

Comments on the NHRMC draft genetics privacy guidelines

Overall the guidelines seem as though they would be helpful for clinicians. It is long overdue that there is an industry paper proposed which attempts to deal with this difficult issue. Clinical geneticists have a "potential" duty of care to people who have not been referred or even seen a clinician.

Research Context

Genetic testing is a common feature of clinical research. For some research projects and abnormal genetic test may arise during the course of research. This may be sent to the patient's general practitioner (GP) for follow-up and/or further clinical testing. In many cases the research participant will have consented to information being sent to their local GP as part of the consenting process for a research project. It is not clear in the document, what is the status of private patients seen and treated in state facilities under the AHCA. Given that a recent report on specialist out patient services encourages the privatisation of outpatient clinics this issue warrants express clarification for the future.

Within the public sector, information relating to research is protected by section 281 of the *Public Health Act 2005*. This requires researchers to apply for approval of the Director-General to release this information. It is unclear whether communicating the results of genetic testing (that arise during the course of research) to the participants GP is considered research information or clinical information.

If it is considered clinical information, it would be subject to the *Health Services Act 1991* provisions which may or may not require the researcher to seek initial D-G approval prior to release. It will be necessary to provide some clarity regarding what legal provisions apply in this context and how it relates to the section 95A provisions. This is to ensure that the researchers satisfy both the legal requirements and the requirement to communicate important clinical information to the patients GPs for further management.

The other issue relates to patient participation in research. Given the disclosure requirements for genetic information outlined in the guidelines, it is important that potential research participants know the possible consequences of participation in research that involves genetic testing. This should include information about how the results will be reported, potential for identification, access to genetic counselling and rights to know results. This also needs to be considered in light of consent to "future, related, unspecified research". The NHMRC "*National Statement on Ethical Conduct in Human Research*" provides general guidance for researchers in terms of consent requirements. This guidance does not extend to the issue of the transmission of genetic information from the research context to the clinical setting and its communication from the public sector to the private sector.

Impaired decision making

The Guardianship and Administration Tribunal (*Guardianship and Administration Act 2000*) is empowered to consent to "special health care" for an adult with impaired decision-making capacity under specific guidelines and principles so as to safeguard his or her rights. The Tribunal appoints a guardian who acts when:

- The adult's decision-making capacity is impaired for the matter;
- The adult's needs are not being met or his/her needs are not being protected; and or
- The adult is likely to make a decision that will put his/her health, welfare or property at risk.

The tribunal has the power to consent to the adult's participation only when the procedures:

- Relate to a condition that the adult suffers from or has a significant risk of being exposed to; and or

- Promote knowledge that can be used in the diagnosis and treatment of a condition that the adult suffers from.

However the guardianship role does not extend to those issues associated with the disclosure of genetic information of a patient with impaired decision making, to their genetic relatives. It would be useful if the guidelines, provided clarity around the role and the relationship between the guardian and the health practitioner who may seek to disclose this genetic information.

Complexity of the and severity of genetic disease

Complexity and severity of genetic diseases can vary between family members, e.g. how mutations are inherited, the degree of genetic penetrance and effects of other factors, such as, lifestyle. A number of these factors are unpredictable and difficult to quantify. The perception therefore, of the 'seriousness' of a genetic mutation/predisposition may vary significantly between individuals. This situation makes it particularly difficult when deciding whether to disclose genetic information to affected individuals and family members, and requires reconciliation between the duty to disclose and prevent possible harm, with a patient's right to privacy and autonomy. This can be further complicated by a person's cultural values.

"Duty of care" obligations and Disclosure

In clinical genetics departments (in the public sector) a medical practitioner would always be responsible for making a decision to disclose information to "at risk relatives". This reflects the clinical and ethical complexity of the decision. It also reflects the potential medico-legal consequences of such a decision and the need for a senior medical clinician to be involved. The document implies that someone other than a medical practitioner takes responsibility for the disclosure. A senior medical practitioner must take responsibility even if another person undertakes disclosure.

If the situation fits the criteria for disclosure (as decided on page 28) and the patient refuses consent to disclose to relatives, the document does not clarify whether the clinician has a legal/ethical obligation to disclose. For example, on page 32 it says that the clinician "must decide for themselves the extent to which they go to contact relatives" however on page 33 in relation to the use of registered mail it says "In view of the non-mandatory nature of disclosure....." These statements make the document confusing.

Greater guidance on how to undertake disclosure would be helpful; it states that a letter may be sent stating a risk but not identifying the condition. In this case, the at-risk relative cannot make a decision about the significance of the information they may receive. If they then call for clarification, what may be said to them? How much can be disclosed outside an appointment? In addition if there is inadequate information upon which to make a decision, the at-risk relative may not seek an appointment at all. If the GP calls asking for clarification, what can the geneticist tell them, and in turn what are they then able to tell the patient? The guidelines talk about that when undertaking disclosure to "pursue only reasonable steps" however there is no guide to what is considered reasonable steps? And furthermore there is a statement about "Repeated attempts should not be made to contact non-responders" with no objective criteria to do this. These Guidelines also direct practitioners to consider the communication style for discussing potential disclosure of sensitive information to genetic relatives; it does not however, tackle the issue of preconception counselling or disclosure to reproductive partner.

It appears that clearer direction on the level of duty of care is also warranted. For example, would a clinician who decided not to disclose, be liable if catastrophic events occur which could have been prevented had they disclosed and disclosure was logistically possible? The legal obligations section states that the patient may not be identified in discussion. However, knowing the context of complex patients and families can help the decision-making process.

Given the rarity of some conditions and the specialist knowledge involved in their care, it may not practically be possible for the person to remain unknown.

Terminology

Clinical geneticists are involved in overseeing the care of patients and see many patients. They are omitted on a number of occasions in the document as clinicians to whom patients should be referred" and only genetic counsellors are mentioned. This needs to be addressed. The term client is on occasion used when patient would be appropriate in the particular setting. "Referrals" are made to clinical genetics services; and not genetic counselling services as the document states. Finally there were several inaccuracies in some of the clinical scenarios used as examples.

Summary

This is a helpful document but it is not clear of its specific role in the clinical context or its force. Given that the document states that it recommends legal consultation and discussion with medical indemnity provider for each case, what would be the standing of the document in a legal context?

It would be useful for Queensland Health to have a document of this kind to guide clinicians and this work could be undertaken by the Clinical Genetics Network however there needs to be a greater focus on risk management strategies and the legal obligations spelt out.