Not all genetic tests should be publicly funded — here's why

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New genetic technologies hold great promise in their potential to treat patients based on their individual genetic information. Advances in mapping the human genome mean the cost of doing a genetic test has

fallen dramatically, though the costs of these tests – and subsequent treatment – are still high.

It's exciting to think we're on the brink of a genomic revolution in health care. But just because new technology becomes available, it doesn't mean it should automatically be funded by the government through Medicare or the Pharmaceutical Benefits Scheme (PBS).

A number of types of genetic tests are currently available, including those for:

a person's whole genome sequencea particular gene that carries the certainty of a diagnosisa gene that increases the person's risk of developing a diseasea patient who already has a diagnosis, to test whether a particular medicine will be effective.

Each genetic test, each disease and each treatment pathway must be analysed to determine the balance of costs and benefits. We need to apply the same principles we do for any test, procedure or new medicine to determine whether it should be publicly funded: it must represent good value for money and be likely to improve health outcomes.

Gene-based therapies

Let's consider the example of cancer treatment. Some medicines work only on tumours with particular genetic markers. By using a test to target the medicine only to cancer patients who have the marker, we can be more confident that the medicine is effective for those who are treated, thus avoiding unnecessary costs and possible side-effects. This could make the new medicine more affordable.

But for the seller of the medicine, greater effectiveness means they can ask a higher price. Indeed, they need to, because now there is a smaller

target "market".

The cystic fibrosis drug Ivacaftor, for instance, cost patients around A$250,000 a year before it was subsidised on the PBS. The clinical trials had only demonstrated effectiveness in patients with a G551D mutation, which is only 8.6% of the population with the disease.

The challenge for the government is whether we can afford to pay higher prices for each of these targeted medicines. Then there's the issue of who will pay for the test, which will need to be done for everyone who might have the genetic marker. Should it be the government, private health insurers or individuals?

Without public funding of genetic testing, access to the effective treatment depends on whether you can afford to pay for the test, which undermines the equity principles of Medicare.

To overcome this challenge, Australia now requires integrated submissions of "co-dependent" technologies. This means, for instance, that if access to a new medicine on the PBS depends on the results of a test, the test should be publicly funded, and at a price that represents good value for money.

Testing for known diseases

More knowledge about your genetic makeup enables you to make better-informed choices: whether to seek preventive treatment; to change your behaviour to reduce risks; or to plan for the future.

In the context of specific known diseases, such testing is best done in a setting with genetic counselling, so the person can fully understand the implications of the knowledge and the decisions that may need to be made.

For a woman who has had breast cancer, a BRCA gene test can inform her choice about, for example, mastectomy to prevent a second breast cancer. Testing of immediate family members can determine if they carry the gene, allowing them to seek preventive treatment or more frequent screening.

But sometimes nothing can be done with the knowledge you obtained from your gene test. Knowing you have a higher risk of, say, dementia, could improve your well-being by giving you the chance to plan. Or it could just make you feel worse.

The costs and benefits of a genetic test depend greatly on whether there is effective prevention or treatment available, and what that treatment is.

Value for money

Australia assesses whether any test in health care represents good value for money by mapping out the treatment pathways that are available for each test result, and evaluating the costs and health benefits of each of these.

Based on such an assessment, the Medical Services Advisory Committee recently recommended a Medicare rebate of A$1,200 for genetic testing for hereditary mutations for breast and ovarian cancer, including the BRCA1 and 2 genes. This would cover most, if not all, of the cost of the test. The committee also recommended Medicare pay a A$400 rebate for predictive testing for family members.

The committee concluded the test would be good value for money, at around A$18,000 per Quality Adjusted Life Year (QALY) gained (from breast and ovarian cancers avoided). A QALY is a way of quantifying the additional survival and quality of life from the test compared with not having the test available.

For a test for a single gene or genes that are a certain marker for specific diseases, assessment of cost effectiveness is relatively straightforward, particularly if there is an effective treatment available.

Predicting future diseases

For a test that indicates increased risk of developing diseases in the future, such as whole genome sequencing, the options are less clear.

The committee would ask: can the person reduce their risk by exercising more and eating better? And will the information increase their motivation to do so over and above medical advice already received? Or will it motivate them to seek more treatment over time? And how effective is this treatment?

Whole genome sequencing and genetic counselling is available privately in Australia now for around A$6,000 (including a health assessment) – so affordable only to the rich. It is not publicly funded because the benefits are uncertain.

It could just be "nice to know" (as such tests are marketed in the US); it could motivate the person to change their behaviour and thus lead to better health outcomes; or it could create anxiety and unnecessary intervention, and thus ultimately increase health care costs, not just for the individual but for the society.

There is no blanket answer to whether genomic testing is cost-effective. Each test, each disease and each treatment pathway must be analysed to determine the balance of costs and benefits, following the same approach as for other new medical technologies.

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