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Public Expectations for Return of Results from Large-cohort Genetic Research

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INTRODUCTION

Rapid innovation in genotyping and DNA sequencing have made it technically and financially feasible to generate tremendous amounts of genomic data. The need for large numbers of research subjects to identify variants that contribute modestly to common complex diseases has led to a proliferation of genomic biobanks (Kaiser 2002). These biobanks contain genetic information annotated with various amounts of medical, environmental, and lifestyle information on thousands of individuals, some of whom are followed over a period of years. Some banks focus on a particular population (e.g. Strong Heart Study) (Lee et al. 1990), or disease or disease group (e.g. National Psoriasis Biobank) (National Psoriasis Foundation 2008) many population-based cohorts designed to collect data on a broad range of conditions now are being established (e.g. Marshfield Clinic Personalized Medicine) (McCarty et al. 2005). These prospective biobanks are expected to support hundreds or thousands of association studies of a broad range of conditions, some of which may not even be anticipated when the biobank is established.

The open-ended and evolving nature of genomic biobanks raises challenging questions about informed consent and the return of individual research results to participants. Currently, in the absence of a universally recognized authoritative policy, there are wide-ranging views and practices about return of individual research results to participants in genomic biobanks (Haga and Beskow 2008). For example, under the National Institutes of Health (NIH) Policy for Sharing Data Obtained in NIH Supported or Conducted Genome-Wide Associations Studies, “the return of individual results to participants... is expected to be a rare occurrence” (National Institutes of Health 2007). However, participants in the Personal Genome Project at Harvard University are “enrolled based on the expectation of full public data release” (Personal Genome

Project 2008). In the United States, the Common Rule for the Protection of Human Research Subjects provides little guidance on returning research results except to state that participants should be given “information that may affect a participant's decision to remain enrolled in the study” (Code of Federal Regulations 1991).

Arguments for and against return of research results

One of the key arguments against returning individual research results focuses on the distinction between research and the practice of medicine (Beskow 2006; Meltzer 2006). Offering individual research results can conflate the role of researcher with that of a physician. Participants may fall victim to “therapeutic misconception” (Clayton 2004; Clayton and Ross 2006; Meltzer 2006) or “diagnostic misperception” (Clayton and Ross 2006) and may mistakenly expect to receive clinically relevant information. Participants who otherwise may not have enrolled in the study may do so based on incorrect assumptions about the nature, meaning, and utility of the information they will receive. Furthermore, individuals may suffer from increased anxiety and be subjected to unnecessary follow-up testing based on inconclusive or uninterpretable results. This issue is even more pronounced when the researcher is a physician from whom the individual obtains medical care.

Other arguments against returning individual research results cite the enormous financial, logistic, and time burdens that responsible return of results would incur on a research project (Beskow et al. 2001; Klitzman 2006; Beskow 2006; Dressler and Juengst 2006; Parker 2006). Researchers providing individual results would need trained personnel with appropriate expertise to report results and to provide referrals for follow-up care, in many cases for individuals with whom they never have interacted. Providing individual research results also could require re-testing of specimens in a clinical laboratory to meet laboratory testing standards set forth by the Clinical Laboratory Improvement Amendments of 1988 (Code of Federal Regulations 1988). The cost for retesting would need to be borne either by the research project or by the individual participant, creating possible inequities in who can and cannot receive results. Contacting study participants to offer or provide study results, especially if this possibility was not outlined in the initial study consent form, may also raise a host of privacy issues, including implications for family members’ right not to know their genetic predispositions (Knoppers et al. 2006). Finally, question arises as to how long would biobank administrators or researchers using biobank data be responsible for the delivery of results. Some opponents argue that the burden of returning results could be great enough to the slow progress of genetic research (Klitzman 2006; Dressler and Juengst 2006). Others go so far as to say that if researchers are bound to return individual results to study participants, “a court may be able to conclude that investigators owe participants fiduciary duties...and their ability to conduct research as we know it may drastically change” (Meltzer 2006).

There are also several arguments in favor of disclosure of research results to participants in biobanks. One argument for full disclosure of research results is based on the principle of respect for persons - that individuals have the right to receive research results if they so choose (Fernandez and Weijer 2006; Partridge and Winer 2002; Partridge et al. 2003; Partridge et al. 2005; Shalowitz and Miller 2005). Sharing results with participants further underscores that the study participant is a partner in the research endeavor, and not simply a means to an end (Fernandez et al. 2007). It also has been hypothesized that providing results to study participants would bring greater public recognition of, enrollment in, and support for biomedical research (Fernandez and Weijer 2006). Those favoring full disclosure acknowledge the significant logistic and financial burdens disclosing results would incur, but feel that these burdens do not outweigh respect for the research subject (Shalowitz and Miller 2005).

Others (Bookman et al. 2006; Manolio 2006) believe that research results that have relevance to health should be returned. However, the definitions of relevance are quite variable. Some

argue that researchers have a duty to inform study participants of all risks discovered in the course of research and that failure to do so is “ethically and legally suspect” and may lead to litigation and negative public opinion about biomedical research (Greely 2007). The National Bioethics Advisory Commission argued returning research results should occur rarely, and only when findings are scientifically valid and confirmed, have significant implications for the participant's health concerns, and dictate an available course of action to ameliorate or treat those concerns (National Bioethics Advisory Commission 1999).

In the current design of a large cohort study proposed by the National Institutes of Health, study volunteers would be able to receive only “genetic results clearly demonstrated to carry important health and management implications” (NHGRI National Institutes of Health 2004).

Two other approaches that have been put forward give greater consideration to study participants' preferences. The result-evaluation approach takes into account the analytic validity and the clinical utility of the specific results, the context of the study, personal meaning to study participants, and the nature of the participant-researcher relationship when determining whether to disclose a particular result (Ravitsky and Wilfond 2006). Another approach, described as ‘tiered disclosure,’ proposes that research participants select from a range of options for research disclosure at enrollment (Rothstein 2006). Participants could select the types of results they wish to receive (e.g. only those with diagnostic or reproductive significance), the length of study time during which they want results disclosed, and the notification method (email, phone call, etc.).

Public/Participant Preferences

While a number of authors have proposed reasons why study participants might or might not want or value research results, few studies have examined the views of participants on return of individual results in genomic biobanks (Asai et al. 2002; Godard et al. 2007; Hoeyer et al. 2004; Wendler and Emanuel 2002). However, those studies, as well as clinical trial literature, have documented participants' support for return of research results (Fernandez et al. 2007; MacNeil and Fernandez 2006; Partridge et al. 2005).

To understand the public's values and preferences about disclosure of individual research results from studies using a proposed U.S. genomic biobank (National Human Genome Research Institute 2004) we conducted 16 focus groups (including a pilot) in six locations across the United States.

MATERIALS AND METHODS

As previously described (Kaufman et al. 2008), in January 2007, applications to conduct human subject research were approved by both Johns Hopkins University and the Abt Associates Institutional Review Boards to conduct focus groups.

The moderator guide included a description of the proposed NIH large-cohort study, followed by questions on a wide array of related topics, including the return of research results. Except in the pilot focus group, a video was used to provide uniform introductory information about the cohort study to focus group members (the pilot was shown a graphic illustrating the steps of the proposed study). The original informational video was shown to the first six focus groups. A short segment of the video showing an NHGRI official describing the potential value of the proposed NIH cohort study was then deleted and the edited version shown to the final nine groups. Following the introduction, participants were asked about their expectations and opinions surrounding the return of results from the initial physical examination and laboratory testing and, separately, return of individual research results during the course of the research.

In January 2007, a pilot focus group with eight participants from the CLUE II cohort study (Trimble et al. 2005) was conducted and videotaped in Hagerstown, MD. The interview guide was revised based on the pilot group. Ongoing minor revisions to the guide were made for clarity and efficiency, but overall content and structure of the guide remained intact throughout the remainder of the data collection. Focus group moderators were trained in the design of the proposed longitudinal cohort study and research aims of the focus groups. Five moderators of different ethnic backgrounds were trained to maximize concordance with the focus group participants.

Fifteen focus groups were conducted in March, April, and May of 2007, in five cities selected to achieve regional representation - Philadelphia, PA; Phoenix, AZ; Kansas City, MO; Jackson, MS; and Portland, OR. Focus group members were recruited to reflect a range of demographics, including age, education, race, ethnicity, gender, and socioeconomic status (Table I); one group had a prevalent health risk behavior (smoking); and one group had been subject to a known environmental exposure (long-time residents near the Three Mile Island nuclear power plant in Middletown, PA).

With the exception of the Three Mile Island group, local focus group facilities in each city recruited 12 participants for each group, with the goal of seating eight to 10 per group. Recruits were sent a reminder letter and telephoned the day before the group. For the Three Mile Island group, a snowball sampling technique was used in which names of potential participants were gathered from recruited focus group participants who had lived in the area during the Three Mile Island accident.

Each focus group comprised individuals who were homogeneous with respect to the characteristics shown in Table I. Focus group members signed a consent form and provided demographic information. Each was given a \$75 cash incentive. The focus group discussions each lasted two hours.

Each group was audio recorded and the transcripts were read into the NVIVO 7.0 software package [QSR International Pty Ltd, 2006]. Primary text codes corresponding to the organizational section headings of the focus group guide were assigned using NVIVO. Three project investigators independently generated a list of potential secondary codes based on three transcripts. The lists were discussed to define a single list of secondary codes. Three additional investigators then applied the secondary codes to a fourth transcript, and compared their coding decisions, developing rules to make coding more consistent. All 16 transcripts (including the pilot transcript) were coded with the secondary codes in an NVIVO database. Responses from the pilot focus group data were included where they provided good examples of points raised in other groups. Text related to return of results was analyzed for common themes. Findings about the return of individual research results are summarized below, using direct quotes to illustrate focus group members' opinions.

RESULTS

Focus group members were queried about their views and preferences relating to return of five different types of research results: (1) identification of a gene variant that increases the risk for asthma (treatable condition), (2) identification of an environmental factor that increases risk for asthma (environmental factor), (3) identification of a gene variant that increases risk for Alzheimer disease (untreatable condition), (4) identification of a gene variant with a higher prevalence in a racial or ethnic group, and (5) identification of a gene variant of unknown significance.

Perspectives on Information

Most focus group members said they wanted to receive results for the two asthma scenarios, while opinions were mixed in the scenarios of an untreatable condition and a finding of unknown significance. Focus group participants expressed different perspectives about the value of information when discussing the return of research results. There were information seekers who wanted all available results, (“I would like to know anything the researchers find that concerns me”, male, Jackson rural African-American); information avoiders who stated that the information would be a burden, (“too much information is a terrible thing”, female, Philadelphia urban African American); fatalists who said the results would be irrelevant to them; and altruists who saw no need to receive individual research results back from the study as participating for the greater good was all they sought.

“[It] would be tremendous for them to go and do this research, but it shouldn't be that then, down the road, no matter what they do, it has to come back to me because I provided things.” (female, Phoenix upper middle class)

Nature of the research result

In considering whether to receive research results, two factors emerged as being important to participants that research findings be accurate, and they be actionable.

The accuracy or validity of research results was an important consideration in whether or not research results should be returned. An understanding of the iterative nature of scientific research, the need for replication, and recognition that early findings are sometimes disproved or contradicted by later studies all were expressed by focus group members. Inaccurate, invalid, or inconclusive research results were viewed by some as not useful and by others as potentially harmful to cohort study participants. This was cited as a rationale not to disclose such findings to participants.

“How conclusive it is? I don't want to know intermediate things that may change later. Why do I want to know that now? If, after 10 years or whatever they are conclusive, then I think I should have a right to choose to receive the information. But I don't want to know intermediate [results].” (male, Phoenix upper middle class elderly)

In discussing the scenario involving identification of a gene variant without any known correlation to health or disease, some focus group members said they felt that disclosure of research findings of unknown significance to participants would be “stupid” or do no good for participants. Some suggested that scientists should study the variant further to understand its meaning. (“Don't tell me until you know what it does.” male, Portland Asian). However, there were a few focus group members who thought it would be important to know if they carried the variant in case its significance became known in the future.

The utility of the information or the ability of the individual to “do” something with the research result was an important criterion for some focus group members in determining whether a research result should be disclosed. Several categories of action based on research findings were raised by focus group members: getting treatment or prevention, informing family members of risk, making reproductive decisions, working for environmental action or remediation, life and financial planning, and participating in further research.

The relevance of the research result to the individual participant's own healthcare decisions frequently was cited as a compelling reason for disclosure. Information that might trigger treatment or prevention of disease -- including lifestyle changes -- was frequently mentioned, particularly during discussions of the scenario involving a gene variant associated with increased risk of asthma.

“If the doctor said I've got a prerequisite to a heart condition and could have a blockage, yes, I might want to know about it. I might want to be checked periodically and make sure of it.” (male, Hagerstown pilot)

“Well, if they can help them prevent or tell them ways to reduce their chances of getting asthma, then I think they should [disclose research results].” (male, Jackson urban African-American)

Conversely, in cases where treatment or prevention would not be available, some concluded that they would not want to learn about the results. Such information was seen as having no benefit for the participants.

“I wouldn't want to be told...because there's nothing you can do about it until you know if you have it or not, so why sit around and worry about getting asthma or whatever?” (female, Kansas City rural white)

Many focus group members indicated that they would want research findings even if the information currently was not actionable because a treatment or intervention might be developed in the future.

The value of information for family members sometimes was mentioned as a reason for returning research results to cohort study participants.

“If I am in a study, I think that they should be releasing information to me so that I can ...give that information to my daughter.” (male, Philadelphia low-income urban white)

In the scenario involving an environmental factor associated with increased risk of asthma, participants expressed a desire to take both individual and community actions to respond to the information. Some participants thought it was important to know about this finding to take personal responsibility for reducing exposure, while others wanted to hold those who caused the environmental factor responsible.

“The neighborhood or an environment needs to know that there's this possible thing in the area, so they could take any precautionary measures available.” (female, Jackson smoker)

Having information about disease risk, even when there is no available intervention or prevention, was viewed as helpful in making plans for the future, including financial decisions. In addition, some said they would want the information so they could live life to its fullest now.

Some focus group members said they felt that offering research results was important because it might allow cohort study participants to pursue opportunities to volunteer for additional, targeted research.

“If somebody has an interest in working on a research project with people who've been identified as being predisposed to asthma, they should be offered the opportunity to be involved in that research. That's the beauty of them having been identified.” (male, Hagerstown pilot)

Obligation to disclose

Many focus group members said that researchers have an obligation to disclose, or offer to disclose, research results to participants.

“You have an obligation to tell these people. They expect something back from you. I'm volunteering some of my flesh for you to evaluate me. Tell me what's wrong with

it. Not that you could do something about it necessarily, but at least let me know.” (male, Hagerstown pilot)

In contrast, some stated that they felt there was no obligation of disclosure, particularly in an observational study.

“If they're giving you some type of a drug or a placebo, then I would think they'd be obligated to tell you. But if all they're doing is taking your blood and your general information, and then watching you from a distance then you know, they're under no obligation to come back to you and say, you're sick or you've got a problem.” (male, Portland middle class white)

Desire for participant choice regarding receipt of results

Members in most focus groups suggested that study participants be given choices about what research results they receive from the study, as well as the frequency and mode of communication in which they receive them, at the outset of the study.

“It would be nice like when you first agreed to this, setting your preferences, what sort of level of notifications you want, how frequently, to what degree, and what methods, email, websites, phone and this way. A lot of websites, they ask you to always set your preferences, how you want your information.” (female, Portland Asian)

Others suggested that throughout the study participants should have the ability to make and change their choices about what research results they receive, how they receive them, and how frequently they receive them. A number of focus group participants made specific suggestions about how options could be provided.

“Whenever there's a new result coming to you, you send letters to all the participants telling them there are some new findings. If you want to know you can call them so it's optional...” (male, Portland Asian)

“Or you could even put a little scratch thing on underneath; if you want to know, scratch it off.” (male, Hagerstown pilot)

DISCUSSION

Focus groups participants voiced a strong desire to be able to access individual research results. Recognizing the wide range of possible types of research results from a large cohort study, they repeatedly and spontaneously suggested that cohort study participants be given on-going choices, often using Internet analogies such as setting preferences or filters. While some discussed having results returned over the phone, face to face, or in a letter, many suggested Web-based methods such as password-protected Websites that would allow study participants to learn about overall study findings, to see what studies used their samples and information, and to retrieve their own individual research results.

The strong interest in receiving individual genetic research results expressed in all focus groups may be the result of several factors: the novelty and excitement of potentially useful genetic information, a climate of patient empowerment in healthcare decisions, desire for access to and control of individual information, improved public understanding of genetics and gene-environment interactions as contributors to health, and frequent media attention given to advances in genetic medicine. This strong interest in personal genetic information is reflected in the dramatic rise of companies selling whole genome sequencing services directly to consumers (23andMe 2008; Navigenics 2008; deCODE 2008; Hunter et al. 2008).

Our focus group analysis indicates that access to individual research results was viewed as a valuable incentive for participating in the proposed study. Because large cohort gene-environment studies require long-term commitments from study volunteers with few incentives in the way of direct medical benefits, offering participants access to their personal research results may be useful in recruiting and retaining research participants.

The expressed desire of research participants to receive their individual genetic research results does not address the issue of how to deliver genetic research results in a responsible, useful, and cost-effective way, although numerous authors (Greely 2007; Kohane et al. 2007; Ravitsky and Wilfond 2006; Rothstein 2006) have opined on various disclosure models and policies. Advocates for non-disclosure of research results argue that the potential return of inaccurate, misleading, or disturbing results violates researchers' duty to protect research subjects from harm. However, there are few data on the actual existence or extent of these harms.

Finally, while this qualitative study found widespread interest in choice and access, quantitative studies are needed to determine the extent to which demographic and other variables might be associated with the desire for research results and their effect on willingness to participate. Furthermore, these data do not measure the relative weight or importance of return of results as compared to other perceived benefits and harms inherent in a large cohort study. We cannot determine from these data whether altruistic enthusiasm for research would be sufficient to motivate participation in cases where results are not returned.

The success of genomic biobanks depends upon ongoing public support, participation, and trust in the research endeavor. Failure to garner public acceptance can halt the creation of these valuable resources and impede medical progress. The results of our focus group research underscore the need for public consultation in the planning and design phases of large population biomedical research endeavors.

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Table I

Focus group characteristics

City	Focus Groups		
	Group 1	Group 3	Group 3
Philadelphia and Middletown, PA	Urban, Lower SES, White	Urban Middle and Upper Middle SES African American	Environmentally Exposed (Three Mile Island)
Phoenix, AZ	Middle SES White	Upper Middle SES Elderly (>62)	Young (<30) Latino/a
Kansas City, MO	Middle SES White	Rural White	Urban, Lower SES, White
Jackson, MS	Urban African American	Rural African American	Smokers
Portland, OR	Middle SES White	Upper Middle SES Elderly (>62)	Asian

Urban: lived within city limits

Rural: lived outside metro area

Lower SES: HHI <\$45K

Middle SES: \$45K<HHI<\$65K

Upper Middle SES: \$65K<HHI