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POLICY

Researchers' opinions towards the communication of results of biobank research: a survey study

This article has been changed from a Short Report to Policy since Advance Online Publication

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Eighty Dutch investigators (response 41%) involved in biobank research responded to a web-based survey addressing communication of results of biobank research to individual participants. Questions addressed their opinion towards an obligation to communicate results and related issues such as ownership of blood samples, privacy, therapeutic relationship, costs and implications for participants. Most researchers (74%) indicated that participants only have to be informed when results have implications for treatment or prevention. Researchers were generally not inclined to provide more feedback to patients as compared with healthy participants, nor were they inclined to provide feedback in return for participants' contribution to the biobank. Our results demonstrate major and significant differences in opinion about the feedback of individual results within the community of biobank researchers.

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INTRODUCTION

To understand the interplay of genetic and non-genetic factors in the origin of multifactorial diseases, biobank initiatives have been launched worldwide. One of the greatest promises of research involving biobanks is that it will lead to individualized medicine. This optimism is counterbalanced by concerns about the ethical, legal and social implications of genomics research. One of the discussions relates to the obligation of biobank researchers to provide feedback to individual participants about research results in general, and individual genetic variations in particular.[1–7] Issues related to the communication of results comprise among other a lack of clarity about what may constitute research results (with discussions about validity, clinical significance and incidental findings versus expected research results); how to accommodate participant preferences in informed consent procedures; the risk of breaching confidentiality and/or fostering therapeutic misconception, that is, the blurring of the relevant distinction between research practice and clinical care; and how to ensure proper disclosure given the complexity of the information and the costs involved.

Professionals involved in genetic research are key figures in this debate. However, only few studies addressed their opinion on this issue.[8–11] We surveyed researchers involved in biobanks to study their opinions towards an obligation to return research results to participants and related issues such as ownership of blood samples, privacy, therapeutic relation, costs and implications for participants.

METHODS

Participants and procedure

A convenience sample was used comprised of researchers recruited using a database as composed by a foresight committee of the Royal Netherlands Academy of Science and Art on behalf of a previous survey among those involved in the banking of tissue as related to common complex disorders.[12] This database comprises individuals working at the departments of various Dutch Academic Medical Centers, including departments of epidemiology, general practice, rheumatology, oncology, pathology, lung diseases and immunology. We added members of the project teams of known Dutch biobanks to this database. However, despite considerable effort, it is not known to what extent members of the final database are representative of the community of Dutch researchers involved in biobanks. All identified researchers were approached via e-mail and received a link to the survey. Two reminders were sent, if needed. Our hospital's Medical Ethics Committee provided an exemption for the study to seek formal approval.

Measures

First we assessed the respondents' eligibility by checking their involvement with a biobank; the survey ended if the respondent was not involved. A biobank, in the survey referred to as DNA-bank, was described as 'a collection of DNA from tissue joined with medical, genealogical and/or other data (ie, lifestyle). DNA is used for scientific research about the relation between genes and environment regarding multifactorial diseases. It is not used for patient care/diagnostics'. Research results were defined as 'results of scientific research concerning the relation between genes and environment related to multifactorial conditions', participants as 'those (18 years and older) who contributed DNA (and other data) on behalf of the DNA bank'. Aggregate results were described as *'findings relevant at a group level'*, individual results as *'information about genetic variations that in some form or other may be relevant for a specific individual participant of a biobank'*. Respondents involved in multiple biobanks were asked to consider the biobank they knew most about.

Opinions toward the duty of researchers to communicate research results were assessed using one statement concerning aggregate and 12 statements addressing individual research results, respectively (see for wording of question, items and response options Table 2). Ten additional questions addressed issues pertaining to the discussion whether individual research results should be communicated (see for wording of question, items and response options Table 3). Participants

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Table 1 Characteristics of respondents and the biobanks[a] they are involved in (*N*=80)

*Characteristics of respondents (*N*=80)*		
Age	Mean: 49.5, SD 8.1	
Sex	Male	71%
Employed in academic hospital	Yes	88%
Profession	Physician	55%
	Involved in direct patient care	84%
	Epidemiologist	18%
	Geneticist	6%
	Clinical chemist	5%
	Biologist	4%
	Social scientist	4%
	Other	9%
Involvement with biobank[b]	Doing research (as project leader) with data biobank	74%
	Project leader of biobank	45%
	Administrator of biobank	25%
	Involved with set up of biobank	58%
	Recruiter of patients for biobank	25%
	Other (METC)	3%
Involved in one or more biobanks	Involved in more than one biobank	56%
*Characteristics of biobanks the respondents are involved in (*N*=80)*		
Scope	Set up for one disease or disease group	58%
	Set up for several (groups of) diseases	43%
Participants	Patients	43%
	General population	40%
	Patients and general population	16%
	Other	1%
Number of participants	More than 10 000 participants	15%
	Between 1000–10 000 participants	58%
	Less than 500 participants	28%
Communication policy	No results communicated	36%
	Only aggregate results communicated	36%
	In some cases, individual results are communicated besides aggregate results	14%
	Do not know or no (general) policy	14%

Abbreviation: METC, Medical Ethics Committee.
[a] There will be a overlap of biobanks as various researchers may represent the same biobank. Respondents involved in multiple biobanks were asked to consider the biobank they were most knowledgeable of.
[b] More than one answer possible.

could not complete the questionnaire unless they answered all questions. We used similar items as in a previous survey assessing participants' opinions concerning the feedback of research results.[13] A first version of the questionnaire was adapted to enhance clarity based on expert review (an ethicist and two genetic researchers). Descriptive statistics were employed, using the statistical program SPSS 17.0 for Windows (Chicago, IL, USA).

RESULTS

Sample characteristics

Of the 278 researchers approached, 164 (59%) responded to the survey; 84 of them were not involved in biobanking (anymore), leaving 80 responses eligible for analysis (41% of the 278 minus 84 potentially eligible respondents). Over half of the respondents (56%) were involved in more than one biobank (see Table 1 for characteristics).

Half of the respondents (49%) expected individual results to become available in the next 20 years, 39% expected that these might become available and 13% expected aggregate results only.

OPINIONS TOWARD THE DUTY TO COMMUNICATE RESEARCH RESULTS

Most (69%) agreed that participants have to be informed about aggregate research results (Table 2). Respondents diverged in their opinion on the communication of individual results: 40% agreed that it is all right when participants do *not* get such information and 40% disagreed. Almost all respondents (95%) disagreed with the statement that participants must be informed about all results even when implications for health are unclear yet. Three-quarter (74%) of the sample indicated that participants only have to be informed when results have implications for treatment or prevention. Two-third (65%) agreed that participants should be contacted when continued research shows results to have clinical implications after all. Most of the respondents (91%) held the opinion that patients are not more entitled than healthy participants to receive individual results, nor do patients who contribute to their own physicians' research as compared with patients of other physicians. According to most respondents, participants have no right to receive results based on considerations of reciprocity. Half of the respondents (48%) felt that participants themselves should organize a genetic test if they want such information. Respondents diverged in their opinion if access to results will increase society's faith in genetic research. Finally, 49% opposed against the statement that DNA-banks require a specific communication policy as compared with non-genetic biobanks, whereas 31% agreed with this statement. We found no differences in opinions between physicians and non-physicians regarding the duty to communicate research results.

OPINIONS CONCERNING ISSUES RELATED TO THE COMMUNICATION OF RESEARCH RESULTS

Over half of the respondents (53%) agreed that participants remain in control over their blood (Table 3). The majority (81%) did not consider confidentiality of information hard to secure. However, more than one-third (36%) had the opinion that personal privacy will be harmed if participants receive individual information. Almost half of the respondents (46%) were of the opinion that provision of individual information would lead to a therapeutic relation. Looking at costs involved in information giving, 44% disagreed that costs would be too high and 24% agreed that follow-up counseling can be organized to a sufficient degree. Only a minority agreed that getting individual information will improve the understanding of illness and health (20%), or will enhance a healthy lifestyle (24%). Finally, two-third (66%) agreed that information on individual gene variations can influence the height of insurance premiums. Moreover, many (81%) agreed that such information may frighten participants.

DISCUSSION

Our survey reveals researchers' opinions that might be considered when discussing the dissemination of individual research results to biobank participants. First, the results demonstrate a lack of consensus on a non-communication policy. Half of the surveyed researchers were content with a policy in which no individual results on genetic variation are disseminated. The other half disagreed, although most considered researchers only to be *obliged* to provide individual results in case of implications for treatment or prevention.

This divide among practicing researchers reflects the current academic debate on feeding back research findings to biobank participants.[1–5,14,15] Our findings are also in line with the results of a recent study in which half of the surveyed researchers had considered the issue of returning research results, and 25% had actually done so, whereas the other half considered data too preliminary and/or

Table 2 Attitudes toward the duty of researchers to communicate research results (*N*=80)

Question: We would like to know your opinion on the communication of research results to participants of DNA banks for scientific research addressing the role of genes and environment in multifactorial diseases. We would like to learn your opinion, regardless of what a participant may prefer. Please indicate to what extent you agree with the following statements.

	Totally disagree (%)	*Fairly disagree (%)*	*Do not disagree, do not agree (%)*	*Fairly agree (%)*	*Totally agree (%)*
Communication aggregate results					
1. Participants have to be informed about aggregate research results	10	13	9	48	21
Communication individual results: general					
2. I think it is all right when participants do *not* get any information about variations in their genes	16	24	20	28	13
Communication individual results: implication for health/treatment					
3. Participants have to be informed about all variations in their genes, even when the implications for their health are unclear yet	79	16	4	1	0
4. Participants only have to be informed about variations in their genes when there are implications for treatment or prevention	6	10	10	51	23
Communication individual results: recontact					
5. If continued research shows foregoing results to have clinical implications, the participant concerned has to be contacted	4	14	18	48	18
Communication individual results: different rights					
6. Patients who contribute to a DNA-bank are more entitled to information about variations in their genes than individuals from a sample of the general population who contribute	66	25	4	5	0
7. Patients who contribute to scientific research of their treating physician are more entitled to information on variations in their genes than patients who contribute to scientific research of an unknown physician	73	18	8	3	0
Communication individual results: reciprocity					
8. Participants have to be informed about variations in their genes in return for their contribution	68	20	9	4	0
9. The more often participants donate data during participation to a DNA-bank, the more right they have on information about variations in their genes	64	23	9	5	0
10. The longer participants participate to a DNA-bank, the more right they have on information about variations in their genes	63	21	13	4	0
Communication individual results: other					
11. If participants want information about their gene variations, they have to take responsibility for a (any) genetic test if desired	9	15	29	30	18
12. A policy that enables participants to get information about variations in their genes will positively contribute to societies' faith in genetic research	15	29	25	25	6
Policy genetic biobanks					
13. Genetic biobanks need another policy on communication of research results than biobanks without genetic material	23	26	20	23	9

unvalidated.[11] Likewise, other studies among professionals reported professionals to largely, albeit not completely, agree that if research results would affect participant's health or health care,[9,10] or have established clinical validity,[8] researchers are ethically obliged to inform participants. Opinions were more divided concerning such an obligation if a participant asked for results or if the researcher felt the participant might be interested.[8,9] The similarity of findings in studies from different countries suggests that researchers share common views. On the other hand, differences in opinions were found between Spanish and US researchers,[8] warranting caution in generalization of study results.

Second, our results point to a considerable gap between researchers' opinions on the one hand and (potential) participants' opinions on the other hand. Using a comparable questionnaire, we found members of the general public and patients to show a keen interest in individual feedback, irrespective of the nature of the disease and the possibilities for prevention or cure.[13] Others also found participants to express a strong desire to be informed about research results.[14,16–18] Once recruited by biobanks, participants will not always want the information they initially desired. Therefore, taking into account that participants may change their minds during the course of the study, assessing information preferences is an ongoing process. However, at least at the outset, participants' expectations are high.[19] These expectations may imply a moral obligation on the part of biobanks to consider them.[1] This alludes to the ethical principle of reciprocity, which is argued to justify routinely offering certain results to research participants.[2,6] Interestingly, few of the researchers in our survey seemed to endorse this principle.

Table 3 Attitudes toward issues related to biobanking and the communication of research results (*N*=80)

Question: This part is about ownership, privacy and implications of communicating research results to participants. Again, we would appreciate your opinion concerning the following statements.

	Totally disagree (%)	*Fairly disagree (%)*	*Do not disagree, do not agree (%)*	*Fairly agree (%)*	*Totally agree (%)*
Control over blood					
1. A participant who donates blood for scientific research on genes and environment remains in control over his/her blood	20	23	5	26	26
Privacy aspects					
2. The confidentiality of information about variations in the genes is hard to secure	45	36	11	8	0
3. The personal privacy of participants will be harmed if information will be given to them about variations in their genes	11	20	33	30	6
Therapeutic relation					
4. As soon as participants are being informed about variations in their genes, a therapeutic relation develops	16	19	19	39	8
Costs and follow-up					
5. The costs of informing participants about variations in their genes are too high	22	23	43	11	3
6. If participants (would) get information about variations in their genes, the follow-up/counseling can be organized to a sufficient degree	13	29	35	21	3
Consequences for participants					
7. If participants (would be able to) get information about variations in their genes, this will contribute positively to their understanding of illness and health	20	28	33	19	1
8. If participants (can) have information about variations in their genes, this will contribute to the adoption or preservation of a healthy lifestyle	16	29	31	24	0
9. Information about variations in the genes can negatively influence the height of insurance premiums	5	8	21	46	20
10. A disadvantage of information about gene variations is that such information can frighten participants	0	5	14	48	34

The discussion about dissemination of results was sparked particularly by the genetic component of biobanks, that is, the technical complexity and uncertain interpretation of genetic data. We found only a minority of the researchers to feel that indeed genetic biobanks need a more specific communication policy.

Researchers' motivation to provide individualized feedback might be decreased by the fact that they seem to feel that information about individual genetic variation may (1) upset participants, (2) will not stimulate them to adopt a healthier lifestyle and (3) may cause them insurance problems. Although few data are available, first indications are that genetic information based on single-gene variants with low-risk probabilities has little impact on individuals' anxiety or health behavior.[20] With respect to insurance problems, Dutch insurance companies are rather restricted in the use of genetic information of their clients.[21] Hence, researcher's skepticism of positive outcomes of individualized feedback may be justified, whereas their fear for detrimental outcomes may not.

Researchers do seem to feel a commitment to inform participants if foregoing results become clinically relevant. Given the complexity of getting in touch with individual participants, biobanks should try to anticipate on such future disclosure issues, especially in case new information could be derived that is not covered by the participants' informed consent.

The limitations of our study lie in the difficulty of addressing the complex issues at stake in a survey, the limited size of our sample and the likely overrepresentation of researchers highly involved in biobank research. Nevertheless, we feel to have demonstrated clear differences in opinion about the feedback of individual results within the community of biobank researchers. Additionally, our results allude to a difference in opinion between researchers and those upon whom they depend, that is, the participants. Especially, the latter gap underscores the relevance of developing a policy to tackle the issue as to whether the decision about individual feedback can be left to the discretion of biobanks or whether they should leave more room for the preference of participants. Institutional Review Boards may have a key role in the development and implementation of such a policy.[11,22] Over the last years, recommendations have been developed that may offer useful guidance in this field.[1]

CONFLICT OF INTEREST

The authors declare no conflict of interest.

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