A discussion paper:

Genomic testing and medico-legal risk

Avant mutual
by doctors for doctors

Genomic testing and medico-legal risk

Executive summary

Context

According to the Australian National Health Genomics Policy Framework, "genomics has the potential to reshape clinical practice and to fundamentally change the way we prevent, diagnose, treat and monitor illness...".[1]

In the rapidly evolving field of genomic medicine, practitioners are increasingly likely to encounter medico-legal risk. Some risks are ones that can arise in other areas of medicine. However, genomic medicine also raises unique issues, both as a developing area of understanding and because of its implications for others beyond the individual patient.

As clinicians, scientists and policy makers in Australia increasingly promote the potential benefits of genomic medicine, Avant is seeking to assist doctors whose work involves this area by:

- raising awareness of the medico-legal issues arising from genomic testing
- facilitating discussion about the kinds of education doctors of different specialties may need
- identifying areas where regulatory reform and policy development is warranted.

Avant's insights to date

In late 2019 and early 2020, Avant interviewed Australian experts working in this field about the medico-legal issues they are currently navigating and the emerging issues they are concerned about. We also reviewed our claims and legal matters that have arisen in this field.

Our research and data suggest genomic medicine still represents an emerging medico-legal issue in Australia, with few cases decided. However, we have observed an increase in requests for our medico-legal advice on genomics issues, from doctors in both general and specialist practice.

It became clear to us from our interviews that much of the current concern among Australian doctors relates to testing and the decision-making processes around testing.

Our analysis of the clinical landscape in Australia reflects recent studies in the US that highlight particular concerns where screening or testing for genetic conditions occurs before birth. However, issues arise across many areas of practice and involve patients of all ages, genders and life stages. Patients may be considering or undergoing genomic testing to diagnose illness, identify the potential of targeted treatment strategies, or detect the future risk of disease.

We identified a number of points along the patient care journey where medico-legal risk is particularly likely to arise. These involve:

- the process of seeking informed consent to test
- offering appropriate tests
- providing test results and follow-up
- the testing process itself
- disclosing information and managing implications for relatives
- testing embryos and foetuses.

In all of these areas, keeping up to date represents its own challenge for doctors.

We identified some overarching themes contributing to these medico-legal challenges. These include:

- **A complex and evolving science becoming mainstream**. Genomic medicine is increasingly a part of mainstream medical practice and doctors are being asked to keep up with the science, often without the benefit of recent training in the field. They may be in the position of having to explain particularly complex questions of risk and uncertainty to patients. These are inherently difficult to understand and weigh up. As the science evolves, lines between treatment and research may blur and patients need to be offered clear information about what they are consenting to and how their information may be used.

  As testing capabilities expand, it can be difficult to know what tests are available, what a particular test is looking for, what it could show and when it should be used. Guidelines are not always available or consistent across specialties and can quickly fall out of date. Considering how to manage unexpected findings, or findings of uncertain significance, adds further layers of complexity. The need for follow-up can also be ongoing, particularly as scientific understanding changes and samples may reveal findings that cannot yet be interpreted but that may become significant over time.
- **Heredity and the human genome**. This impacts many aspects of genomic medicine with particular areas of concern relating to the challenges of explaining issues to one person that may also impact on their genetic relatives. Patients may discover information they were not expecting, about themselves or about relatives. This can raise issues for doctors and patients when patients are consenting to some tests, and when results of testing are being discussed. Doctors may also be confronted with conflicts between obligations to maintain patient privacy or to disclose information that would enable genetic relatives to avoid harm.

- **Healthcare system pressures**. At the centre of consultations involving genomic medicine are individuals and families grappling with complex and often life-altering decisions. They often need support both to understand the issues involved and to deal with the impact of their decisions. Doctors we spoke with recognised that it can take considerable time and multiple consultations to work through decisions with patients and to provide support – time which may not be factored into current healthcare treatment and funding models.

  Doctors also noted the importance of being able to engage with genetic specialists and counsellors. They reported that patients may have needs in relation to genomic expertise and mental health support. Currently, there can be delays and challenges accessing these practitioners.

  Follow-up can be complex and sensitive in genomic medicine. It can be more so in an environment of population mobility and fragmented care, which can make it difficult to maintain contact with patients over extended periods.

- **Commercial pressures.** The widening range and availability of tests in Australia and overseas may make it increasingly difficult for doctors and patients to choose between available options and to interpret results.

  Direct-to-consumer genomic testing may lead patients to undertake more tests than doctors may have recommended and have unrealistic expectations of what a test may tell them.

  Overseas testing may offer different, or less expensive testing. This can add another layer of complexity as patients and doctors try to understand the implications of having testing done in jurisdictions where privacy laws differ from Australia.

Conclusion

The potential for genomic medicine is great. The challenges it presents are also significant. As increasing numbers of doctors find their practice intersecting with genomic medicine, the level of concern we are hearing from doctors is growing. While the number of legal cases in Australia is still relatively small, this moment in time represents an opportunity to develop tools, training and support so doctors and their patients can benefit from the advancing capabilities. Having drawn attention to these issues, we seek to explore opportunities to implement strategies for fostering high quality healthcare and mitigating medico-legal risk. The questions at the end of this document aim to facilitate discussion about these opportunities.

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Background

The field of genomic medicine recalls yet again a truism of medico-legal practice, that as medicine evolves, the law sometimes marches "with medicine, but in the rear and limping a little".[2] This can present medico-legal risks for doctors.

On one view, the medico-legal risks linked with genomic medicine are not unique to this field. Problems with providing information and consent, missed diagnoses, conflicts between duty of confidentiality and obligations to prevent harm to others can arise in any area of medicine. However, genomic testing does raise particular medico-legal issues, given its potential to predict future health issues, identify individual responsiveness to treatment, and unveil information relating to a person's genetic relatives.

Increasingly, Avant is hearing from doctors in general and specialist practice who are anxious to understand the implications of genomic medicine for them. There is also increasing concern about the potential for medico-legal liability.

Current context and findings

To better understand the medico-legal risks and the concerns of doctors about genomic medicine, in late 2019 and early 2020, Avant conducted interviews with medical and legal experts from a range of specialties whose fields involve this area of care. We spoke with doctors practising in specialist genomics as well as in general practice, obstetrics, paediatric and adult medicine, and pathology. In addition, we conducted a review of the literature and Australian law on this topic.

Avant's data suggest genomic medicine still represents an emerging medico-legal issue in Australia. Avant has seen relatively few claims or complaints over the past 10 years and there have only been a few decided legal cases in Australia that specifically involve genomics. However, we have received increasing numbers of calls for medico-legal advice in relation to genomic issues in practice. This has occurred in an environment where the role of genomic medicine continues to grow rapidly.

New applications of genomic screening are being researched and identified for use in general and specialist practice. As an example, recently in Australia, a study of reproductive genetic carrier screening, the Australian Reproductive Carrier Genetic Screening Project (Mackenzie's Mission), has been launched, funded by the Medical Research Futures Fund.

There is also increasing expectation from policy makers and the public about the promise of genomic medicine. In Australia, the National Health Genomics Policy Framework and an Implementation Plan for that Framework were endorsed by the Council of Australian Governments Health Council in 2017. The National Health and Medical Research Council (NHMRC) has also produced guidance on this area of care. Cases in which medico-legal issues have arisen worldwide are increasingly being reported in the press.

Aims of this discussion paper

While the number of legal cases in Australia is still relatively small, we concur with US researchers who have suggested that the current moment "provides a window of opportunity for the medical profession to get its house in order for implementing genomic medicine. This might include better training of physicians, clearer guidelines on when genetic testing is indicated, more consistent and evidence-based reimbursement policies for genetic testing, and better clinical decision support infrastructure for physicians".[3]

Our aim with this body of work is to assist doctors to provide high quality care for patients and to minimise their medico-legal risk in relation to genomic testing. It became clear to us from our interviews that much of the current concern relates to testing and the decision-making processes around testing. We have therefore focused this paper in this area. We see opportunities in particular to raise awareness of the medico-legal issues arising from genomic testing; prompt discussion about the kinds of education doctors of different specialties need; and identify areas where regulatory reform and policy development are needed in relation to genomic testing.

Scope and terminology

In this paper we have adopted the terminology of the Australian National Health Genomics Policy Framework; we use 'genomic' and 'genomic medicine' to refer to treatments and tests involving single genes, as well as those involving an individual's entire genetic makeup and its interaction with environmental factors.[1]

We use the term 'uncertain' when the implications of a test finding are unclear. An 'incidental finding' refers to a finding that was not deliberately sought, i.e. was incidental to the reason the test was undertaken.[4]

In our analysis of medico-legal issues, we have considered testing for conditions related to genetic or chromosomal variants however performed, as well as those tests that specifically look for genetic markers. Tests for genetic conditions can be undertaken for screening or diagnosis. These can include single gene tests, targeted panel tests for certain conditions, chromosomal microarray tests, exome sequencing and genome sequencing. Tests can be focused on an individual's inherited DNA (germline DNA) or on the DNA found, for example, in a tumour (somatic DNA testing).

Doctors may now encounter genomic medicine in many areas of practice. In addition to conditions that have long been understood to be linked with genetic factors, such as Huntington's disease or cystic fibrosis, there is an increasing understanding about genomic links in other conditions such as familial cancers, or to a propensity to develop some diseases. Genomic testing may also be used to detect genetic conditions with no inherited link such as certain chromosomal conditions. Pharmacogenomics may help predict a person's response to medications or their likelihood of experiencing an adverse reaction.

This paper is limited to medico-legal issues likely to confront doctors involved in genomic testing in the setting of general and specialist patient care. We recognise the practice of genomics frequently involves doctors working in teams with professionals from multiple disciplines – including nursing, counselling and others – and many of the issues we address will have relevance for other clinicians involved in the patient care process.

The implications of genomic testing for access to life insurance have been the subject of considerable discussion in Australia to date. A moratorium currently prevents insurance companies from using genetic test results as part of the risk assessment for insurance policies up to $500,000 for death or total permanent disability. This moratorium is in place until 30 June 2024, when it will be reviewed.[5] While this issue is beyond the scope of this paper, we recognise it may add another layer of complexity for patients who are making decisions about testing.

As the scenarios in this paper make clear, genomic medicine can raise complex legal and ethical issues for practitioners. We have considered both long-standing issues involving genetics, such as testing for genetic and chromosomal conditions, as well as more novel issues arising from genomic medicine. While acknowledging that boundaries in this field are blurred, we have not addressed ethical issues specifically. We have not canvassed issues for those engaged in genomic research or providing gene therapies; sequencing genomes of viruses or cancers for tracing or treatment; nor have we explored forensic DNA testing, gene patenting or intellectual property issues.

Types of testing discussed in this paper

- tests involving single genes
- more extensive testing of a person's genome, including testing for genetic or chromosomal variants and genetic markers
- other tests that can be used to screen for, or identify, inherited and non-inherited genetic conditions.

Informed consent to testing

The consent process for patients considering genomic testing can raise particular medico-legal risks. Testing has been available for some time for the purposes of screening for, or diagnosing genetic conditions. Advancing technologies and the increasing availability of genome sequencing mean the practitioner and patient may need to process more complex information and face more complex choices before deciding to go ahead with a test.

The classification of human genetic tests from the National Pathology Accreditation Advisory Council (NPAAC) recognises that some tests have greater potential to raise complex clinical and ethical issues. Some tests will require more detailed consent conversations, counselling and support.[6]

We understand that a consent form is being developed under the auspices of the National Health Genomics Policy Framework, following the work of the Australian Genomics Health Alliance.[7] As doctors are aware however, the consent discussion goes beyond a form and involves a process of doctor and patient reaching a shared understanding and decision about care.

Communicating about uncertainty, risk and options with patients may be complex and time-consuming in any context. The unique features of genomic medicine, some of which are highlighted below, can make it particularly difficult for doctors to satisfy their obligation to provide patients with clear and sufficient information to decide whether to consent and proceed with testing. For patients, the complexity is clearly challenging and so information provided should be clear and up to date, including about the risk of uncertainty itself. This is particularly challenging, as genomic medicine is both rapidly evolving and becoming more mainstream, with doctors who have not been trained specifically as specialists in genomics having to provide information in the consent process.

Assessing risk and prognosis

Genomic medicine presents particular complexities for doctors and patients trying to weigh up risks against potential benefits of testing in an environment where the scientific understanding of the functional significance of genetic information may still be uncertain and is changing rapidly.

While some genomic variants are strongly predictive of disease, others are associated with only a small increase in the chances of a condition occurring. Others may identify a risk of a condition but give little indication of the degree to which an individual may be affected by the condition, or the extent to which other lifestyle factors may influence a prognosis. Some variants may exist and be non-pathogenic. Finally, the meaning of some findings may simply be 'uncertain'.

Examples: Challenges in explaining risk

- The NHMRC has provided different scenarios doctors may face.[8] For example, when the genetic variant that is the marker for progressive muscular dystrophy is identified in a baby boy, this means the child will go on to develop this condition and will have a high risk of a shortened lifespan. Over time, research and treatment may extend length and improve quality of life but the diagnosis is clear cut.
- By contrast, a young Australian woman in the general population has a lifetime risk of developing breast cancer of approximately 10%. A test showed that she had a pathogenic variant in the BRCA2 gene, which is linked with a high risk of breast and ovarian cancer. The lifetime risk of breast cancer for her is 60–70%. While this puts her at higher risk than a woman without the variant, there is still a 30–40% chance she may never develop breast cancer.[8]

Understanding the implications of preconception and antenatal screening

Prospective parents may seek genomic testing for different reasons: general screening for chromosomal conditions; seeking a specific test in light of a known family history or carrier status; or seeking diagnostic testing following an identified anomaly. Tests can be more or less invasive and some can give more certain results than others.

To make autonomous decisions in response to the results of preconception or antenatal screening, prospective parents need to understand what the test results might mean before the tests are performed. This includes the conditions being tested for, the implications of positive, negative and uncertain results, and the actions that may be available in light of results. The challenges of providing complex information may be compounded by heightened concern that may occur in the antenatal period.

Implications of unexpected findings

Depending on the genetic test being considered, it may be necessary to explain to a patient that their test may identify issues in addition to the original reason for the test.

Genomic testing, in the preconception and antenatal context, and later in life, may reveal findings that were unexpected, and these may have implications for the individual being tested or their genetic relatives. In addition to medical implications, results may have social or legal ramifications.

With some types of testing there is a chance the test could identify what is often referred to as an incidental finding – a condition or risk of a condition, other than that for which the test was undertaken.

Information on an individual's genome could also be found on the genome of their children and other genetic relatives.

Scenario: Information can reveal medical issues in genetic relatives

"A man has a rare autosomal dominant disease and the causative mutation has been identified. His daughter is asymptomatic and does not wish to know her genetic status. However, her child (the man's grandson) has predictive genetic testing for the disease. If the grandson has inherited the familial mutation, his mother must also have inherited it. Her genetic status is revealed without her being tested."[9]

Testing may also reveal unexpected information about paternity or maternity.

Scenario: Revealing information about paternity

In the case of an autosomal recessive condition, a man who has the condition must have two faulty copies of the gene. His child would inherit at least one faulty copy, and therefore would be a genetic carrier for the condition. Results indicating that a child does not have a faulty copy of that gene could raise questions about whether the man who has the condition (i.e. two faulty copies of the gene) is the child's biological father.

Some individuals may not be aware of these types of implications about testing. A person should consider at the time of consent whether they want to be tested - particularly when there could be information revealed that may be important for their relatives to know, or that may raise privacy issues for themselves or their relatives. When a test result is available, results will generally be shared with patients to share with their relatives but situations can arise where the patient refuses and a doctor may be faced with considering the need to disclose the information to prevent harm to others.

See also under

- Limitations on confidentiality: permitted disclosure to others at risk (page 13)

Consent to genomic testing or consent to research

While genomic testing is subject to different regulatory processes in clinical and research settings, boundaries between clinical and research uses of genomic test findings can be blurred. A sample taken for a clinical purpose may be important for research – for example, to add to the body of information that informs the significance of a rare variant that might have been identified. This can give rise to concerns among doctors about whether they need to seek consent for potential research in addition to consent for clinical use. The challenges of this have been evident in the ongoing efforts in Australia to develop a standardised consent process for genomic testing in clinical settings.

These lines may become blurred in part because of the potential for more precise interpretation of results about variants when this is informed by large datasets of genomic markers. The hope is that, over time, these datasets will become more valuable for this purpose as more testing samples are added to them. There are, however, many other possibilities for conducting research linked with genetic materials. Although in Australia, there are very clear mandates in relation to research governance processes, these may not apply to laboratories in other international jurisdictions. In addition, a situation may arise in which a patient might feel pressure to consent to research so they can access a screening or diagnostic test.

Other consent concerns

Other concerns about the consent process include whether people understand what they are consenting to when tests are conducted in a laboratory outside Australia. Doctors may not be familiar with the accreditation standards or privacy regulations that apply to international laboratories.

A further consideration is that the nature of genetic materials provides a strong potential for re-identification of individuals and expectations of anonymity may be increasingly unrealistic.

Practical challenges in providing information

Addressing all the issues involved in the consent process and ensuring that patients absorb the information will likely take a considerable amount of time, with multiple consultations. Emotional support and counselling may also be needed for patients faced with challenging decisions. This was identified as a concern in our research. One issue raised was the fact that the amount of time and number of repeat consultations needed for the consent process may not be factored into current healthcare treatment and funding models.

In the context of antenatal care, the very tight window of opportunity to intervene imposes significant time pressures when doctors see a need to spend multiple consultations or refer a patient to a genetic counsellor to ensure full understanding of the implications of testing and to explore patient preferences.

Accessing specialist advice

The challenges for doctors in communicating information about what a test might involve and what the results might mean, may be compounded by difficulties in accessing genetic counsellors and specialists.

According to some of the experts we spoke with, the wait for patients to see a genetic specialist in some parts of Australia can be 6-12 months. The inability to access specialist advice is likely to be a barrier to facilitating the process of informed consent. Lack of access may also impact emotional well-being. Especially in the antenatal setting, weeks can make a significant difference to the options available for patients. In this setting, and others, a patient may not understand the importance of specialist advice if the referring doctor did not fully understand the potential condition and emphasise the nature of its risk.

Scenario: Misunderstanding need for specialist advice

A couple commenced fertility treatment. The husband suffered from a hereditary condition. Their doctor recommended the couple contact a genetic counsellor, but the couple claimed they had not understood the reason for the referral nor that their child may be at risk of inheriting the condition. They did not speak to the counsellor before becoming pregnant. Their son was born with the condition.[10]

This was a complex case that involved many issues but, in the course of the case, the court made it clear it was the doctor's responsibility to provide information to the parents about the importance of seeking genetic counselling and to adequately explain the reason for the referral.

Offering appropriate tests

Medico-legal risk may arise if a doctor does not offer or recommend an appropriate test and later is alleged to have missed a diagnosis, or to have undertaken inappropriate testing.

Failure to offer genomic testing

Some legal cases have involved allegations that a doctor failed to offer diagnostic or screening testing or advised a patient that they did not need testing. This has particularly arisen in antenatal screening and testing. It also arises in relation to diagnoses that can become evident later in life, such as hereditary cardiac conditions.

In these cases, the factors that contribute to the problem are often similar to those that arise when a diagnosis is missed for a non-genetic condition: symptoms were missed or misinterpreted, the doctor failed to take an adequate family history which would have suggested the need for further investigation, the doctor was unaware of the test, or the test was simply overlooked through administrative error. Doctors might also not order or recommend a test for a genetic condition when the family history is not evident, or when they are not aware of a potential connection with genetics and the signs or symptoms occurring in a patient.

In these types of cases a diagnosis might not be made in time to prevent an adverse outcome, or for an individual to make an informed decision.

Failure to offer pharmacogenomic testing

The potential for pharmacogenomic testing as an element of 'personalised medicine' is being seen as an opportunity to ensure that, based on their genome, patients are offered the most effective drug treatments and/or can avoid adverse reactions.

An increasing number of drugs are being listed as having some drug-gene interaction and linked with warnings about these. Sometimes the issue is simply that the medication may not be effective in the particular patient. In other cases, results may guide prescribers to adjust dosing, or to avoid prescribing a medication to reduce the risk of an adverse drug reaction. Pharmacogenomic testing can also be used to help predict a person's response to medications.

As knowledge in this area develops, there may be an increasing expectation that doctors more routinely offer this type of testing – particularly where there is significant potential for harm from an adverse drug reaction. Our interviews indicated there was a lack of widely accepted and available guidelines on the appropriate application of pharmacogenomic testing, suggesting that strategies are needed to assist prescribers to understand the potential of these tests.

See also under

- Direct-to-consumer testing results (page 11)

Pre-symptomatic testing of children

For childhood onset conditions consideration of testing may be appropriate, however, a specific issue raised in the literature relates to predictive and pre-symptomatic testing of children. In particular, concerns are raised about how to manage requests to test for a condition which has not yet manifested and where there is no known treatment or preventive strategy available in childhood.

Legally, whether a pre-symptomatic person can consent to a predictive test involves the same questions of capacity as apply to consent for any medical treatment. In genomics, this is considered a particularly difficult issue in relation to minors. While recognising the need to carefully consider the child or young person's wellbeing in each situation, the Human Genetics Society of Australasia recommends that where minors do not have capacity, the default position should be to delay pre-symptomatic or predictive testing for adult-onset conditions until they achieve capacity. This applies whether the conditions are treatable or preventable (e.g. hereditary breast/ovarian cancer) or not (e.g. Huntington's disease).[11]

Scenario: Acceptability of testing minors

A 16-year-old sought testing for Huntington's disease, knowing that she was a 50% risk as her father had the condition. She was not symptomatic and simply wanted to know her risk of developing the disease.

Her GP was concerned genomic testing was not in her best interests and referred her for genetic counselling.

While recognising the young woman was competent to make decisions about her medical care, the counsellor also believed having the test was not in her best interests. These concerns were discussed with senior colleagues and with the young woman at a series of appointments.

The counsellor continued to support the young woman over a period of 18 months. Ultimately, she and her treating practitioners agreed testing was reasonable and it was arranged.[8]

Offering inappropriate tests

Another consideration for doctors is whether the test ordered is appropriate to diagnose, or screen for, the condition in question. This is likely to be a growing problem as the array of available tests increases. For example, doctors may order a test that does not include the relevant genetic variant, or is not comprehensive enough to enable a diagnosis to be made.

Other issues

There will be times when an individual seeks a test and the doctor feels they should refuse the request or that a second opinion on whether to test is appropriate. The doctor may be concerned that the test is not clinically indicated, is not in the patient's best interests, or that consent cannot be fully informed or is being influenced by family coercion. Concern may also arise when a patient refuses to consider counselling.

A doctor might also refuse to order a test because of logistical reasons or because they feel it is ethically inappropriate. The NHMRC provides considered advice on this, including about second opinions and counselling, but conflicts may still arise.[8]

Conversely, situations may arise where doctors offer patients tests that are unnecessary and not in the patient's best interests. While rare, cases have arisen that suggest a doctor may have been influenced by a conflict of interest - such as through a commercial relationship with the laboratory undertaking testing.

Following up and explaining test results

The rapidly changing understanding of the human genome presents concerns for doctors when they are explaining test results to patients. A consistent concern from experts is that "our capacity to generate data through massively parallel sequencing has outpaced our capacity to determine its functional significance".[12] Counselling and management paradigms that were developed to support single gene testing do not necessarily support panel testing.

Testing is becoming more complex and more widely recommended. Finding results that are complex or uncertain is not uncommon. In many settings, there is limited access to specialist geneticists and genetic counsellors. In this context, it is inevitable that genetic information will be sought by patients and their relatives from doctors who are not specialists in genomic medicine.

Questions also arise about whether, and how, patients should be advised about uncertain or incidental findings, if their preference for this was not adequately covered during the consent process. Another subject of discussion has been if, and how, doctors should communicate with patients if the scientific understanding of the significance of a test result they received changes over time.

A related, and growing, concern is the uncertainty that can result as patients can access broader testing, including panel testing and genome sequencing. To date, research about variants and their links to specific diseases has largely focused on patients who are symptomatic for a particular condition or have a relevant family history of the condition. Knowledge about the pathogenicity of some gene variants in asymptomatic people, or those without family histories, is still incomplete. This can lead to people being over-diagnosed when they receive a genetic test result, or being faced with questions and uncertainty about the meaning of a result.

Scenario: Uncertain implications of a genomic test

In a case reported in the US press, a woman in her 30s, with a relevant family history of breast cancer, sought testing to address concern about her genetic status for BRCA1 and BRCA2. During the consent process for testing she was offered – and consented to – panel testing for 20 other cancer-related genes. While the results did not show a pathogenic BRCA1 or BRCA2 variant, a variant in a gene linked with stomach cancer was identified. Interventions to reduce this particular risk could include surgical removal of stomach, however, in the the absence of any family history, her lifetime risk of any gastric cancer and the optimal intervention, was uncertain.[13]

See also under

- Direct-to-consumer testing results (page 11)

Misinterpreting test results

In this field, information is complex, and the nuances of reporting may be difficult to understand without specific expertise in the area. As genomics becomes more 'mainstream' and reports more complex, there is a risk that doctors will be in the position of having to explain results that are complex or unclear.

In addition, testing has limits. Some tests are undertaken to explore the probability of a disease occurring, or risk being present, and when the test result comes back 'negative', there is a risk that this result may be interpreted as being definitive by the doctor and/or the patient. As an example, genomic testing may not provide a clear explanation for a strong family history of a cancer, but this does not mean familial issues and risks for the patient do not exist. This highlights the challenges in an evolving field, where some information is still unknown and knowledge is rapidly changing.

Reporting on incidental findings

As it becomes more feasible to provide broader testing with exome or genome sequencing, the likelihood of incidental findings increases. This raises issues that need to be considered in the consent process.

See also under

- Implications of unexpected findings (page 6)

The Royal College of Pathologists of Australasia recommends that doctors use standard practice in deciding to return incidental findings, as long as the protocol that the clinic uses is clearly provided to the patient and the patient has agreed to it.[14] The NPAAC also addresses this issue and outlines the ethical issues testing providers need to address before providing genome sequencing. They advise that testing providers should give consumers their written policy on reporting incidental findings, and testing should only be performed when the consumer has received appropriate counselling, including discussion about expected and incidental findings.[15]

Changing classifications of variants

The field of genomics is dynamic, with changing understanding and reclassification of genetic variants. Genome sequencing can generate large numbers of variants for which the association with disease risk is not clear. As additional research gradually identifies the clinical significance of some of these variants, the results of genetic sequencing performed in the past could provide more clinically actionable information about a genomic finding linked with a specific condition.

This may mean:

- a patient may have been advised of results that were not seen as having any clinical implication at one time, but these may become significant because of evolving knowledge; or
- it may become apparent over time that a variant once thought to be pathogenic is not.

When a variant is classified as pathogenic, a patient may proceed along a care pathway that could involve a range of interventions from surveillance over time to surgery. A change in classification may have significant personal and family implications for the patient.

For pathology laboratories and clinicians, the optimal approach to reporting on, and providing information to patients about variants of uncertain significance is a difficult area. Accredited laboratories in Australia are required to have a formal process regarding the review of variants and re-contacting clinicians.[6] Presently however, in practice, different policies exist across different laboratories.

A recent review of medical liability in this area suggests that, while currently laboratories may be the focus of attention when disputes arise in this area, over time there may be an increasing focus on clinicians from a range of specialties.[16] In Australian clinical practice, protocols vary in relation to how far into the future, and for whom, a doctor or laboratory will monitor variant classification and communicate with patients about changes.

The evolving science may mean doctors are faced with medico-legal challenges in the form of a kind of 'hindsight bias', where a patient later claims that doctors ought to have known at the time of the test what the variant meant, and that they incorrectly reported it as a variant of uncertain significance.

Scenario: Reclassification of a variant over time

In an ongoing case in the US, a woman claims a laboratory made an error in 2007, when it tested her son and classified a variant in SCN1A gene as having unclear links to Dravet syndrome (a rare epileptic condition). The laboratory changed its classification to disease-causing in 2009, more than a year after her son died.

A paper published in 2007 noted the variant in a Dravet patient. The woman claims there was enough information at that time to classify the variant as disease-causing and that the laboratory had knowledge of this paper. She alleges the laboratory was negligent in failing to diagnose her son's condition.[17]

Consistency and clarity of pathology reports

In the context of genomic testing becoming more mainstream, there is an increasing emphasis on consistency in standards of reporting for Australian-accredited pathology laboratories.

That stated, doctors, including specialists in genomics, have told us it is not always clear what a report indicates, given tests are being conducted in multiple laboratories and locations. For example, it may not be clear how to interpret a report that says something akin to 'variant detected', or a poorly translated report from an overseas laboratory.

Direct-to-consumer testing results

Concerns arise as the availability of direct-to-consumer testing increases.

The Therapeutic Goods Administration (TGA) currently prohibits supply in Australia of "self-testing in vitro diagnostic devices for genetic tests to determine the presence or susceptibility of disease". Direct-to-consumer testing is addressed in guidance issued by the NPAAC.[15]

However, as noted in the TGA's recent review of these types of self-tests in Australia, regulation has not prevented patients from accessing tests from overseas, often via the internet.[18] Patients may present to their doctor with a request for interpretation or advice on an appropriate response to the results of such tests.

There are concerns among doctors that the increasing marketing of direct-to-consumer testing, may lead some patients' expectations to outstrip reality. They may understand claims about the availability of 'personalised medicine', for example, to mean they can always be prescribed treatments perfectly tailored to them. If they experience side-effects or if treatments are ineffective, they may believe they should have been offered more testing. They may not appreciate that understanding is still evolving about how genetic factors might interact with other variables such as diet, lifestyle or environmental factors in influencing an individual's responses to medications.[16,19] The Australian Competition and Consumer Commission (ACCC) has stepped in on some advertising of direct-to-consumer testing which it considered was misleading and deceptive.

Scenario: Misleading and deceptive conduct in advertising genetic test

A pharmacy chain was promoting a direct-to-consumer DNA test customers could take to identify their response to certain drugs.

The ACCC was concerned that statements in the pharmacy chain's catalogues, television infomercials, in-store brochures and other promotional materials risked conveying a false or misleading impression regarding the usefulness of the genetic test, and the consumers for whom it may be appropriate.[20]

Testing process errors

This paper mainly focuses on the role of doctors involved in direct patient care. That said, doctors more broadly need to be aware that, as with all testing, there are risks inherent in the testing process.

Testing laboratories in Australia, most commonly, have processes in place to avoid errors and misreporting of results. Clinical doctors working with genomic test results can be more assured about the laboratory quality processes when dealing with accredited laboratories and this will be the case with most laboratories in Australia. However, given the breadth of testing being undertaken worldwide, quality and accreditation processes can vary and be difficult for doctors to assess.

Of course, process issues and errors can occur in accredited laboratories as well. Importantly, the NHMRC has highlighted that mislabelling or switching of blood or DNA samples remains the most common cause of laboratory error and should always be considered before assuming that a result, which is very unexpected (e.g. misattributed paternity or maternity), is correct.[8]

Scenario: Mishandling of test specimens

A pathology laboratory in the US inadvertently switched blood samples and informed a breast cancer patient she had Li-Fraumeni syndrome: a genetic condition that increases the risk of a person developing multiple types of cancers. She had her ovaries and uterus removed to try to reduce her risk, but was told she was likely to die as a result of having this condition. She was concerned her children would inherit the same condition. Months later, the laboratory revealed they had inadvertently switched the blood samples and the test result was wrong.[3]

Implications for genetic relatives

A patient's genomic profile can reveal information relevant to their genetic relatives. If a patient does not share relevant information with relatives, a doctor may be confronted by the conflict between their obligations of confidentiality and a concern to lessen or prevent harm to the patient's relatives.

Limitations on confidentiality: permitted disclosure to others at risk

Health practitioners in Australia covered by the Commonwealth Privacy Act are permitted to share genetic information with genetic relatives, even without patient consent, provided they follow the guidelines and process for engaging with patients established by the NHMRC and endorsed by the Office of the Australian Information Commissioner.[21] In these settings, if reasonable steps to obtain consent prove unsuccessful, genetic information can be disclosed if it is necessary to lessen or prevent a serious threat to the life, health or safety of a genetic relative. This, however, may still raise concerns for doctors about how they should assess what represents a serious threat.

Further, Commonwealth privacy provisions do not apply to health organisations covered by state information privacy provisions (e.g. public hospitals). These provisions vary from state to state, which can make the situation more complex for doctors in those organisations.

The position at common law has been recently considered in the UK.

Scenario: Duty to tell daughter of genetic risk

A patient returned a positive test for Huntington's disease and expressly refused permission for doctors to inform his pregnant daughter of his diagnosis. The daughter had been involved in the patient's care and had participated in family counselling at the hospital. The doctors knew she was pregnant and recognised she could be harmed by not being informed about her father's diagnosis.

The UK court acknowledged a duty of confidentiality to a patient is not absolute and that confidentiality can be breached where the benefit to an individual or society outweighed the public interest in maintaining confidentiality.

The court ultimately recognised that this is a question for doctors' clinical judgement. Having weighed up the relative harms, doctors could decide against telling the daughter, unless that was a decision that no reasonable professional in the doctor's position could have reached.[22]

The question of disclosure is also complicated where a relative may choose not to know about a test result.

In practice, experts we spoke to suggested that with time and counselling, it is generally possible to reach agreement with patients so that relatives can at least be informed a variant has been detected in the family and that they should consider testing.

Duty of care to relatives

Another issue that has arisen in overseas jurisdictions has been whether doctors may be liable to genetic relatives where a missed or misdiagnosis meant the relatives were not able to consider whether to be assessed or tested.

While Australian law is not clear on this issue, it has been considered in the UK, where courts have found (or decided) that doctors have no general duty of care to genetic relatives.

UK position: Failure to diagnose condition in patient led to lost opportunity for relatives

An order for a scan was overlooked, leading to a delay in diagnosing a patient's genetic condition, adrenomyeloneuropathy. Relatives of the patient later claimed the doctor had breached his duty to them by denying them the chance to seek testing.[23]

The case was dismissed as doctors had no duty of care to genetic relatives.

Another recent case in the UK[22] has confirmed in that jurisdiction, while doctors may have a duty to relatives who may be harmed by not knowing about a genetic diagnosis, there is no broad duty to all relatives in respect of genetic information.

Issues in testing embryos

In this area, there are aspects of decision-making that doctors encounter which can present challenges and where the potential exists for conflict to arise.

Appropriate uses of preimplantation screening or testing

Preimplantation screening is generally accessed by women or couples who know they have a higher chance of passing on a genetic condition.

The NHMRC has produced detailed ethical guidelines on the use of assisted reproductive technology (ART) in clinical practice and research.[24] Clinics accredited by the Reproductive Technology Accreditation Committee are required to comply with these guidelines, as well as relevant state-based laws in the jurisdictions with ART legislation (NSW, Victoria, South Australia and Western Australia).

The guidelines provide that the results of preimplantation diagnostic genomic testing or screening may only be used to:

- "select against genetic conditions, diseases or abnormalities that would severely limit the quality of life of the person who would be born
- select an embryo with compatible tissue for subsequent stem cell therapy intended for a parent, sibling or other relative
- increase the likelihood of a live birth.

[It] may not be used to preferentially select in favour of a genetic condition, disease or abnormality that would severely limit the quality of life of the person who would be born."[24]

The guidelines, which ART clinics must adhere to for accreditation, limit the use of embryonic sex selection to the above reasons and do not currently support sex selection for non-medical reasons. Some jurisdictions have taken legislative steps to clarify the legal position of this practice, restricting sex selection for non-medical reasons. The NMHRC recognised the likelihood of ongoing public discussion about this topic.

Keeping up to date

A significant challenge for doctors is keeping up to date in the rapidly evolving field of clinical genomics. This applies at all stages of the process, from providing pre-testing information, following up on test results and advising on treatment options. The NHMRC has noted the importance of ensuring that as evidence changes, it is communicated and taken up within the relevant fields of clinical practice so that the care is based on current evidence.[8] However, in a developing area of medicine, there can be debates as to what a reasonable practitioner in the specialty should have known at the time.

In the setting of changing possibilities for testing and evolving science, we heard from doctors about the difficulties they experienced in accessing information that is timely, clear and consistent. We also heard about the challenges professional organisations face in providing such guidance. This arose in a number of areas as genomics spans such a wide spectrum of medical practice.

Example: Updating guidance

The importance of updates is highlighted in recommendations for antenatal screening and testing, which is now widely undertaken. The Royal Australian College of General Practitioners issued guidance in 2018. In 2019, advice issued by the Royal Australian and New Zealand College of Obstetricians and Gynaecologists included specific recommendations about genetic carrier screening. These expanded on previous recommendations. They now include a recommendation that all couples who are pregnant or intending to have children be offered information on carrier screening for other genetic conditions: "Options for carrier screening include screening with a panel for a limited selection of the most frequent conditions (e.g. cystic fibrosis, spinal muscular atrophy and Fragile X syndrome) or screening with an expanded panel that contains many disorders (up to hundreds)."[25]

Conclusion

Our research into the clinical landscape in Australian genomics reflects recent studies in the US which highlight antenatal genomic testing as a particular area of medico-legal concern. Other aspects of clinical genomics are also being discussed in the context of risk. These include genomic testing to diagnose conditions and/or identify the potential for, or risk of, particular treatment strategies and screening tests to detect the future risk of disease.

Our research has highlighted that issues arise at many points in the patient care journey as doctors aim to:

- enable patients to make informed decisions about genomic testing
- order appropriate tests
- provide test results and follow up with patients
- avoid testing process errors
- protect patient privacy and confidentiality while also considering the impact on others who may be affected
- ensure appropriate decision-making about testing embryos and foetuses.

Questions to consider

Guidance and information for doctors

In your specialty area of practice:

1. What level of understanding do doctors have about genomic medicine as it applies to their practice?
2. How useful is existing guidance for doctors to equip them to:
   - provide patients with the information needed to evaluate risks and consent to testing?
   - understand what is expected of them when recommending specific tests?
   - interpret test results (meaning and test quality)?
   - communicate results to the patient?
   - consider treatment options with patients?
   - understand and manage privacy and disclosure issues (e.g. with patients' relatives, or in relation to overseas testing)?
   - follow up with the patient appropriately?
3. To what extent is it clear where responsibility lies, for example:
   - communicating and interpreting test results?
   - following up with patients?
4. What are the greatest needs in relation to minimising medico-legal risk in genomic medicine?

Barriers to better care

1. What are the practice-level and system-level barriers in your specialty area of practice to:
   - providing patients appropriate options for testing?
   - delivering the kind of consultation required to support patients to make informed decisions?
   - accessing specialist support?
2. Are there any areas requiring system or regulatory change, for example related to:
   - the consent process for genomic testing?
   - providing accessible and updated information to help doctors and patients understand genomic testing?
   - guidance about quality and reporting processes for laboratories in Australia?
   - consistent privacy guidelines across all Australian jurisdictions?

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Acknowledgements

Avant thanks all those individuals external to Avant who have generously provided their time and expertise to help us in the preparation of this paper, including:

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