, however, and explained to the project team that most of the individuals who participated in the Spanish-language focus group could understand and speak English well enough to participate in the English portion. Moreover, attendees expressed that they would prefer to discuss the issues generated across focus groups together. Consequently, the Spanish-language portions were abandoned in favor of larger, more inclusive dialogue sessions.

The PEGV project also accomplished its objectives to implement a community engagement model, to document the concerns of the lay public thus engaged about genetic variation research, and to make recommendations to address them. In August 2005, the PAC produced and delivered a 176-page report[40] to the NHGRI's HapMap project team, which included a list of recommendations (Table 4) to guide further genetic research. Findings from the project have been presented at conferences and were made available through the Iona College Web site. PAC members also have disseminated PEGV Project findings while contributing to manuscripts on the HapMap Project.[8,41] Dissemination of findings continues, and will be the focus of future articles.

While the project team was able to complete all objectives, a process review revealed mixed opinions about how well community members were able to participate in the im-

Table 4. Recommended guidelines produced by the PEGV Project

Access

- All people will have equal access to any therapies or medical procedures derived from this research.

Control and Profits

- Control and profits should be regulated by considering international and national issues.
- Current biomedical research should be regulated as well, by a combination of the government and the research community.
- The globalization of research should be heavily considered – this should not be a US-centric activity.

Misuse of Information: Confidentiality and Privacy

- Coded and uncoded information should be considered differently
  - Coded information should be freely released to research community without any identifiers.
  - Uncoded information should remain in the clinical domain, shared with medical professionals with patient's authorization.
- Confidentiality should be a step-by-step process.
- Ethics committees should oversee the information to prevent its misuse.
- Privacy legislation should cover information learned from the human genome.
- There should be no forced disclosure of genetic information to insurance companies and no one should be discriminated against based on the Haplotype Map.

Race

- Race needs to be defined carefully.
- Ethical principles should not be compromised based on race – no one should be discriminated against regardless of the findings of the haplotype mapping project.
- Information from the HapMap based on race and ethnicity should be disseminated to the public.
- Haplotype mapping information should be used to disclose facts about human civilization regardless of race.

PEGV, Public Engagement in Genetic Variation and Haplotype Mapping Issues.

plementation of the project. Most team members felt that the overall strategy was one that could and should be replicated. Iona faculty and Village Team members called the PEGV Project "a model for future interdisciplinary projects" and stated that it was a model "that could be replicated in other parts of the US as well as other communities in the world." The partnerships between organizations and across disciplines also received praise, with people stating that the PEGV Project developed the "kind of partnership that is rare for professional engagements" and that "it allowed us to do something that we have always wanted to do on campus, namely dissolve the barriers that our disciplinary differences erect."

At the same time, many project team members felt that the PEGV Project did not sustain momentum after the initial enthusiasm. At least 1 project team member also felt that only a specific subgroup within the Village Team participated in the PEGV Project, stating, "The opportunity existed for greater participation from Village Team coalition members but only a few truly enthusiastic persons/organizations linked into the project."

Evaluations by team members also showed that the project had limited effectiveness in engaging people with little interest in science and genetics. One team member commented of Iona faculty, "I didn't see large numbers of non-science personnel attending." Another commented about lay participation, "I don't feel that the City of New Rochelle was specifically vested in the project as a community or as an entity" with the effect that "the 'average Joe,' or the census tract model citizen from New Rochelle, may not be informed about the project and is no closer to capturing the essential message about community engagement in the realm of human mapping." The differential participation in the project seems to have been attributed to a lack of interest rather than a lack of effort, though. One evaluator stated, "I do believe a cross-section of the New Rochelle community was represented in the engagement. Certainly the offer to be engaged was there and promoted."

Discussion

Many scholars call for increased community engagement and ongoing discussion to ensure that genetic research is responsive to the concerns of the public.[16,17,42–45] However, only a few examples exist that demonstrate how to do so.[25,46,47] The PEGV Project shows how genetic policy recommendations in diverse communities can be developed through an interactive process that educates community residents and allows them to examine values, attitudes, and beliefs. The PEGV Project was able to bring people with diverse backgrounds together by using approaches that adhere to fundamental principles of CBPR. CBPR approaches used for this project included, but were not limited to, using local leadership from within the community,[48] locating project activities at familiar locations throughout the community,[49] forming a community advisory body,[49,50] and developing a sense of trust.[51] Establishing connections with multiple perspectives within a community may be particularly important in genetics research, considering that characteristics such as race, age, and education often have strong associations with knowledge and attitudes about genetics.[29,30] Such "grassroots" engagement is implemented rarely in genetics research, and only partially so in the International HapMap Project.

Empowering the community to help develop the PEGV Project resulted in a protocol that was different from one that only researchers would have developed. For instance, some focus groups would have been determined by race if left to the project director and principal investigator. Recall the deliberate decision to forgo a separate focus group of African Americans. This was a surprise to the project leaders from outside the community.

The Spanish-speaking focus group participants engaged in the consent process in a novel manner. Our facilitator was bilingual and began the consenting process for the focus group in Spanish as planned. Very shortly into her introduction, she was asked to stop. A community leader, a very articulate Latina woman, took over the discussion. In Spanish, she told the other 8 individuals in the group that she was not going to sign the consent form to allow us to audiotape the focus group. The 8 individuals decided they too would not sign. A 20-minute discussion ensued between the self-appointed leader and the facilitator. The discussion centered on the concern that the data would be given to the government and that the government would then penalize this group of people in some way. After extensive discussion about the removal of all identifiers, and no direct access to the audiotape by the US government, the leader signed, and all of the other individuals followed.

Dialogue sessions would not have been as integrated as they were without the intense involvement of the community. It is also unlikely that community participation in the focus groups, dialogue sessions, and final conference would have been so large without the Village Team's effort. Admittedly, the effort to develop relationships was substantial. A common criticism articulated during process evaluations, though, was that community partners wanted more responsibility and did not always feel engaged themselves. Part of the problem seems to have been a lack of regular updates, with people suggesting that the Village Team in particular needed "more detailed reports more frequently on the progress to keep the interest." It is likely that a more equitable division of responsibilities could reduce the burden on the project team while making community partners feel more invested in the work.

The time it takes to execute this kind of engagement model is substantial. The PEGV Project took over 2 years to complete despite a number of advantageous factors: extensive collaboration during grant preparation; existing relationships between Iona College, the Village Team, and the community at large; and protocols and procedures that had been honed in 2 prior engagement efforts. At the same time, the project also faced a number of challenges uncommon in many genetic studies. Many steps were time-intensive because the PEGV Project actively targeted a diverse range of backgrounds and perspectives, whereas many genetic studies—including the HapMap Project—specifically target populations that are assumed to be relatively homogenous. It is naïve to say that attitudes and concerns about genetics are consistent within populations such as racial groups, but addressing multiple populations adds the complexity of managing intergroup differences in attitudes and concerns to that of intragroup differences. Nevertheless, genetic researchers who hope to implement our model of community

engagement need consider these factors as they evaluate how much time such strategies will entail.

This report is not meant to criticize HapMap researchers. Indeed, the HapMap Project succeeds in exploring the genetic variation between population groups in part because it has empowered communities that provide DNA to establish research procedures specific to local needs and norms. Furthermore, HapMap researchers are cognizant of limitations in their engagement strategies, such as omitting input at project planning stages and soliciting engagement from only the localities that provide DNA.[23] This summary of PEGV Project methods demonstrates just how difficult expanded models of engagement can be to execute.

The participants in our project wanted fair and equitable access, and wanted a voice in the process. The recommendations of the participants (Table 4) make a clear statement about this when taken as a whole. They ask a great deal in the recommendations, but their requests articulate for some New Rochelle residents the key principles of engagement, both in the HapMap and in research projects in general. Skepticism about how much an effort as extensive as the PEGV Project would have affected planning for the HapMap Project is legitimate. The consensus guidelines generated as a result of this project are echoed in many statements about genetic research (although few studies capture the viewpoints of multiple stakeholder subgroups simultaneously). Researchers considering incorporating aspects of the PEGV model into their work must recognize that many of the main benefits of community engagement result from the process, not necessarily from the output. Such benefits can be substantial. Despite reservations about the potential for misuse of genetic variation research, participants in the PEGV Project felt that it was important and should proceed with protections in place. In addition, responses from Iona researchers and Village Team participants suggested that the project enhanced connectedness between organizations and with the community.

Of note, the PEGV Project made a strong effort to provide education in addition to policy development. To maximize the ability of participants to contribute meaningfully to the discussion, the first step of the focus groups, the first dialogue session, and the conference was a presentation of concepts relevant to genetic variation research including basic genetics, patterns of inheritance, and DNA segregation patterns. Policy makers often exclude the general public from debates about genetic policy development, arguing that the ability of people to contribute meaningfully to such debates may be compromised by misunderstandings about the subject.[52–54] Moreover, people who feel they have a poor understanding of genetics often are reluctant to engage in policy discussions.[55] The effectiveness of the educational component was not evaluated, but one CAC member remarked that it "left all involved with a knowledge base that was personally enriching and an asset for community development."

Limitations

The PEGV Project was limited in a number of respects. Project participants clearly were not a representative cross-section of New Rochelle and, therefore, external validity is limited. It is impossible to assert that the process produced policy recommendations that represent the consensus of the community. Furthermore, the focus of the PEGV Project on genetic variation research was not developed mutually by community members but instead was imposed on the community. Some focus group participants were unsure why we would focus on this topic rather than more pressing issues such as health care access. This discrepancy in what priorities are addressed violates basic CBPR principles and may undermine the sustainability of project outcomes.[21] Additionally, in an ideal setting, many focus groups would have been conducted multiple times until no new themes emerged,[33] but to ensure that the PEGV Project would be completed within the project funding period, focus groups were limited in number.

Another shortcoming of the PEGV Project was the lack of a rigorous evaluation process. Per evaluations by CAC members, the project appeared to strengthen networks connecting Iona College, the Village Team, and project participants, but data about the perceptions of community residents are lacking. A more thorough evaluation would measure participant satisfaction and effectiveness of educational presentations. Sense of community and strength of networks may be additional constructs to measure to ascertain whether such an engagement project increases community capacity.[56]

Moreover, it is unclear whether participants who did engage in many of the project's steps felt that they could express their opinions openly. Researcher–community power dynamics, compounded by discordances in race and social class between investigators and research subjects, can stifle people's willingness to provide meaningful responses.[57] The protracted informed consent process of participants in the Spanish-speaking focus group demonstrates how an engaged community can and will control the flow of dialogue of entire groups. Participants were not asked about how well they were able to contribute during focus groups, dialogue sessions, or the conference. Future evaluation efforts will need to collect this kind of information.

Conclusion

Advances in genetics have the potential to bring considerable benefits to communities and populations, not just individuals; some academics believe that the technologies that emerge have the power to reduce health disparities.[19,58,59] We believe that engaging communities and individuals in discussion about genetic research–and genetic variation research, in particular–will help maximize its potential benefits and minimize potential harms. Projects that engage community members as primary stakeholders take significant effort and time to implement correctly, but help ensure that benefit accrues to the community as a primary outcome. The PEGV Project provides a model to consider when developing research protocols if investigators want to ensure that the benefits of their work are distributed across all segments of the population. Researchers should be aware that such processes might not have immediate benefits, but likely have important long-term outcomes for participants and groups alike. Communities receive information and education that leaves them better prepared to integrate genetic and genomic discoveries into their lives. Individuals can make more informed decisions because of the clarity of information pre-

sented in multiple ways, and are able to determine the focus and outcomes of research projects in a meaningful way.

Acknowledgments

The authors appreciate the assistance of Vivian Ota Wang, Ph.D., at the National Human Genome Research Institute at the National Institutes of Health for her assistance with manuscript preparation.

The Ethical, Legal and Social Implications of NHGRI through the Communities of Color and Genetics Policy Project at the University of Michigan funded this project [NIH-ELSI Grant: #2 RO1 HG01005-01]. We are grateful to the immense contributions of Iona College, Sound Shore Medical Center, and the Village Team of New Rochelle. The men and women of Westchester County have made this project possible and contributed in a meaningful way to the HapMap dialogue.

Author Disclosure Statement

Ms. Terry, Mr. Christensen, Ms. Metosky, Ms. Rudofsky, Ms. Martinez, and Drs. Deignan, Moore, and Citrin disclosed no conflicts of interest.

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