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Preferences for results delivery from Exome Sequencing/ Genome Sequencing:

Genome results preferences

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Abstract

Purpose—To explore the implications of sequencing information and stated preferences for return of results among research participants.

Methods—Six focus groups were held with 39 ClinSeq[®] participants. Groups included participants who had received results, those who had not, those affected with cardiovascular disease and healthy adults. Audio recordings of the sessions were transcribed and coded and analyzed for themes.

Results—All participants expressed interest in receiving results that are medically actionable, non-actionable, carrier and less so variants that cannot be interpreted. Most participants preferred to receive results in person although several endorsed use of Internet-based resources that they could return to. Participants identified benefits for health management along with satisfying curiosity, making scientific contributions, and partnering in research. Value was seen in gaining control over health risks. Concerns were distress and/or fear that may result. Some participants were opposed to or ambivalent about learning certain types of results, particularly those having to do with diseases that were incurable or that might have implications for the health of their children.

Conclusion—There was relative enthusiasm about the value of learning sequencing information, yet it was tempered by concern about negative feeling responses and aversion to learning about incurable conditions.

Keywords

genome; sequencing; results; preferences; expectations

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INTRODUCTION

The declining cost of genome and exome sequencing (hereafter referred to as ‘sequencing’), release and marketing of clinical sequencing tests, and development of tools to facilitate the interpretation of genetic results, signal the emergence of sequencing as a clinical tool.¹ With the shift from bench to bedside underway, the necessity of developing an approach for the return of clinical genomic results has gained urgency. In their scope, scale, and uncertainty, the potential sets of results generated by sequencing represent a radical departure from the results patients expect to learn in clinical care.^{2,3} The clinical testing with which patients are familiar typically yields a single result or limited set of results, aimed at uncovering the etiology of an existing medical complaint.^{3,4} Those undergoing sequencing generally lack clinical experiences that prepare them for the psychological impact of receiving unexpected results of varying medical significance and relating to one or more among a vast array of conditions.⁵

Both genetic research participants and laypersons are eager to learn about sequencing results, especially those with potential clinical utility, suggesting a high response efficacy about plans for acting on those results.^{6–10} With the advent of clinical sequencing, healthcare providers will be increasingly responsible for consenting individuals to genomic sequencing aimed at uncovering disease-associated variant(s) and revealing additional information. Conveying unexpected, uncertain and abstruse results sufficiently that one can make an informed choice about learning results is challenging. To effectively meet this challenge, it will be important to understand the expected benefits and value. A focus group study of 89 individuals from the general public explored the issue of return of individual results from genetic research.⁷ Participants strongly supported the return of results, citing among their chief reasons the potential clinical utility of results, a sense of ownership of their genetic information, and personal empowerment. It is important to extend this hypothetical investigation to actual research participants facing these choices. In a survey of research participants, we previously identified enthusiasm for learning all types of results;¹¹ however, this conveyed limited understanding of the underlying perceived value of the information. We have advanced this agenda by conducting a series of focus groups with ClinSeq[®] participants to explore in-depth expectations of findings, positive and negative, and preferences for how results are returned.

MATERIALS AND METHODS

Participants were recruited from the ClinSeq[®] cohort for participation in focus groups conducted in Bethesda, MD. ClinSeq[®] is a longitudinal study of individuals with a spectrum of atherosclerosis from unaffected to severe, most of whom have been evaluated by exome or genome sequencing.¹² Participants meeting criteria of four different cardiovascular health bins were actively recruited for ClinSeq[®]. The bins were defined according to a 10-year risk of developing coronary artery disease (CAD): Bin 1, < 5%; Bin 2, 5–10%; Bin 3, >10%; Bin 4, known CAD. To elicit an array of responses, focus group participants were selected for characteristics that may affect their responses or the group’s responses: sex, health status, and prior receipt of a result. Those who participated in a prior quantitative study were not eligible.

The size of the groups ranged from four to eight. Participants for two groups (4 & 5) were selected randomly from a subset of the cohort who had not yet received genetic results and were in Bin 1. Participants for three groups (1, 3, 6) were selected randomly from the subset who had not yet received genetic results and were in Bin 4. Participants for one group (2) were selected randomly from participants who had received at least one genetic result from the study (Table 1). A randomized numbering system was used to select eligible participants. We recruited focus group participants by applying eligibility filters to the cohort database, calling the participants according to the system, and enrolling them in order of response. A number of people were not reached by telephone and six declined participation citing scheduling conflicts or ill health. There were three no-shows to the groups.

Participants consented verbally by phone. Groups were held locally on and off the NIH campus in conference rooms and each lasted about 90 minutes. Sessions were audio-recorded and transcribed. Responses on benefits and value noted by the moderator on an easel pad were also coded. Participants received \$50 gift cards as compensation.

A professional moderator, aided by one of the investigators, conducted a discussion about the benefits and value of sequencing in accordance with a discussion guide. The discussion guide was developed based on quantitative data from a sample of ClinSeq® participants¹¹ that informed the content we aimed to explore further. Participants were asked about the types of information they expected to receive from sequencing, the ways in which this information might be valuable to them or their families, their preferences regarding the logistics of receiving genetic results, and how they intended to use their genetic information. Perceptions of uncertainty were also assessed for a larger purpose, which will be reported separately. The discussion guide for group 2 was altered such that participants reflected the experiences of receiving results. The discussion guide for group 1 was revised and shortened for groups 3–6 reverting to broader questions on the same topics.

Focus group transcripts were generated from recordings and notes and coded in NVivo QSR 9.0. Two staff developed a preliminary codebook based on the discussion guides. Focus groups 1 and 2 were coded and preliminary secondary and tertiary codes created independently. Codes were collaboratively defined and a final codebook created. All focus group transcripts were coded and discrepancies reconciled. The kappa score for inter-coder reliability was 0.95.

The National Human Genome Research Institute institutional review board approved the study.

RESULTS

Participants

A total of 39 ClinSeq® patients participated in six focus groups between March and May 2012. Participants ranged in age from 47–69 and were largely white, college-educated, and had household incomes of >\$100,000/yr (See Table 2). Focus group participants demographically represented the overall ClinSeq® cohort except that there were more males

(59%) than in the cohort (49%). The responses by focus group participants comprised of individuals who had received a sequencing result did not differ from other focus groups. The data were therefore aggregated.

Perceived Benefits and Values

Participants voiced a strong desire to learn results from genomic sequencing. Chief among their reasons was the belief that results will confer specific benefits to the participant, the participant's family, and society or the scientific enterprise at large. Yet participants also expressed concerns about learning certain information and discriminated circumstances where they would not want to learn results. These findings suggest that attitudes toward sequencing results are not uniformly positive, nor were they necessarily fully considered as concerns evolved during the focus group discussions. Our results offer new insights into the complexities of the variation in the type of health information that may be revealed by sequencing.

On a personal level, participants expected that they would gain insights about their current or future health, and that they could use sequencing results to make lifestyle changes or institute preventive measures to extend life length or quality. Additionally, they believed that genetic results might be useful for future planning purposes. Intellectual curiosity was also frequently mentioned as a motivator.

Group 4 Participant: "If you make those changes, I mean, depending on the information that comes from the study and what that is to the individual, you might live longer..."

Group 4 Participant: "Planning. With your family or future. With your financial papers. Making sure everything is up to date, so [your family doesn't] get hit with a ton of things; they have no idea what's out there."

Group 2 Participant: "...I like information. The more information I have, the better."

Participants expected that their own results, if they chose to share them, could potentially benefit family members by alerting them to health risks. Some participants also conveyed altruistic reasons for enrolling; they believed that, independent of any personal benefit, their data would contribute to scientific progress and benefit others.

Group 5 Participant: "You learn what we possibly have and what we possibly would be passing on to our children and future generations. To make them aware of the fact that, I have this, you may have it, your children, so that somebody is aware of it. So it's not just like, 50 years from now, 'Oh yeah, back then Grandma had it.'"

Group 6 Participant: "Population health: if they found a relationship between genes and a disease it could influence large-scale decision making."

When asked to describe the *value* of receiving genetic sequencing results, as distinct from the benefits, participants frequently mentioned attaining an increased feeling of personal control, "peace of mind," and the alleviation of fear.

Moderator Recorded Responses: “Minimize stress”; “Peace of mind”; “More control, fewer surprises.”

Group 4 Participant: “I think that’s a great value about what [Other group member] has mentioned about how his daughter was reacting. It’s great information the family is getting. They know what they have to do to prevent certain diseases in the future.”

Group 6 Participant: “Alleviate personal fears of going to the doctor.”

The majority of participants anticipated choosing to learn genetic sequencing results that were described to them as “clinically non-actionable”, perceiving them to have value and potential benefits. They expressed intentions to use “non-actionable” results to make more informed future planning decisions. They suggested that the understanding of uninterpretable variants may evolve and eventually have more utility for themselves or their relatives.

Group 2 Participant: “...all knowledge is beneficial, I think, and you never know what might come out of it...something later in life. Maybe it could be caused from that and...something might have developed three years from now that says, yeah, that is the cause of, you know...the doctor might say, oh yeah, I did read a report that that could be the cause of that.”

Group 4 Participant: “[A non-actionable result] is something I really want to know about because that’s a different life expectancy and a different plan for your life, very much.”

Concerns

Some participants acknowledged that while genetic information might be reassuring and empowering, it could also be a source of distress and/or fear. A few mentioned others who they thought would not want to learn genetic results; some wondered about the moral implications of learning their own genetic results as it concerned an obligation to inform relatives.

Group 1 Participant: “Now, you have a bias in the [study] population because...all of these people want to know more. That’s a, a kind of bias...not the whole population wants to do that.”

Group 5 Participant: “...if my tests come out that I have a predisposition for Huntington’s, does my brother want to know? Do I have to tell him? What if he doesn’t want to know?”

Group 2 Participant: “I do have a half sister who,...the team suggested that I contact her and let her know [actionable test results]. And it’s just a little awkward because we are not, um, the only time I’ve met her was at my father’s funeral, so it’s a little awkward...And I haven’t figured out how to do it.”

In contrast to the majority of participants who expressed a strong desire to know all available results, some individuals were opposed to or ambivalent about certain types of

results, especially those having to do with diseases that were untreatable or that might have implications for their children's health.

Group 3 Participant: "If it had to do with the mortalities of my children and was absolutely not actionable, I would not want to know...If there's nothing I can do about it, I wouldn't want to know."

Group 3 Participant: "I was talking to a friend of mine. Both of our dads died of complications related to Parkinson's. And we were saying that we were really a little on the fence about whether we would want to know something like that...We wondered if knowing something that awful, because it was really awful for our dads and our families, we wondered if that would be a place where it would be harder to know than not to know."

Group 4 Participant: "I'm still not really sure if I want to know all that's out there. I'm still kind of on the fence."

Group 5 Participant: "...I don't want to know anything about anything that your information shows for conditions that I may have which are either incurable or untreatable."

Intentions

Participants were asked how they intended to use or had used their results. Many indicated that their results might motivate them to make lifestyle changes, especially diet-related, or to engage in planning activities, such as financial planning or changing life priorities.

Group 3 Participant: "If there was something I could do right now to live a healthier, better life, I would want to know. Especially if it was something easy. If it was something like I need more iron."

Group 6 Participant: "It might be an inspiration to do things you wished to do and put off doing, depending on what you find out...travel or changing jobs perhaps, or pursuing some interest."

Group 2 Participant: "Makes me feel guiltier if I don't get to the gym [laugh]... maybe I should put it more positively. That it reinforces...the need to do what I've been trying to do."

The intention to share genetic results with others, especially siblings, spouse, children, and physicians, was prevalent. Sharing genetic information with family members was often viewed as part of future planning; in addition to alerting a family member to their potential health risks, it could help the family to prepare, pragmatically and emotionally, for a potential health event. Participants emphasized sharing results with their children in an advisory manner.

Group 3 Participant: "One thing I thought about is if we have children that we would be able to let them know, if there's something they should be aware of before they might have children. Especially if it's something that their spouse might also carry, so the risk to their grandchildren in this case would be..."

Group 2 Participant: "...I understood why people in my family have had this cholesterol issue...it's actually useful...it gives you something to tell your relatives to look out for."

Many participants expressed an intention to integrate their genetic sequencing results with other health information resources, such as advice from their physicians or the Internet, to help them understand the information, allay fears, and inform their healthcare management.

Moderator Recorded Response: "Alert one's doctor about things not known."

Group 3 Participant: "I think doctors. I would probably go to doctors who could give me support in whatever way, or confirmation of the information."

Preferences for Return of Results

Participants were asked questions about preferences for receiving genetic results from the study. The moderator posited that a participant might be invited to the NIH for each result, necessitating multiple trips over several years. In contrast, participants were told, the release of results to participants could be delayed until all their results had been generated, necessitating only one trip to the NIH. There was a strong preference by the majority of participants for the iterative process. Participants stressed that actionability might be time-sensitive, and that getting results piecemeal would make comprehension easier. They were generally amenable to making multiple trips to NIH to receive results, within limits.

Group 2 Participant: Moderator: "But [Name], it sounds like, to you, is there a frequency with which...that would...be considered too much?"

Participant: "Just because of the distance, yeah."

Moderator: "...So what would be...is there a point that would be too much as opposed to, you know, being more acceptable?"

Participant: "Well, maybe once--once a quarter."

Group 4 Participant: "I think if they have the information that they do, it's better to give it to me at the same time, so I know what I'm going to do with it. There's no reason to delay. If I have to plan for something, to go to the doctor and do more testing or something, the sooner the better."

Group 5 Participant: "I would rather have [the results] at different stages as it comes out. Because my mind is prepared for it now; I don't know what it's going to be like in four years. I would like to have it in stages as they become available."

Participants were introduced to the concept of "bundled" results—that is, results grouped according to categories (i.e., carrier testing results) and returned in batches. While some responded positively, it was not well understood. They were asked follow-up questions about their tolerance for receiving up to twenty results at once or results with distinct health implications simultaneously. Some participants were wary of the implications such streamlining had for personal choice about what types of results to learn. Groups were ambivalent about their capacity to process large numbers of results simultaneously; a few said they could handle twenty or more results only if they received a written report or detailed explanation.

Group 5 Participant: “I would like to have more specific information so that I can have a choice about what type of information I want. That’s kind of like…what you’re suggesting is you go into a restaurant for a set dinner. I want to order what I want to order.”

Group 5 Participant: “I think it would depend on what level it is. Someone mentioned ‘laymen’s terms;’ if it is in laymen’s terms, then 20 may be easy to digest. But if it’s complex stuff that nobody but a scientist would understand, then I think 20 would be a bit much.”

Participants had varying preferences for how they wanted results, or invitations to receive results, communicated to them. Many endorsed the approach intended for the ClinSeq® study: an invitation to receive results, communicated by phone, followed by an in-person meeting and a written report. However, they stressed that the lag time from the phone call to the meeting should be as short as possible, to minimize anxiety. Participants favored methods that allowed for mental preparation for receiving results and stressed the importance of providing resources (i.e., the phone number for a genetic counselor, web-based information) for more information.

Group 4 Participant: “...I would like a phone call. I’d like to have the time between the phone call and when I come in to be very short. I get very anxious and I start imagining all kinds of things, so I would love it if they didn’t say, ‘You can come in next month.’ I’d rather it be in a couple of days or something.”

Group 4 Participant: “I think you need some registered mail or something to that effect. I don’t want somebody calling me at 3:30 in the afternoon and say, ‘Hey, got a little information for you.’ I need something to come to me and say, ‘We have some findings, we need to meet with you to discuss them.’ It’s too quick; it’s too fast.”

Group 5 Participant: “I would want that in writing so I could go back and digest it.”

DISCUSSION

More than a decade after the completion of the Human Genome Project, myriad qualitative studies show that positive attitudes about, and optimistic expectations of, sequencing persist. Both research participants and the public anticipate that sequencing could provide them with actionable information about individual disease risk.^{7,9,11,13,14,16} The majority of our focus group participants were eager to learn about genetic results of all types, including those of uncertain significance. This is consistent with results from our prior study of intentions to learn results among a large sample,¹³ though it was critical to understand why. The focus group discussion concurred not only with our published quantitative results from a distinct ClinSeq® sample but importantly, also with those reported by others that indicate genetic research and bio-repository participants similarly express a strong desire to learn sequencing results. Many of our participants’ reasons for wanting these results are consistent with those described in hypothetical studies.^{7,11,13–15} Their reasons included the perceived benefits of acting on the information to extend length or quality of life and making informed decisions about financial planning and future care. However, participants also expressed a desire to

learn medically non-actionable or uncertain results; they regarded the knowledge itself as valuable. “Peace of mind” about what to expect in the future and “more control” were cited in discussions of the value of sequencing results.

Yet the focus group discussions revealed instability of preferences. As members imagined various types of results, they began to distinguish what they wanted to learn and what they did not. When hearing of the example of an incurable disease risk for one’s child, some did not want to know and others felt strongly that they would. Untreatable progressive disease risk was also subject to concern with many participants drawing a line at this information. Concerns were raised about the emotional impact of such findings and the potential obligations to at risk relatives. So while benefits to relatives were uniformly endorsed, the downsides of communicating genetic information within families arose upon further consideration. Overall, these findings suggest that attitudes toward receiving sequencing results are not fully formed and that education and counseling will be essential to help patients make informed choices.

While the profile of, and public attitudes about, genome sequencing resemble those of other biotechnologies¹⁷, the nature of sequencing and its implications for patient experience are new. There is no model for giving or receiving multiple results, relating to different medical conditions of varying significance. Unprecedented, too, is the amount of time it would take medical providers to educate their patients about the results of sequencing. The expectation already exists: in a study about public attitudes toward direct-to-consumer personal genome testing, a majority of participants indicated they would want their physicians to help them interpret the results.¹⁶

The practical preferences expressed by ClinSeq[®] participants have important implications for healthcare providers offering such sequencing. Healthcare providers must be mindful that participants perceive results as time-sensitive, necessitating fast turn-around times and efficient scheduling of result return visits. The iterative nature of results return was popular both because it minimized the delay from generating information to sharing it, and because it limited the amount of information returned in one sitting. In a clinical setting, it is likely that many genetic results will be generated for an individual patient at one time, rather than piecemeal. This will pose another challenge: how to deliver many results at once, to avoid withholding information, in a way that is manageable for the patient. Our participants also provide some evidence that these results are potentially anxiety-provoking, particularly those that are of unclear significance or not medically actionable. Some participants may require psychosocial support in coping with not just receiving results, but anticipating them.

Limitations

There are limitations to focus group research. This method is used to explore the scope of responses to new information and here to understand the basis of participants’ preferences and the value they conferred. The majority of participants had not yet received genomic sequence results and so their preferences were hypothetical. Further research into actual choices to learn information will reveal how accurately participants’ predict their behavior. While the participants were representative of ClinSeq[®], they are highly educated and value

science. Although they do not represent the general public, our findings are similar to those of the public as sampled by Bollinger and colleagues.

Conclusion

There remains work to do with regard to clarifying how many and what types of results individuals want returned. Upon further exploration of the generally strong desire to receive results, some of the focus group participants admitted that there were limits to what they wanted to learn. This suggests that individuals' attitudes toward sequencing may be newly formed and that counseling to address these preferences will be essential. As translational efforts continue, researchers and healthcare providers should intensify efforts to educate patients about sequencing and prepare them for its scope and uncertainties. This will necessitate a multi-faceted approach; it should include guidelines for healthcare providers, policy recommendations, and public Internet resources.

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Table 1

Group Characteristics

Group	# Participants	Received Results?	Bin	Gender
1	5	No	4	Both
2	4	Yes	Mixed	All Women *
3	7	No	4	All Men *
4	8	No	1	Both
5	7	No	1	Both
6	8	No	4	Both

* Groups not selected for this criterion

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Table 2

Participant Characteristics

	N (%)
<i>Gender</i>	
Male	23 (59)
Female	16 (41)
<i>Age</i>	
45–49	4 (10)
50–54	4 (10)
55–59	10 (26)
60–64	15 (38)
65–69	6 (15)
<i>Race</i>	
White	34 (87)
Asian	5 (13)
<i>Annual Household Income</i>	
\$25000–\$49999	1 (3)
\$50000–\$74999	1 (3)
\$75000–\$99999	8 (21)
\$100000	29 (74)

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