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How Genetic Testing Is Accessed, Can We Regulate?*

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The paper looks at how to regulate access to genetic testing, other than through a medical practitioner as part of health services provision. It examines the steps by which genetic testing services may be obtained from laboratories and the implications of these processes for individual access to testing services. It also discusses the quality assurance and accreditation standards which regulate genetic testing laboratories. Further, this paper looks into issues concerning the availability of home use testing or over-the-counter. Furthermore, we consider whether there should be additional legal protection against the taking and testing of genetic samples without the knowledge and consent of the individual concerned through the use of criminal sanctions.

Keywords: genetic testing, medical practitioner, health services, legal protection, Papua New Guinea

Situation in Papua New Guinea (PNG)

In the country, many health care facilities are owned by churches, majority by Catholic Church, in rural areas and a few have a medical professional (or a doctor). In the public healthcare sector, doctors serve as far as the district hospitals and occasionally they visit health centers. Private health care services are mainly in major towns, in terms of genetic testing and counselling only a few public hospitals and private medical hospitals and clinics operate such services but mostly available in the National Capital District.

For this paper we studied patients who are either out-patients or in-patients and their families who are affected by a particular genetic factor or genetic disorder, and the use of institutional facilities to conduct genetic testing. The emphasis in this paper is on the legal aspects of genetic testing in PNG. It is important in learning more about the health and well-being of genetic patients and their families, promoting disease prevention and knowledge about taking and testing of genetic samples without consent. Efforts to educate patients and general public against the importance of genetic factors and disease disorders have had limited success. The success against the situation in PNG of both educations for the general public and through school education programs and other conventional and modern methods are all promising.

We provide highlights of the development of genetics, ethics, and law and describe how the development of genetic regulations to accessing genetic testing against non-compliance reflects those advances. We say that

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while admiring successful genetic control programs in many countries, for example, Australia, UK, the USA, Japan, China, it is motivating, we suggest, that much can also be learned from both past successful and failed efforts, as doing so will increase our ability to improve future activities.

Advances in Science and Technology

Advances in science and technology have made it possible for the medical community to diagnose and detect genetic abnormalities before the people who have these abnormalities become symptomatic (Furrow et al., 2004). These advances will give doctors the ability to prevent and treat life threatening conditions with early and aggressive treatment. As a result of this ability to detect diseases and debilitating medical conditions before they arise, employers now have the ability, and are utilizing this new medical advance, to screen potential employees. This screening takes place before employees have been hired and the result can affect employers' hiring decisions (Furrow et al., 2004). With the possibility of putting their current or future employment in jeopardy, people who might benefit from the use of genetic tests may not undergo these tests if the results are made public.

Health professionals have been the means of entrance or exit of access to genetic testing and the genetic information[1], derived from it, at least for clinical purposes, but there are other means by which genetic testing may be accessed. These include direct access to testing services[2] provided by laboratories and through home use genetic testing kits.

Process for Genetic Testing

There are steps individuals follow in order to obtain a genetic test. The process for genetic testing varies according to the type of testing sought, the laboratory concerned, and whether there is a request from a health professional. However, the process and the consequent ability of individuals to gain independent access to genetic testing may be constrained by laboratory and health professional practices and protocols. Genetic testing for medical purposes usually requires a referral from a medical practitioner.

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[1] Genetic information means information about an individual's genetic tests, the genetic tests of family members of the individual, the manifestation of a disease or disorder in family members of the individual or any request for or receipt of genetic services, or participation in clinical research that includes genetic services by the individual or a family member of the individual. The term genetic information includes, with respect to a pregnant woman (or a family member of a pregnant woman) genetic information about the fetus and with respect to an individual using assisted reproductive technology, genetic information about the embryo. Genetic information does not include information about the sex or age of any individual. Genetic Information Nondiscrimination Act expands the genetic information nondiscrimination protections included in Title I of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), U.S. Department of Labor Employee Benefits Security Administration.
A manifested disease is a disease, disorder, or pathological condition for which an individual has been or could reasonably be diagnosed by a health care professional (with appropriate training and expertise in the field of medicine involved). A disease is not manifested if a diagnosis is based principally on genetic information. For example, an individual whose genetic tests indicate a genetic variant associated with colorectal cancer and another three that indicate an increased risk of developing cancer, but who has no signs or symptoms of disease and has not and could not reasonably be diagnosed with a disease does not have a manifested disease. Genetic Information Nondiscrimination Act expands the genetic information nondiscrimination protections included in Title I of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), U.S. Department of Labor Employee Benefits Security Administration

[2] Genetic services mean genetic tests, genetic counseling, or genetic education. Genetic test means an analysis of human DNA, RNA, chromosomes, proteins, or metabolites, if the analysis detects genotypes, mutations, or chromosomal changes. A genetic test does not include an analysis of proteins or metabolites directly related to a manifested disease, disorder, or pathological condition. Therefore, some examples of genetic tests are tests to determine whether an individual has a BRCA1, BRCA2, or colorectal cancer genetic variant. In contrast, an HIV test, complete blood count, cholesterol test, liver function test, or test for the presence of alcohol or drugs is not a genetic test. Genetic Information Nondiscrimination Act expands the genetic information nondiscrimination protections included in Title I of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), U.S. Department of Labor Employee Benefits Security Administration.

There is no Accreditation Advisory Council in PNG.[3] Professor Andrew Masta says that in Australia Pathology Accreditation Advisory Council, Standards for Pathology Laboratories ensure that all laboratory specimens are fully identified and, except in the case of urgent histopathology specimens, are labeled and accompanied by a written request by a medical or dental practitioner or other authorized person.[4] Professor Masta says that the medical practitioners may request various types of genetic test, which may in turn require referral to a medical specialist, such as a clinical geneticist, or to a genetic counselor.[5] In Australia and New Zealand, the technical competence of genetic testing is regulated by an accreditation scheme operated by the testing authorities.[6]

PNG has within hospitals guidelines and rules to follow and the National Department of Health (NDoH) has yet to develop its local quality assurance and accreditation standards which would regulate genetic testing laboratories in the country. Whilst there already are policies made in this area, NDoH should move into developing legislation to check on testing competence of private laboratories and establish a testing authority.[7] Nevertheless, experiences are learnt from Australia and this study is informed that most requests for genetic tests are forwarded to Australian laboratories.

We have noted that the ambit of any legislation requiring accreditation would have to be carefully considered. This would mean all laboratories must be accredited by the accreditation authority. If a prohibition were adopted, there may need to be an exception made for genetic testing conducted in the course of medical research. A distinction may need to be drawn between testing used to provide clinical or medical advice, and testing used for research. An additional means of discouraging the use of some non-accredited genetic testing would be to restrict its use as evidence in court proceedings. For example, legislation might provide that genetic test results are admissible as evidence only where the testing is conducted by an accredited laboratory in accordance with the accreditation standards recognized by the standards authority. There may be no compelling argument to regulate genetic testing in these ways when medical testing generally is not subject to a similar regime. However, ensuring accreditation of all genetic testing performed will not necessarily overcome concerns about access by individuals to non-accredited genetic testing conducted overseas.

Testing Genetic Samples Without Consent

Genetic information may be derived from easily accessible bodily samples such as hair follicles (humans shed hundreds of hairs every day), saliva left on a glass or cigarette, cheek cells on a tooth brush, sloughed cells deposited on an item of clothing, or mucus in a tissue, etc. Together with the above is the advancement in the biomedical technology nowadays and the ubiquity of human genetic samples leaves open the potential for bodily samples to be taken and tested without the knowledge or consent of the individual to whom they relate.[8] For

[3] Personal communication with Mr. Francis Possy, Principal Legal Officer, Department of Health, Aopi Building, Waigani, NCD PNG.
[4] Personal communication with Dr. Andrew Masta, Clinical Geneticist, Port Moresby Private Medical Specialist Center and Associate Professor Biochemistry Department of Basic Medical Science, School of Medicine, University of PNG.
[5] Ibid., see Note 4, supra.
[6] Advisory Committee on Genetic Testing, Code of Practice and Guidelines on Human Genetic Testing Services Supplied Direct to the Public (1997), Department of Health, London. See also Commonwealth Department of Health and Ageing, Submission G150, 15 April 2002.
[7] Personal communication with Mr. Francis Possy, Principal Legal Officer, Department of Health, Aopi Building, Waigani, NCD PNG.
[8] The term used is non-consensual genetic testing.

example, the reason former United States President Bill Clinton's bodyguards collected a pint glass after he had drunk from it in a British pub was to ensure that his DNA could not be obtained, this for fear of "genetic trophy hunters".[9] In PNG, access to genetic testing and potential for improper use of the service is a concern. That is, genetic information might be collected surreptitiously for example, from a sample of skin, hair roots, or saliva for unauthorized purposes.[10]

Although in PNG this conduct would generally breach the "National Privacy Principle"[11] or the "common law", there is an argument that criminal penalties should apply.[12] Similarly, the concern was over the problems involved in a person's obtaining genetic information about an individual for the wrong reasons without the individual's knowledge or consent, whether by mail-order or through testing. This issue raises, among others, proof of *bona fides*, proof of the identity of the person requesting the test and possible criminal sanctions for the unlawful use of genetic information without the knowledge and consent of the individual. The national privacy principle provides general protection in many of these circumstances but developments in this area should be monitored closely.

In Australia, Department of Health and Ageing agreed that "over-the-counter" testing creates the potential for genetic testing of an individual without the individual's knowledge or consent.[13] The DNA profiling technologies enable accurate results from very small samples such as a hair and these can be easily obtained without a person being aware of it.[14] Regulation of this practice raises difficulties because testing services are available internationally, often through internet marketing.[15] Nonetheless, commercial and unaccredited laboratories and regulation of "DNA theft" are important issues which affect many developed countries. In PNG the non-consensual collection and use of bodily samples for the purpose of genetic testing should be proscribed by law so that it is necessary to closely examine the harm that may arise from this conduct. The harm caused by non-consensual genetic testing may be categorized in various ways, depending on whether one looks at the collection of the genetic sample, the testing of the sample to derive genetic information from it or the possible uses of the information so derived.

First, the collection of the sample may in some circumstances involve a physical harm or a trespass to the person or a battery. The collection may be intrusive of the physical space of the individual and, where it is known about, result in emotional harm. Emotional harm may result from situations where, from the perspective of the individual concerned, intimate bodily samples such as menstrual blood or semen are taken, or kinship relations or identity is questioned.[16] As stated, genetic testing may result in the disclosure of sensitive personal information of many kinds.

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[9] Law Reform Commission, Protection of Human Genetics Information, Issue Paper 26 (2001), ALRC, Sydney. See also National Association of Testing Authorities, NATA Directories, http://www.nata...

[10] The risk is increased by the availability of over-the-counter and over-the-internet services as there are already increasing needs for those services among families in PNG.

[11] Constitution, Section 49 "Right to Privacy", GovPNG (1975).

[12] Personal communication. Late Mr. Hudson Ramatlap, First legislative Counsel. National Legislative Counsel, National Executive Council, Waigani, PNG. Also similar views were expressed from Mr. Leslie Mamu, Legal Counsel of the Public Solicitors' Office, Garden City, Boroko, NCD, PNG.

[13] Law Reform Commission, Protection of Human Genetics Information, Issue Paper 26 (2001), ALRC, Sydney. See also National Association of Testing Authorities, NATA Directories, <http://www.nata...

[14] Ibid., see Note 13 supra.

[15] Ibid.

[16] The most obvious harm arising from the testing of the sample is the intrusion on basic human dignity and autonomy. The harm may be also characterized as involving a breach of information privacy.

And second, testing can reveal information about the present and future health of an individual; an individual's identity; and his or her parentage or kinship. The fact that harm may be caused by the non-consensual disclosure of these kinds of information should be recognized by laws that proscribe disclosure in other contexts, including legal and statutory duties of confidentiality and information and health privacy legislation.

The possible uses of the information derived from non-consensual testing may also give rise to obvious harm, including harm caused[17]:

(1) by the use of genetic information by employers, insurers, and others for discriminatory purposes;

(2) to individuals who involuntarily learn about their long-term health prognosis and other physical and behavioral characteristics, in breach of their "right not to know";

(3) by media publicity about an individual's genetic characteristics, especially where that individual is a celebrity or otherwise newsworthy;

(4) by the use of genetic information by police in criminal proceedings or by litigants in civil proceedings; and

(5) by disruption to family relationships and harmony where parentage or other kinship information is disclosed.

To What Extent the Law Offers Protection?

Given that the conduct of non-consensual genetic testing gives rise to clear potential for harm, it is necessary to ask to what extent existing PNG's national privacy principle offers protection.

In PNG, the national privacy principle under Section 49 of the Constitution offers a blanket cover but only limited protection. There is little protection against collection and testing of genetic samples without consent in the kinds of circumstances identified by this study, for several reasons. We elaborate on these. First reason is that there is no information and/or a health legislation which currently apply to genetic samples, even genetic information derived from them. The collection of a genetic sample without consent (for example, from a beer glass) may not be a breach but there is some protection through Section 49[18] and common law through tort of trespass to the person. Second, leaving aside the distinction between a genetic sample and genetic information derived from it, the coverage of the Constitution Section 49 is limited because acts done, or practices engaged in, by individuals are exempt if done or engaged in "other than in the course of a business carried on by the individual" as noted under Section 38 of the Constitution. And third, the national privacy principle does not apply to the collection, use, or disclosure of personal information by an individual "only for the purposes of, or in connection with, his or her personal, family or household affairs". Arguably, many of the circumstances in which genetic testing might take place surreptitiously have purpose that may relate to an individual's personal, family, or household affairs. These might include purposes relating to family health, personal identity, or "peace of mind" in parentage testing.

In the circumstance identified by this study, in the three examples above, the acts of Person "X" generally will not be regulated by the Constitution Section 49, unless done in the course of a business not withstanding Section 38 under the Constitution. Even then, if X is a journalist and the collection and testing of the sample is done in the course of journalism for example, for the purpose of a news story relating to a celebrity paternity

[17] Law Reform Commission, Protection of Human Genetics Information, Issue Paper 26 (2001), ALRC, Sydney.
[18] Constitution, Section 49 "Right to Privacy", GovPNG (1975).

dispute, the acts may be exempt under other provisions of the Constitution dealing specifically with journalism or freedom of information.[19]

In order to derive information from a genetic sample, an individual ordinarily would need to submit the genetic sample to a laboratory for testing. It is relevant, therefore, to consider the obligations of the laboratory under a national privacy law which PNG does not have. At least in the case of a private sector organization, the collection, use, and disclosure of personal information by the laboratory will be subject to the national privacy principle. However, the laboratory may not know the identity of the individual from whom the sample was derived. If so, the laboratory is not dealing with "personal information" covered by the national privacy principle even though the individual who submitted the sample for testing knows from whom it came. Even assuming the laboratory, by analyzing and reporting the results of testing, collecting and disclosing personal information in terms of the national privacy principle, the legal protection extended to the individual from whom the sample was derived appears limited in PNG.

In the United Kingdom, it has recently been considered by the Human Genetics Commission that there are scenarios where current legal remedies may not offer sufficient protection against breach of an individual's genetic privacy.[20] For example, X takes Y's beer glass and obtains an analysis of his DNA. He or she sells to a newspaper the information that Y has a particular genetic condition. X de-encrypts anonymized genetic information about Y from a research study for some wrongful purpose. X obtains a sample from Child A, for who he has no parental responsibility, in order to ascertain whether he is the father of the child.

In PNG, legal protection against the non-consensual collection and use of bodily samples for the purpose of genetic testing is similarly limited. Some protection exists under the common law through tort of trespass to the person. In PNG any touching of a person's body without consent may constitute trespass.[21] However, this would not apply to the collection of "discarded" genetic material, such as hair from combs, saliva from a glass, cheek cells from a tooth brush, or mucus from a tissue nor is the taking of such genetic samples likely to constitute theft. In PNG particularly hospitals' policy regards bodily samples, patient's records or charts as property only in the very limited sense that hospitals and other organizations that have preserved them have a right of possession over them.

How Should Non-consensual Genetic Testing Be Penalized?

Question which comes to mind is that, if unauthorized non-consensual genetic testing should be proscribed by law, how should the practice be penalized? In particular, should the relevant conduct be subject to criminal or civil remedies, or both, as in the case, for example, with battery? Decisions about the form and level of penalty to be applied to proscribed conduct should depend on the purpose of the penalty, as well as the area of activity, the type of wrongdoer, and the nature of the wrongdoing. The purposes of penalties may include punishment or retribution, social condemnation, deterrence, protection of third parties or the public at large, and payment of reparation or compensation.[22]

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[19] Constitution, Section 46 "Freedom of Expression", GovPNG (1975).
[20] Law Reform Commission, Protection of Human Genetics Information, Issue Paper 26 (2001), ALRC, Sydney.
[21] Constitution, Section 49 "Right to Privacy", GovPNG (1975).
[22] The main purposes of criminal law are traditionally considered to be deterrence and punishment. The aim of social condemnation, or stigma, traditionally applies more to the criminal than civil penalties. Civil sanctions generally have the practical function of discouraging undesirable behavior by imposing a financial cost on it.

One guide to the appropriateness, or otherwise, of subjecting non-consensual genetic testing to criminal penalty is the criminalization of analogous conduct. While it is difficult to identify close analogies, existing crimes legislation in addition to stealing offences contains offences[23] relating to:

(1) unauthorized supply of forensic material for a DNA database;

(2) unauthorized access to data held in computers;

(3) "peeping or prying" near building;

(4) stalking or intimidation; and

(5) interference with human remains.

In other countries, particularly Australia, analogous offences are contained in other legislation. For example, there are offences in the Human Tissue Act concerning removing tissue from persons, living or dead, without consent or authority.[24] PNG does not have a legislation to cover human tissue. The unauthorized disclosure of health information obtained by public sector health administrators and employees in the course of their employment could be subject to criminal penalty in PNG. The present Criminal Code Act (1974) proposing civil remedies should be created to deter non-consensual genetic testing in PNG. This approach could be taken instead of, or in addition to, the creation of any new criminal offence. One such approach would be to include this into the criminal compensation law to ensure that the conduct involved in non-consensual genetic testing constitutes an interference with privacy in a broader range of circumstances, enabling the individuals concerned to seek compensation under the law. This could be backed by an enabling legislation preventing the use of non-consensual genetic test results in court proceedings.

Compliance with Ethical Standards

Conflict of Interest

The authors declare that they have no conflict of interest.

Disclaimer

The content is the responsibility of the authors and does not represent the official views of the University of Papua New Guinea or those who provided feedback.

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[23] The criminal law covers a vast array of activities and offences. These range from murder and assault to offensive language and jay-walking. At the national level, criminal law includes customs infringements and breaches of consumer protection laws. Criminal law is not only concerned with the most serious offences. There are, for example, scores of low-level record-keeping and information offences which are treated criminally in many regulatory regimes. In some states, parking offences are criminal. In fact, outside areas of regulatory law it is relatively rare for the conduct of individuals to be made subject to non-criminal penalties.

[24] Law Reform Commission, Protection of Human Genetics Information, Issue Paper 26 (2001), ALRC, Sydney.