CASE STUDIES

CASE STUDY 3: Tonga

Introduction

In 2000, an Australian biotech company, now known as Autogen, secured an agreement with the government of Tonga, an archipelago nation in the South Pacific, to collect blood samples for genetic analysis. The Tongan population seemed well suited to genetics studies of factors relating to diabetes and obesity, since the island community had had relatively little immigration, was genetically isolated, and in recent years has had a high incidence of the diseases in question. The agreement was announced in the Australian press and in stock market reports, but encountered vigorous opposition from Tongan community groups. Ultimately the plans were shelved. Autogen did not collect or analyze samples and instead formed new agreements with Polynesian groups on other islands to gather genetic information.

Background

Tonga is an archipelago nation in the South Pacific, about 2/3 of the way between Hawaii and New Zealand, consisting of 169 islands, about 36 of which are inhabited. The current population (108,000) of Tonga consists of descendants of Polynesians who colonized the island over 3000 years ago.[1] There is little to no immigration to the islands, and hence little genetic admixture with other groups. The relative genetic homogeneity of the population, along with a high incidence of certain diseases, are seen as an advantage by some researchers looking for specific alleles associated with multifactorial diseases.

Tonga was united into a kingdom in 1845, and was a British protectorate from 1900 to 1970, when it became independent. The government of Tonga is a monarchy, and includes a prime minister and a cabinet of 12 members, all chosen by the king. There is a legislative assembly of 30 members, of whom 9 are chosen by popular vote.[2] The Tonga Human Rights and Democracy Movement has been pressing for more democratic representation and free press in the country. The church is influential, and approximately 50% of the population belongs to the Church of Jesus Christ of Latter Day Saints (Mormon church) and the majority of the population overall are members of one of several Christian denominations present in the country. Tonga national Council of Churches is a member of the World Council of Churches, which has been involved in supporting human rights movements in various countries around the world.[3]

The economy of Tonga is supported by a narrow agricultural base of exports, and some tourism. GDP is approximately $2,200 per capita (2001).[4] Most food is imported ($30 million, 1999), and the country experiences a chronic trade deficit ($96 million in 1999). Australia and New Zealand have both provided economic aid to the country in different forms. There is 13% unemployment. The health profile of the Tongan population is relatively good and literacy is 98.5%; health services are provided free of charge. One of the rising health concerns has been the rate of diabetes and obesity; it is estimated that 15% of the population has diabetes,[5] twice the prevalence reported 25 years ago. Changes in diet and physical activity, including increased consumption of imported fatty foods, overlaid on a probable genetic predisposition for the disease, are believed to account for the rising prevalence of diabetes in this and in other Polynesian populations.

The Autogen agreement.

In November 2000, through negotiations with the government of Tonga, and in particular, the minister of health, Autogen announced an agreement to conduct genetic research for the purpose of discovering disease-related genes in the relatively isolated and homogeneous Tongan population[6]. Newspaper accounts in the Australian press[7] described arrangements for the company's "exclusive rights" to collect samples, with individual informed consent, for genetic analysis. However, the chief scientific officer of the company stated that the word "exclusive" appeared nowhere in the Tonga/Autogen agreement.[8] It is important to note that at this stage there was no existing intellectual property, and so the notion of exclusivity could not have related to an IP-based claim to existing property, but rather, apparently, to a perception that the Tonga government had pledged not to make similar agreements with groups other than Autogen. The company planned to target families already identified with diabetes for sampling and genetic analysis.

Autogen made a commitment to donate a certain amount of financial support to the ministry of health, including plans for construction of a new research center in the country, and to share some portion of royalties of any commercial products subsequently developed from the Tonga project. The Autogen CEO stated that "This major research initiative will benefit Tonga as well as Autogen's gene discovery program. The establishment of a research center will create many new job opportunities in scientific research and provide opportunities for Tongan graduates overseas to return to the country and participate in world-class scientific research. "We expect the research facility to grow into a major Autogen initiative over the next few years."[9] Autogen had also included an explicit ethics statement in the project agreement; a bioethicist at Boston University, reviewed the agreement and described it as 'unacceptably vague.'[10]

Reactions in Tonga.

The Autogen/Tonga agreement was announced in the Australian stock exchange and in the popular press in November 2000, and was immediately the target of strong criticism from Tongan community groups. The head of the Tonga human rights and democracy movement stated several objections,[11] among them a) lack of public discussion of the project in Tonga; b) lack of transparency on the part of the Tongan government about its actions; c) lack of consideration of privacy concerns for families whose members might participate in the project on the basis of individual consent; there was particular concern about stigmatization and discrimination against individuals in the relatively small and insular Tongan society; d) opposition to the notion of patenting DNA and other 'life forms'; e) no guarantees of any benefit for the Tongan people and f) colonial appropriation of resources of the Tongan people. The human rights and democracy leader remarked that the benefits were "a drop in the bucket" for the Tongan people[12] compared to the material gain that might be realized by the biotech company in attracting new capital and producing successful products. He also pointed out that at the time Tonga or other Pacific Forum countries[13] had no existing intellectual property law or regulation of biologic research, and thus limited ability to protect its own IP interests.

In March 2001, the Tonga National Council of Churches and the Geneva-based World Council of Churches convened a meeting in Tonga, attended by other Polynesian representatives as well, to discuss the project and the concerns it engendered. The Tonga National Council of Churches published a statement in the Journal of Medical Ethics in 2001, stating opposition to the Autogen project based on religious beliefs, namely, that patenting of 'life forms' was a violation of respect for the sanctity of life and fundamental religious principles. Moreover, this patenting was not in the interest of the Tongans: "The conversion of lifeforms, their molecules or parts into corporate property through patent monopolies is counter-productive to the interests of the [people] of the Pacific." The statement also affirmed the Tongans desire to control research conducted in their country: "The peoples of the Pacific have the right to manage their own biological resources, to preserve their traditional knowledge and to protect these from expropriation and exploitation by scientific, corporate or governmental interests."

Shortly after the protests by Tongan groups, Autogen withdrew its plans for the project and pursued agreements to gather samples elsewhere. Meanwhile the news of the planned project and the controversy had spread and various news accounts were posted on websites and in international media.

In commentary on this and other genetics projects, Boyes and Senituli[14] remarked that in the context of national debate about genetic research, "informed consent thus becomes a question of public consultation and how political will is mobilized, as much as it is about the components familiar to western bioethics of disclosure, comprehension, voluntariness, competence and consent or refusal." They also note that study of decision making in groups may be inherently difficult: "Anthropology has well defined methods for the study of collective decision-making, but bioethics is only beginning to articulate the mismatch between individualistic disclosure models of informed consent and population genetic research."

Combined Discussion Questions, for Tonga and Estonia

Genetic information, somewhat paradoxically, is both a shared heritage among humans-- even more so among those of common ancestry-- and also an intensely private matter. Decisions about gathering data on genetic profiles of groups raises simultaneously the issues of group ownership and of individual consent, and the potential tensions between these claims.

Ownership claims

- Does a group of people (such as the residents of Estonia or Tonga) have collective ownership of, or collective interest in, their genetic heritage? If so, how could this ownership or interest be described, both in terms of what 'genetic heritage' means and in terms of how the population of 'owners' might be defined?
- Would some kind of collective claim or ownership have implications for individuals who wish to join a research project without an agreement established with wide discussion and general agreement among Tongan community members?
- In cases where group leaders, such as national governments, make decisions to engage in national genetics projects, are the rights or interests of individuals who oppose the project subsumed by those who support it? Are special informed consent procedures needed to take account of family issues in genetic research with large populations?

Governance and Benefit-Sharing

Commercial benefits of genetic research are difficult to predict, especially in the short term. In cases where benefit-sharing agreements are constructed around potential commercial profits, these benefits may not emerge at all in the short- or medium-term. There are also questions about the form and disbursal of benefits to populations, for example as up-front payments or percentage of future royalties that may be dedicated to projects or programs, or as free provision of commercial products of research resulting from the genetic information.

Genetic research is often described as holding a promise of increased understanding of multifactoral disease, and better health care for individuals. Some commentators are concerned that these promises are not balanced in relation to more immediate public health concerns for populations that participate in genetic research. In some cases there are expected benefits from the results of genetic research that may be applicable to specific health problems. In the Tongan case, some commentators believed that unraveling the genetic basis of diabetes and obesity would be critical in addressing their increased incidence in Tonga. Experts note that it is a relatively recent phenomenon, and environmental conditions such as Western diet and decreased exercise probably play a key role, as well as genetic background.1 Some public health experts believe that focusing on genetic research in relation to diabetes and obesity might be inappropriate, in comparison to preventative approaches or use of existing treatment modalities.

Some observers are concerned that it is risky to return results of genetics studies to individuals when there is no evidence for making medical decisions based on the new genetic information.

This risk might be higher in situations where medical records are linked to genetic analysis. There is also widespread concern about privacy in genetic research, in particular, breaches of privacy that might result in stigma or discrimination, such as denial of employment or insurance. At the same time, there is little documented evidence of harms that have arisen as a result of disclosure of genetic information gathered in research. Some individuals associate genetic research with fears about manipulation of the genome and devaluation of the natural life of human beings. Others claim that some or all of these fears are unwarranted, and that genetic research is inherently no more or less risky than other kinds of non-invasive biomedical research.

- In the two cases described, historical context, governance and decision-making regarding genetic databases at the national level were quite distinct. What ethical concerns arise concerning the ability of national governments to negotiate and decide agreements for genetic research concerning their populations? Can decision-makers be unduly swayed by the potential for commercial profit or valuable collaboration with scientific groups? The islands of Tonga have a history of relationships with colonial powers, including current economic dependence on more industrialized nations. Is this an interesting footnote, or a substantive concern in the negotiation of agreements with foreign companies?2

- Would it have made any difference if the genetic research project was carried out by a non-profit entity, as opposed to a for-profit commercial entity? Non-profits can also acquire patents to DNA sequences or products derived from research on specific genes. Do the overall goals of the research matter?

- Are risks of research and potential benefits characterized adequately and analysed as part of the decision-making process at the national level? Was there sufficient public discussion of potential risks or benefits in the two cases? How can benefit-sharing arrangements be evaluated in terms of fairness, transparency, and responsiveness to national needs? How can it be determined that benefits that may accrue to a body or governmental organization in the country can serve the interests of the population?

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[12] Griggs K. Tonga Sells Its Old, New Genes. Wired News. http://www.wired.com/news/technology/0,1282,40354,00.html

[13] Cook Islands, Fiji, Kiribati, Marshall Islands, Federal States of Micronesia, Nauru, Nieu, Palau, Papua New Guinea, Soiomon Islands, Samoa, Tonga, Tuvalu and Vanuatu

[14] “Tonga and Iceland, Biotech, ownership and consent,” Australasian Bioethics Association Annual Conference, Adelaide, Feb 14-16 2002

COMBINED DISCUSSION FOR ESTONIA AND TONGA

Rapporteur:

I would first like to point out that the discussion was particularly heated. I encountered a few problems in controlling the debate. Each participant expressed his/her personal view of the case at hand. In the absence of the main interveners in both cases, we listed a certain number of points that we would like to submit to Rev. Simote Yea and Dr Ants Nomper for their consideration.

We started out by reflecting on the fundamental differences that exist between Estonia and Tonga, as well as the reasons behind Tonga's refusal to participate in the NDTI, while Estonia accepted to participate.

The discussion heated up as soon as the question of religion was brought forward. The church is of considerable importance in Tonga. It offsets the absence of certain institutions, ethics committees are an example. In contrast, Estonia, a former Soviet bloc country, has a less significant religious background. The authority of the State is respected by the population.

The perception of science is another dividing line between these two countries. Estonia has a relationship with science that goes far back. This tiny little country holds internationally renowned, scientific institutions: the Estonian population seems to be aware of scientific imperatives and actively participates in experiments. Conversely, we believe that the inhabitants of Tonga have a very remote relationship with science.

Strong ideas came out of this discussion which, I repeat, was heated to say the least. Let us just say that, whatever our perception of science, the absence of respect for those involved results in the mistrust of innovation. It is vital and urgent that we question the differences between the benefits and profit. The next few interveners will develop this point.

Rapporteur:

Our group discussed the Estonian benefit sharing arrangement and decided that it was not fair, as the shareholding is too small and the level of profit-sharing with the community, at around 3%, is too low.

On the question of community consent, it was felt that in Estonia, the public agreed as they were approached in a way that encouraged them to support the project. In Tonga, the public was alienated by the approach which was taken but, in any case, would have been less likely to be supportive, given their moral attitudes.

We could not agree whether the economic philosophy of the groups involved is an important factor as it is difficult to draw an accurate dividing line between for-profit companies and non-profit organisations.

Rapporteur:

A number of interesting issues were discussed in our group. First, we considered how the governance process in Estonia and Tonga affected the outcome of the project. It was questioned whether governments should be allowed to be make such decisions on the part of the population and whether, in Estonia, the public genuinely understood the nature of the project prior to giving their consent. Where issues of stigmatisation or exploitation could arise from individuals, families or groups being identified as having a defect, it was felt that consent should be given at individual or community level and not simply at a national level.

Intellectual property rights have an important link with risks and benefits. We discussed the inequalities which exist between developed and developing countries, particularly in terms of infrastructure and political background. The political situation of a country has a significant impact on the creation of benefit sharing agreements, on the potential for exploitation and stigmatisation, and on/the question of whether data should be owned on an individual or a collective basis. Although consensus exists that the interests of the people involved must be considered; this does not necessarily extend to collective input into research subjects or genuine collective consent.

The long-term potential benefits of gene databases were considered. It was noted that, although these databases can be very beneficial, they can also be extremely dangerous. It was questioned whether genetic studies should be a priority in countries where basic problems such as AIDS, political turmoil, and access to primary healthcare remain unsolved.

Rapporteur:

During our discussion of ownership claims, it was noted that the discussion paper uses the phrase "collective interest in genetic heritage". We felt that the notions of genetic identity and property should be associated, so that the property rights of a group of individuals would be governed by their collective interest in their genetic identity. In this way, a group could not object to some individuals choosing to participate in a genetic study. Given that losses might be experienced by those who did not take part, two possible safeguards were suggested. The first proposes that any benefits which were obtained would be shared by everyone with the same genetic identity. The second proposes that a minimum level of consensus be agreed. Individual property rights are important but it is important that there is a collective sharing of the genetic interest. Words like 'community' and 'collective' are being used very loosely at present and might benefit from tighter definitions.

It is important that governmental commitment is obtained once a study is proposed. The perception which a population has of science was also felt to be an important factor. In some countries science and technology are viewed as having a positive impact but this attitude is not shared throughout the world.

Somewhat provocatively, it was suggested that democracy should be a pre-condition for these kinds of studies. This would, of course, require a significant amount of debate in order to determine the quality of democracy and the quality of mandate which would be acceptable.

The final proposal of the group is that discussions be held to debate the creation of an accreditation process for research companies. Drawing on the analogy of the human rights movement, it was felt that it would be beneficial to conduct ethical auditing, which would allow communities to feel confident that they were negotiating with a responsible body. We believe that this could be implemented as a concrete process.

Chairperson:

Thank you to all those who chaired and reported from the workshops. We shall now take brief questions and comments relating to ownership.

Comment:

In Malawi, genetics is considered to be a private thing. However, it is acknowledged that as the results of genetic research may affect a third person, it is not entirely private but also has public aspects. When the risks of an individual's actions can have an impact on a third person, the benefits of those actions should also be shared with the third party. The individual can benefit from collective ownership but when risks go beyond the individual realm, benefits must also go beyond the individual realm. In such a situation, individual autonomy can no longer take precedence.

Comment:

I am wondering about the guarantees that could preserve the countries of the South from their current feelings of anxiety. I have two questions.

First of all, should we contemplate the implementation of a sort of international solidarity in order to offset the issue of risk benefits in terms of research and good practices?

My second question deals with the concept of vulnerability. The case study showed that situations are different from one country to another. So, should controversies and contradictions be managed by project or by country? The country approach seems ineffective to me since, for example, it clashes with religious obstacles. In other words, the concept of informed consent and the distinctiveness of the individualism necessary for a research protocol would not be considered in anticipation of a benefit for the collective good.

Lastly, it seems to me that we cannot take the stigmatization associated with vulnerability-defined as a predisposition to an abnormality and not a pathology -as a criterion: the biological, cultural and psychological diversity, as well as the consent of the subject must be deontological factors rather than commercial ones.

Comment:

Although we have talked about the collective ownership of the community and of individuals, we must remember that the company which collects the data also wants to own it and control the use of this information.

Comment:

In my opinion, the whole concept of ownership is not appropriate in this context and that a different approach should be considered.

Comment:

Would it not be appropriate to clearly distinguish between the benefits issue and the question of added value? Benefits oppose risks while added values are economic elements. This semantic distinction is essential: maybe you could clarify this.

Chairperson:

Thank you. Our panel members, Dr Annts omper and the Rev. Vea, will now respond.

Comment:

The issue of ownership affects the many different levels of community which are involved in collective ownership. It also applies to the question of entitlement to genetic heritage, that is, the ownership rights of those individuals who inherit the genetic ancestry concerned. The wide-ranging impact of genetic knowledge must be considered, particularly as whole families may be stigmatised or discriminated against as a result of research identifying one member as having a disease. This situation has already arisen with AIDS and HN. Decisions regarding collective claims must be taken in the context of collective genetic heritage and must therefore consider the whole community as well as the individual. When the wider national community is implicated, decisions must benefit the whole population and not simply the company or the government.

The important question of international solidarity gave rise to our proposal for an auditing and accreditation programme for companies which want to conduct research, whether in developing or developed countries. These companies must also be considered when discussing collective and individual ownership as, in the end; they own both the genes and the benefits. Ownership and benefits are so closely inter-related that a joint approach must be taken when discussing them.

Comment:

The comment regarding the 25-year ownership of tissue and data highlights an important misconception about the Estonian database. All of the data and tissue samples stored in the genome database are entirely owned by a specially created foundation, which is controlled by the Estonian state. While commercial companies can use the data and tissue, they do not, under any circumstances, have ownership of it.

Chairperson:

Thank you very much. Unfortunately, we do not have time for questions on governance and benefit sharing, although I am sure that you are very keen to exchange views on these subjects. I would like to thank the speakers and other participants for their contributions this morning, which have highlighted many important points and which, I am sure, will be the focus of further discussion during the Forum.