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Incidental Findings in Genomic Research

A Review of International Norms

Ma'n Zawati, Brian Van Ness, Bartha Maria Knoppers

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Atlantic Institute for Market Studies

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Abstract

Human genomic research will influence the practice of medicine by further exploring the vast potential of large-scale biobanks and associated pharmacogenomics and clinical research initiatives. While population studies of normal genomic variation may assist in understanding heterogeneity and allow for targeted therapies, researchers may well discover incidental findings – discoveries that go beyond the aims of the intended study - especially when using whole genome sequencing technologies. Policies as well as literature have dealt with the issue of managing these findings in research in general, but a review of international norms governing genomic research will give us a more comprehensive look at the state of the legal and ethical guidance.

Introduction

98% of the human genome has been sequenced[1]. Research is paving the way for a shift from genetic to genomic research[2] as our understanding of "normal" genomic variation in common diseases and the role of rare variants has increased[3]. Accordingly, there is a proliferation of longitudinal large-scale biobanks that are collecting tissue and data from individuals across whole populations in order to understand gene-environment contributions to disease risk and health[4].

These scientific advances have had their share of ethical and legal debates. Issues such as consent, confidentiality, intellectual property and access, have been - and still are – discussed in the context of genomic research. However, it seems that the debate has now shifted towards the return of individual findings to research participants and whether a "no returns" policy is still acceptable[5]. This text focuses on incidental findings, that is, research discoveries that do not fall within the aims of the study in question[6]. The issue has become all the more compelling as researchers accessing population studies or disease-specific research begin to employ whole-genome sequencing. While authors have provided some guidance on how to manage incidental findings in general[7], our research concentrates on the international norms. More particularly, we sought to determine if these norms provided guidance as to whether incidental findings could be returned or not in the genomic research context, and if so, under what criteria, when, how, and, by whom. In brief, before presenting our results, we will outline our research methodology and explain – according to the literature – what constitutes an incidental finding and how whole-genomic sequencing will further complicate the issue.

Methodology

The international norms analysed were retrieved using the HumGen International database[8], an on-line resource of more than 4000 documents specialising in the legal and socioethical issues in human genetics. For normative documents pertaining to incidental findings, keywords such as “incidental”, “findings”, “results”, “unexpected”, and “unanticipated” were used. The timeline covered ranged from the year 1990 to 2010. In total, 53 different documents were retrieved and analyzed. Only 10 documents were deemed relevant to the issue of incidental findings in genomic research. As to the relevant literature, it was retrieved using PubMed and Google Scholar. The search term used was “incidental findings”, as well as each of the following keywords: ethics, researcher, unexpected, and, duties.

1. What are Incidental Findings?

In the literature, the term incidental finding has been defined as "a finding concerning an individual research participant that has potential health or reproductive importance and is discovered in the course of conducting research but [is] beyond the aims of the study[9]". Incidental findings are endemic to human research involving humans[10]. That said, it is important to mention that the likelihood of coming across incidental findings intensifies proportionately with the amount of information collected. Accordingly, with whole-genome sequencing, the possibility of discovering incidental findings in the context of genomic research has increased exponentially[11]. In fact, increasingly powerful technologies and research instruments are able to generate massive amounts of information using whole-genome sequencing[12]. The data sought by the researchers to answer their research question now unwittingly includes a large number of "incidental" information[13]. Indeed, while such data might not ineludibly be pertinent to the research question, it may yield genetic information, not only on misattributed paternity, but other misattributed lineage or "unanticipated genetic or chromosomal variant[s] beyond the genes or chromosomes being studied[14].

Consequently, does a researcher have a duty to disclose potentially medically significant information to research participants? Could the researcher breach the duty of confidentiality in order to warn at-risk relatives of a genetic predisposition incidental to the research conducted? These questions are usually examined in the context of research results, where this issue is still under discussion[15], but where at a minimum, a specific mention of the steps to be taken is included in the consent process. Incidental findings, however, pose a unique problem, because researchers may not only lack the expertise to properly interpret such findings[16] but because usually there are no plans to address them if and when they arise. Additionally, there remains the issue of clarifying whether researchers are obligated to look for variations that might have health importance or if they are limited to what they find "accidentally".

The literature addressing the issue of the return of incidental findings currently concerns three types: findings with strong net benefit, findings with possible net benefit and findings with unlikely net benefit[17]. The first category refers to information about conditions that can likely be life-threatening, the second category refers to information about non-fatal conditions that are likely to be grave or serious but that cannot be ameliorated or avoided[18], and finally, the third category pertains to information revealing a condition that is unlikely to be of serious health or reproductive significance[19]. For the first, the suggestion by Wolf et al. is that researchers should disclose such incidental findings to research participants unless the latter have chosen not to know. For the second, the decision to disclose is left to the discretion of the researcher, unless the participant elected not to know and for the third category, they recommend a no disclosure policy[20].

However, the nature of genomic research adds complexity to the equation. Indeed, most disease predictions based on genomics are probability estimations, where genetic modifiers can increase the prospect of disease or resistance thereto depending on exposure to environmental factors[21]. As well, "most researchers understand that results that may show genetic associations with an outcome are not precise, but rather shift the probability of an outcome"[22].

Finally, there is the question of what areas of expertise are required to recognize relevant, health-related variations. Thus, it is pertinent to expand the purview of the topic by reviewing international norms for a more in-depth assessment of legal and ethical guidance on the issue.

2. International Norms Addressing Incidental Findings

Our review of international norms that provide guidance, even minimally, on the issue of incidental findings in genomic research addresses questions such as who should recontact participants, when, and according to what criteria. Two types of normative documents are covered in this section. The first are legal norms, that is, binding documents such as laws and regulations. The second are non-binding in nature and typically function as guidance for ethical conduct. Examples of non-binding normative documents are guidelines, policies, recommendations, opinions and consultation papers, to name but a few. As non-binding norms, they are usually flexible (i.e., easier to modify than laws and regulations) and play an important complementary role. In these documents, we have noted three approaches: the "choice" of the individual participant, the familial model and, the researcher responsibility approach.

Interestingly, the issue of incidental findings was mentioned as early as 1996 and typifies the "choice" approach that followed. Indeed, paragraph 5 of the Statement on the Principled Conduct of Genetics Research[23] of the Human Genome Organization (HUGO) distinguishes between results and incidental findings: "choices to be informed or not with regard to results or incidental findings should [...] be respected."[24]. The paragraph continues by stating that "such choices bind other researchers and laboratories[25]", and encourages respect for personal, cultural, and community values[26].

Estonia's 2001 Human Genes Research Act[27], for its part, does not mention incidental findings specifically, but states that "data on hereditary characteristics and genetic risks obtained as a result of genetic research"[28] might not always be warranted by gene donors. In managing the disclosure of such data to participants, the Act uses a distinct approach on the matter. According to this Act, it is not up to researchers to return these data to participants, but for the latter to request access: "Gene donors have the right to access personally their data stored in the Gene Bank[29]".

The 2007 Recommendations on the Ethical Aspects of Collections of Samples or Human Tissue Banks for Biomedical Research Purposes[30] of the Ethics Committee of the Rare Disease Research Institute of Spain is general in scope. This document suggests that the issue of incidental findings should be discussed in the consent procedures and that the participants be given the choice of whether or not they wish to be informed[31]. The same guidance was provided by the European Society of Human Genetics in 2002. It mandates that the consent procedure must specify the will of the research participant (donor) to receive "unexpected findings concerning his (her) health by analysis of the given tissue"[32].

The Canadian College of Medical Geneticists & Canadian Association of Genetic Counsellors goes further and typifies the familial model. They provide in their 2008 Joint Statement on the Process of Informed Consent for Genetic Research[33] that if individual results should be disclosed, then participants should be made aware that "unexpected results" could be obtained. The participants' wishes should be respected as to whether they wish to be notified or not. Moreover, the Statement requires that participants be informed of policy "with regards to disclosure of such results in the context of significant health implications for the individual and/or his family.[34]"

Some normative documents hold the researcher responsible for deciding whether incidental findings should be disclosed. In this situation, when confronted with such findings, the researcher is either permitted, encouraged, or obligated to inform the participant, having taken into consideration the potential risk of harm associated with non-disclosure. The Norwegian University of Science and Technology's 2004 Medical Technology: Health Surveys and Biobanking[35] is an example of such a position. It iterates

that "some individuals could possibly benefit by being contacted when unexpected genetic risks for future disease were discovered[36]." However, in order to return such information, it mentions two conditions that need to be met: "1. The information must qualify as scientific knowledge [and] 2. The donor must have consented to being contacted in case of unexpected genetic risk[37]." No further direction is provided on what constitutes scientific knowledge.

In the same vein, the European Partnership on Patients' Rights and Citizens' Empowerment (EEPRCE) notes that since "research includes matters of unknown future import, sometimes unexpected findings can be generated[38]." It adds that if "an immediate and clear benefit to identifiable individuals can be achieved, and if this will avert or minimize significant harm to the relevant individuals[39]", then it may be legitimate to disclose these findings. It is clear from this citation that the level of urgency, actionability and identifiability should prevail in any decision to return such findings. Interestingly, the EEPRCE expands the radius of outreach by permitting disclosure to "third parties" (without further definition), regardless of the wishes of the person from whom the original data was provided if the situation satisfies the above-mentioned criteria. In such cases, an ethics approval should ideally be sought[40].

In the United Kingdom, the Medical Research Council (MRC) provides that if a result that can be linked to an individual has "immediate clinical relevance (for example, if it reveals a serious condition for which treatment is required)"[41], there is a clear duty to inform research participants, either directly by the researcher or through the clinician usually affected to their care. It is worthy to note that this passage from MRC's ethical guidelines on Human Tissue and Biological Samples for Use in Research is intended for clinicians involved in research projects.

Spain's Law 14/2007, of 3 July, on Biomedical Research[42] highlights the country's civil law tradition by emphasising the duty to rescue in article 4.5. Indeed, while the Spanish Law confirms the existence of the participant's right "not to know" about incidental findings, it nonetheless allows a close family member or a representative to be informed if this avoids serious damage to the health of the participants or that of their biological family[43]. Researchers are encouraged to consult with the clinical ethics committee, if it exists, and are asked to provide only the necessary data when communicating with a close family member or a representative[44]. According to the Spanish Law, the necessity to undertake such communication must be assessed by a doctor.

Finally, without opting for any of the three approaches mentioned, the 2010 2nd Edition of the Canadian Tri-Council Policy Statement[45] specifies that "researchers have an obligation to disclose to the participant any material incidental findings discovered in the course of research[46]". In this Policy Statement, material incidental findings are broadly defined as having "significant welfare implications for the participant, whether health-related, psychological or social[47]". Also, it requires researchers to develop a plan indicating how they will disclose material incidental findings to participants. Such a plan must be submitted to a Research Ethics Board for review[48]. Importantly, the Tri-Council Policy Statement encourages researchers to consult with colleagues on how to interpret incidental findings. It also calls for researchers to direct participants to a qualified professional, when necessary, to discuss the impact of the incidental findings on their welfare[49].

Bearing in mind that providing health-related information might be more credible when coming from a health professional - such as a physician or a counsellor – the TCPS guidance seems beneficial in the current context of genomic research, where most of the data collection and analysis is performed by nonphysicians. Indeed, it would be more reliable if medical recommendations and courses of action are provided by an expert in that particular field, hence the need to "direct participants to a qualified professional".

Discussion

In light of these normative documents, various conclusions can be drawn. Most strikingly, there is a clear lack of uniformity in both the terminology employed and the three approaches identified above.

Depending on the document analyzed, incidental findings are referred to as “unexpected findings”, “unanticipated results” and are sometimes qualified as “material” in nature. This diversity in terminology calls for a standardization process that will effectively allow for uniformity (if not at least concordance) in the use of terms relating to incidental findings. Indeed, standardization will allow international norms to be more easily compared, and will aid researchers as they draft research protocols and informed consent forms.

As to the content of the normative documents analyzed in this text, most of them call on researchers to be clear on their practices concerning incidental findings with their participants at the time of consent. This procedure is meant to allow participants to explicitly state their choices and exercise their right not to know, although we have seen that in some instances, the right not to know does not necessarily mean that no findings are returned[50].

Interestingly, most of these international norms address the issue of the conditions for return of individual results generally: urgency, actionability and identifiability, but rarely provide guidance on associated issues, such as “who should identify the incidental findings”; “who should return findings”, “how” and “when”. Moreover, none of these guidelines provide clear guidance on the question of whether researchers are obligated - in the context of the incidental findings - to list possible potentially health-important information that may be discovered/revealed. While it could be argued that the mere idea of anticipating all the possible findings before starting a given study depletes the notion of unexpected “incidental” findings, it remains important that the issue be resolved.

Creating an obligation to identify other possible findings at the onset of a study puts a significant burden on the researchers and could open the doors for potential liability. That being said, this particular issue requires a more in depth analysis and consideration, especially with regard to the mechanisms possible to support researchers faced with such questions.

This lack of guidance leads us to question whether the return of incidental findings is a tech-driven issue - triggered by the capacity to collect and share vast amounts of data[51] - or a rights-driven issue, where the participants are given choices and protected from potential harm.

This point is important, as we are seeing an unprecedented expansion of “duties” involving researchers. In fact, the longitudinal and international nature of some genomic research initiatives might not make it feasible to respect such an increase in the obligations of researchers. Greater consensus is required on the management of incidental findings in the field of genomics and for a proportionate approach to the responsibilities of all stakeholders involved in this process.

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