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SHARING THE KNOWLEDGE: SHARING AGGREGATE GENOMIC FINDINGS WITH RESEARCH PARTICIPANTS IN DEVELOPING COUNTRIES

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Abstract

Returning research results to participants is recognised as an obligation that researchers should always try to fulfil. But can we ascribe the same obligation to researchers who conduct genomics research producing only aggregated findings? And what about genomics research conducted in developing countries?

This paper considers Beskow's et al. argument that aggregated findings should also be returned to research participants. This recommendation is examined in the context of genomics research conducted in developing countries. The risks and benefits of attempting such an exercise are identified, and suggestions on ways to avoid some of the challenges are proposed. I argue that disseminating the findings of genomic research to participating communities should be seen as sharing knowledge rather than returning results. Calling the dissemination of aggregate, population level information returning results can be confusing and misleading as participants might expect to receive individual level information. Talking about sharing knowledge is a more appropriate way of expressing and communicating the outcome of population genomic research. Considering the knowledge produced by genomics research a worthwhile output that should be shared with the participants and approaching the exercise as a 'sharing of knowledge', could help mitigate the risks of unrealistic expectations and misunderstanding of findings, whilst promoting trusting and long lasting relationships with the participating communities.

Keywords

returning results; genomics; aggregate results; developing countries

INTRODUCTION

Do researchers have a moral obligation to return research findings to the research participants? This question has been at the epicentre of research ethics discussions for the past decade.¹ The discussion most often revolves around the obligation to return individual

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findings, and, specifically, clinically valid findings and health-related information of reproductive significance. Although researchers do not have a duty of care toward their participants, like clinicians do towards their patients, the discovery of clinically important information for individuals, that might have significant health implications, indicates an obligation, a 'soft' duty of care for biomedical researchers. It has been argued, therefore, that researchers have an obligation to inform research participants of clinically valid individual findings of health significance and reproductive relevance.

There are types of biomedical research that do not produce individual, clinically valid findings. This is the case in population genomics research where the aim is to look at the genome of a large number of individuals in order to discover any genes that associate, positively or negatively, with diseases and health conditions. Researchers pool the genomes of all the individuals they have sampled and analyse this pool for markers, points of difference in the genome, which might have an association with the diseases they investigate. In the majority of cases the samples are fully anonymised. Also, the techniques used for genotyping are not clinically valid. This means that the accuracy of an individual's genetic information is very low, but, because of the high number of samples pooled together, low accuracy does not affect the statistical significance of the results. Many such studies take place in developing countries, investigating the genomics of diseases such as malaria, tuberculosis and HIV-AIDS. Considering the lack of clinically valid individual results, the question arises of whether researchers undertaking genomic research have a moral obligation to return findings to their participants.

In this paper I investigate the question of disseminating aggregate results to participants but in the particular context of population genomic research conducted in developing countries. I examine its moral justification and consider risks and practical challenges involved. I conclude that researchers have a moral obligation to inform participants of aggregate findings based on the duty for reciprocity, building trust and promoting education. I propose that communicating aggregate findings should be perceived as 'sharing knowledge' and not as 'returning results'. The main output of research is the generation of new knowledge and this is particularly true for basic biomedical research, such as population genomics, in which results are still far from the bedside. Framing the dissemination of aggregate findings as sharing of knowledge not only describes the exercise more accurately but can also help mitigate some of the risks involved with returning non-individual aggregate results.

RETURNING FINDINGS TO RESEARCH PARTICIPANTS

There is a general consensus that returning results to research participants is part of good practice, based on the moral obligation for respect for persons² and on a 'soft' duty of care towards research participants, especially when the results are of clinical importance.³ In 1999 the National Bioethics Advisory Committee (NBAC) published a report on the use of stored tissue and recommended that researchers should inform participants of research results when the results are valid, reveal a real health risk and are readily actionable.⁴ The report also stipulated that when results are returned to participants 'appropriate medical advice or referral should be provided' too.⁵ More recently two major funding bodies in the UK, the Medical Research Council (MRC) and the Wellcome Trust, launched a framework

to help researchers plan the dissemination of findings that have ‘potential health or reproductive importance to an individual participant.’⁶

The moral obligation to disclose research findings of clinical importance to participants is based on a ‘soft’ duty of care researchers have towards participants.⁷ It is ‘soft’ because it is not equivalent to the duty a clinician has towards their patients, but, when research reveals health information about an individual that has potential important health implication, ‘these are data that trigger a duty to consider the question of disclosure’.⁸ For Wolf this constitutes a reason for re-examination of the strict distinction between clinical care and research needs.⁹

Although the moral responsibility to return health-related individual findings is widely acknowledged, the way this moral responsibility should be fulfilled hinges on a number of factors. Depending on the type of research project, the types of results produced, the relationship between the participants and the researchers, the nature of the findings and the expectations of participants, the level of responsibility a researcher has to inform participants and participating communities might vary.¹⁰

While returning individual findings has attracted considerable attention in the past ten years, by contrast, the question of returning aggregate genomics findings has not, to the author’s knowledge, been examined at any length.

RETURNING AGGREGATE GENOMICS FINDINGS TO RESEARCH PARTICIPANTS

Aggregate genomics findings are the outcome of population genomics research that investigates genetic signs of disease susceptibility or resistance in a population or populations. Scientists genotype a great number of individual genomes in order to discover genetic markers that associate with a disease.¹¹ The outcome is usually in the form of a percentage of the population that carries a significant marker. Samples can come either from biobanks or *de novo* collections, and in the majority of the cases are fully anonymized. It is also important to note that the techniques used in genomics projects are not clinically valid, meaning that the error rate is much higher than what would be acceptable at a clinical setting, but it does not affect the statistical validity of the analysis.

Population genomic research cannot provide any individual and clinically valid health related information, and for this reason it has been suggested that aggregate findings are exempt from the obligation for disclosure:¹² as this type of findings cannot reveal any personal information of clinical relevance, no duty of care can be evoked. Furthermore, it has been argued that aggregate scientific findings could be misunderstood by the research participants, and hence, lead to feelings of confusion, fear, anger or anxiety.¹³ Participants might misinterpret the significance of these findings and treat them as results with personal significance. This could be particularly problematic when researchers are not in a position to answer or appease their fears by offering individual results.

Beskow and colleagues are the first to attempt an ethical analysis specifically on the issue of returning aggregate genomics results to research participants.¹⁴ They offer a justification that moves beyond arguments concerning the utility of the results and the associated risk-benefit analysis. Rather, they suggest that researchers should return aggregate results to participants as this acknowledges their contribution to science and affirms their role in scientific development. Also, it helps participants that have given broad consent for the use of their samples to understand ‘whether and how their contributions are serving social goals.’¹⁵ It encourages public trust in the research enterprise, and it can play an important educational role by promoting public understanding ‘of the incremental nature of research, potentially shedding light on what is for many a foreign and unfamiliar activity’.¹⁶ The authors acknowledge that there is a risk of aggregate findings being misunderstood by the participants, leading to feelings of anxiety, even anger. Therefore, they suggest that a careful consideration of the nature of the results and the method of communication is paramount. In particular, when results are of limited personal significance, a passive and impersonal dissemination, via a website for example, should be the preferred option.

Given that many genomics projects are happening in low- and middle-income countries, it is important to examine whether Beskow and colleague’s suggestions can also be applied with equal force in these settings.

RETURNING AGGREGATE GENOMICS FINDINGS TO RESEARCH PARTICIPANTS IN DEVELOPING COUNTRIES

A large proportion of biomedical research, including genomic research, is conducted in developing countries. Since 2005, funding bodies such as The Bill & Melinda Gates Foundation (<http://www.gatesfoundation.org/>), the United States National Institutes of Health (<http://grants1.nih.gov/grants/index.cfm>), The Wellcome Trust in the UK (<http://www.wellcome.ac.uk/funding/>) and others have been increasing funding for research on diseases that affect poorer countries, in an attempt to address the infamous 90/10 gap in global health research. This initiative prompted a new interest in diseases such as malaria and tuberculosis, and genomics projects that are looking into these diseases, such as MalariaGEN (<http://www.malariagen.net/>), emerged from it. The interest in genomic research has also been increasing: a survey in 2008 showed that countries such as China, South Africa, the UK and the US were spending significant amounts of public money on genomics,¹⁷ and in 2011 the WHO announced a new initiative to identify the way genomics could help address public health issues in developing countries, giving a new impetus to conducting genomics research in these parts of the world.¹⁸

Conducting research in developing countries comes with its own ethical and practical issues, and ethical guidelines and suggestions developed for research in first-world settings need to be checked for their appropriateness and feasibility for application in low- or middle-income countries.¹⁹ It should be examined, therefore, whether Beskow and colleagues’ justifications for returning aggregate results can be applied with equal force in the developing world setting, and what, if any, particular issues might arise in the process.

Whereas returning individual findings is based on a 'soft' duty of care, the obligation to return aggregate results stems from the obligation for reciprocity, the recognition of the importance of building and promoting trust relationships and the value of educating participants about genomic research. Fulfilling a duty of care, albeit a soft one, suggests greater urgency than showing reciprocity or raising scientific awareness might do. Returning results requires time, effort and the availability of funds. With finite resources available to biomedical research one could reasonably query the importance of returning aggregate findings, when the utility of these findings for the individual participants is low, and there are risks associated with it. Are duties for reciprocity and promoting trust something researchers can aspire to but should not be required to fulfil?

Building Trust

For decades, a common problem with research in developing countries was the so-called 'helicopter research'. Researchers would enter communities, collect samples and data, and then leave for their home institutions without ever returning back to their study sites to inform participants of the findings or their research.²⁰ This way of conducting research resulted in a lot of suspicion and mistrust towards researchers and biomedical research in general. The Havasupai case is a good illustration of the effects 'helicopter research' and inappropriate consent can have on medical research, on the community, and on the relationship between researchers and participants.²¹ Also, a study exploring the ethical issues in the collection, export, storage and use of human biological samples in Africa identified trust, or the lack of, as one of the main problems that needs resolving.²² Community engagement projects have gone some way to address this problem.²³ Nowadays the majority of RECs and local health institutions require researchers working in developing countries to engage with the communities, particularly before a project commences. Yet, engagement with participants and communities is equally important after the project has finished, especially for genomics projects that are likely to seek further use of the data.

However, given the lack of empirical data on the effectiveness of returning aggregate research findings to participants in developing countries, one might only infer the reaction of participants by looking at similar exercises in other parts of the world. Studies in developed countries have shown that participants are interested in aggregate findings, even when researchers cannot offer them individual results.²⁴ Participants wanted to know that their samples were put to 'good use' and viewed the returning of findings as an act of reciprocity²⁵ and acknowledgment of their contribution.²⁶ This interest is unlikely to be different in developing countries. One researcher who had been working for years in the Gambia, and who routinely returned findings to participating communities, suggested that participants are very interested to know the outcomes of scientific efforts, and claimed that the decision to feedback findings to the community helped substantially in building long lasting and trusting relationships with the community (pers. comm.). While such anecdotal evidence requires substantiation with empirical research, it appears likely that participants from developing countries are equally interested in learning about the new scientific advances to which their contribution has led as their counterparts in the developed world.

Education

Apart from building trusting relationships, sharing research findings with the participating communities could also fulfil an educational role. Presenting research findings to participants could increase their knowledge of genomics and enhance understanding of the nature of this type of research. Greater knowledge and better understanding could also lead to better decision-making regarding their future participation in genomics projects, and also to more accurate understanding of the particular associated risks and benefits. Such understanding is important given the particular difficulties identified in consenting participants for genomic research in developing countries,²⁷ and also the fact that the consent process for genomics projects has moved from the project-specific model to more open models like broad consent and dynamic consent.²⁸ Genomics data are usually stored in repositories for future use by the same team, and for sharing with other researchers working on the same or other disease.²⁹ Many developing countries and communities view the sharing of genetic and genomic data with suspicion and have introduced rules and regulations in an attempt to control and regulate the use of their information.³⁰ This creates great difficulties to researchers, who usually are required by their funders to release genomic data into the public domain, and often rely on having access to more data for the continuation of their research. A study on genomic research participants' attitude towards broad consent suggested that greater understanding of the research could help address the scepticism and hesitation especially participants with lower income and education feel towards further use of their data and broad consent.³¹

Furthermore, offering participants the findings of a genomic project could emphasise the difference between research and therapy, and thus help address the problem of 'therapeutic misconception', the failure of a research subject to understand the difference between medical research and medical care.³² When participants see that the blood sample or mouth swab they gave some time ago was not used for individual diagnosis but rather to answer a scientific question,³³ this could help further clarify that medical research does not aim to improve the health of the individual participants but works towards finding new knowledge to help future patients.³⁴

The presentation to interested populations and research participants of the importance of genomics in combating disease could provide a platform where the value of genomic research is explained by using concrete examples and demonstrating how their involvement in research can drive medical innovation forward. Moreover, given the suspicion of many local populations towards research, and the popular beliefs associated with drawing blood – a common sample taken for genomics research- such as devil worship beliefs, going back to tell participants what researchers have done with the samples and what they have found could go some way to dilute such beliefs and diffuse tensions between researchers and participants.³⁵

Promoting trust, acknowledging and respecting the role of participants in research, and supporting science education amongst the participating populations is crucial for conducting ethical research in developing countries and building long lasting collaborations. It is also important to consider the practical issues that might arise in attempting to inform participants of aggregate results and to consider options of overcoming them.

Reaching Participants

Reaching the research participants is one practical issue facing researchers attempting dissemination of aggregate genomics results. Genomics projects can require hundreds, even thousands, of samples in order to achieve statistical power, and very often the samples are anonymised. The results themselves may be yielded a number of years later. Trying to reach hundreds or thousands of participants many years after the samples are collected can be a logistic and practical impossibility. Beskow et al. suggest that returning aggregate results should happen in an impersonal way that has the potential of wide outreach, for example through a website. However, this might not be possible in developing countries: although the uptake of smart phones is significantly high,³⁶ it remains true that accessing populations in low income countries in Africa and Asia is much harder than in the UK or the US. For example, in 2013 the estimated rate of internet access in Africa was at approximately 16% of the population, c.f. 75% in Europe, and the gap in internet use between developed and developing African countries has widened rather than shrunk in recent years.³⁷ Therefore, attempts to access the participating individuals in a passive and impersonal way through, for example, a website, would fail to reach the majority of the population. For populations in less technologically advanced countries, then, researchers might need to turn to more traditional methods of communication. This might include community meetings where presentations of the findings and discussions can take place or door-to-door visits to distribute written material such as leaflets.

However, these methods of communication require organisation and availability of both time and funds, which are not always readily accessible either to researchers or to participants. Furthermore, and perhaps more importantly, using active and more personal methods of communication could heighten expectations by giving the impression to participants that the information offered is of great personal importance. Creating false expectations and then failing to meet them, even if unintentionally, could give rise to feelings of frustration and even mistrust. Research participants might feel that researchers are just wasting their time, or even worse, that they are hiding information from them, causing anger, mistrust or even suspicion towards them as individuals and the research enterprise in general. The problem of creating false expectations is, also, linked with the second issue regarding informing participants about aggregate genomics results; the problem of misinterpretation of findings.

Misinterpretation of Findings

The difficulties of explaining genomic research to populations in low income countries are known.³⁸ High levels of illiteracy and low levels of science awareness make explaining concepts such as 'gene' and 'DNA' challenging. This, combined with the high recorded incidence of therapeutic misconception³⁹ could lead to miscomprehension of genomics findings. It is recognised that people are particularly bad at comprehending statistical risk.⁴⁰ Aggregate genomics results could be easily misunderstood, leading people to mistakenly believe, for example, that they are at risk of a getting a particular disease or a condition, causing them stress and anxiety. Trying to make sense of statistics, participants might request personal results from the researchers. When they realise that the researchers are unable to provide them with any more specific, individual, information about their status,

feelings of anger and frustration might arise. In communities where health care provision often comes in the form of ancillary care from medical research projects, viewing researchers as healthcare providers is not uncommon.⁴¹ Therefore, the method and the mode used for dissemination should be very carefully thought and planned in order to avoid conveying the wrong message or raising unrealistic expectations. For example, if participants were summoned to a community event with the promise of returning findings, there is a risk that participants would assume that they would be given personal results back. The personal character of the invitation to an event – extended only to individuals who contributed samples to the project- and the announcement that results will be returned during the event, could lead to their misunderstanding and misinterpretation. A new approach is suggested below that could help address this problem.

SHARING KNOWLEDGE

Promotion of trust and knowledge emerge as the two main foci of the issues surrounding returning aggregate results. But the acknowledgment that it is precisely these two points that if the returning of results goes badly could be at stake might discourage researchers from even trying – primarily do not harm, they might think. I would like to suggest that a different framing of the exercise, could help address some of these risks regarding false expectations and misunderstanding of findings leading to stress, anxiety and suspicion towards researchers. I propose that thinking of and talking about the dissemination of aggregate findings as ‘sharing of knowledge’, rather than as ‘returning results’, is more accurate and more appropriate.

Population genomics biomedical research aims at discovering the genetic underpinnings of disease and the interaction between humans and pathogens at a genetic level. The outcome of basic research is the discovery of new information, new knowledge that can then be used for further research leading, eventually, to new drugs and therapeutic methods. Genomic researchers should make clear when communicating with their participants that what their research is producing and what they can share is new knowledge rather than results. Using the term ‘returning results’ can be confusing and misleading. It creates particular expectations from the side of the participants and places special demands on the scientists. Participants might assume that what they will receive will be something akin to clinical test results. Talking about returning results might also make researchers apprehensive and more anxious because, sensing the expectation from the participants, they might assume that their findings are of no importance to research participants. Aggregate genomics findings are not ‘test results’; they are population level information. These types of information could be useful at a population or public health level, but they carry no clinical value at an individual level. What genomic researchers produce is new knowledge about diseases and health conditions, and information on how these can be seen at a genomic level across groups and populations. The production of new knowledge is the major outcome of a research project, therefore, it seems appropriate that researcher will engage with research participants in order to share and communicate the outcomes of their scientific endeavours.

It is important that dissemination of findings is planned with the active participation of local researchers, ethics committees, advisory boards and community engagement officers. Local

institutions and representatives will have a better understanding of the needs of and the possibilities in their communities. Hence, they will be well placed to guide researchers and advise them on the most appropriate way to share knowledge with the local population.⁴² It will also be important for researchers who undertake such activities to publish their experiences, so other groups can learn from their successes and mistakes. It is true that more empirical research on the topic and more practical experiences are necessary before one can say with any degree of certainty how one should communicate aggregate findings to communities in developing countries. MalariaGEN is planning to undertake such an activity in a number of its research sites, and hope to soon be able to report back with some experiences and lessons learned for the benefit of the wider research community.

CONCLUSION

Acknowledging participants' contribution, building trust relationship, and educating people about genomic research constitute a strong argument for attempting dissemination of genomics findings to participating communities in developing countries. It is important, however, researchers planning to undertake such an exercise in developing countries to consider the particularities and individual needs of their sites. Although the justification and motivation for sharing findings with the participating communities might be the same between developed and developing countries, the different context in which this would take place indicates that the adoption of different methods might be necessary. Furthermore, it is crucial that researchers consider carefully not only the method for dissemination they use but also the way they communicate their intentions to the participants. If the only findings they can reasonably expect to share with the participating communities are aggregate genomics findings, as is in the case of population genomics epidemiology studies, announcing the intention to 'return results' might create false expectations from the side of the participants and of the researchers. Of course, the same applies to researchers attempting sharing of aggregate findings with participants in developed countries. Being clear and avoiding confusing statements is an important communication skill applicable to any setting.

Considering the knowledge produced by their research a worthwhile output that also should be shared with the participants and approaching the exercise as a 'sharing of knowledge', could help mitigate the risks of unrealistic expectations and misunderstanding of findings, whilst promoting trusting and long lasting relationships with the participating communities.

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Biography

Angeliki Kerasidou is a bioethicist with background in theology and philosophy based at the Ethox Centre, University of Oxford. Angeliki is also the Malaria Genomics Epidemiology Network (MalariaGEN) Ethics-Coordinator.

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