Direct-to-Consumer Laboratory Testing

Approved August 2018

This position statement relates specifically to laboratory tests that are offered directly to people without requiring a request by a doctor or other appropriate health practitioner. Such tests are marketed directly to people, usually through public media such as the internet and magazines. People opting for such tests generally deal directly with a laboratory; purchasing tests, collecting and sending / depositing samples and receiving results. While there are some parallels with direct-to-consumer advertising (DTCA) of prescription medicines, the NZMA has developed a separate position statement on DTCA.[1]

The NZMA supports the informed participation of patients in decisions about the management of their health, including tests for screening and diagnosis. We believe that such participation occurs best in the context of a partnership between a doctor (or other appropriate health practitioner) and their patient. The NZMA is opposed to direct-to-consumer laboratory testing. We believe that such testing is wasteful, may cause serious harms to patients, will add to the workload of already stretched GPs, blurs boundaries of clinical responsibility, and exacerbates fragmentation of care. While such testing is currently available in New Zealand, we are opposed to its expansion and call on the Government to limit this practice by methods available to them, including regulation / legislation.

Background

1. Clinical laboratory testing plays a critical role in health care and evidence-based medicine. Laboratory tests provide essential data that support clinical decisions to screen, diagnose, and treat health conditions.

2. Clinical laboratory tests should only be requested when they are clinically indicated and appropriate. This requires an understanding both of prior probability and of the accuracy of the tests. Without this prior knowledge, results from inappropriate tests may be misleading. Clinical input, including a diagnostic history and informed discussion prior to testing, provides this safeguard.

3. Interpreting clinical laboratory test results requires an appropriately trained expert health practitioner to review the results. Results must be interpreted within the context of a person's medical and family history. Analysis of a single test result, taken in isolation and without awareness of the patient's wider circumstances, will be of little clinical value.

4. Clinical laboratory tests that are inappropriately requested and / or inappropriately interpreted may cause serious harms to patients and their family / whānau. For example, a false positive result or a spurious abnormality has the potential to trigger anxiety and cascades of unnecessary additional testing, some of which may be invasive and carry a risk of harm in their own right. Conversely, a false negative result could falsely reassure patients with significant symptoms and

[1] Available from https://global-uploads.webflow.com/5e332a62c703f653182faf47/5e332a62c703f650522fc4d1_Direct-to-Consumer-Advertising-of-Prescription-Medicines_June-2018.pdf

deter or delay further investigation of their condition.

5. Direct-to-consumer laboratory testing is wasteful and counter to the objectives of Choosing Wisely, a global initiative that aims to promote a culture where low value and inappropriate clinical interventions are avoided.[2] Patients and health professionals need to have well-informed conversations around their treatment options, which leads to better decisions and outcomes.

6. People who are most vulnerable such as those with low health literacy or anxiety about health issues may be exploited by being marketed tests of questionable value and / or tests for dubious indications.

7. Direct-to-consumer laboratory testing may divert diagnostic resources and attention away from necessary testing in people who cannot afford it, and therefore have a negative impact on health equity.

8. There are serious concerns around the follow up of patients who request direct-to-consumer laboratory testing. These include the additional demands placed on a GP workforce that is already stretched, and the blurring of boundaries of clinical responsibility. It is not appropriate to pass responsibility on to a GP who was not involved in ordering the test in the first place, but neither is it appropriate to leave responsibility with the patient.

9. Direct-to-consumer laboratory testing that relies on systems and mechanisms outside existing reporting and shared health record systems runs counter to integration, and will exacerbate fragmentation of care.

Recommendations

1. Medical and health organisations should work collaboratively to dissuade existing providers from expanding the provision, marketing and promotion of direct-to-consumer laboratory testing, and to help achieve the discontinuation of direct-to-consumer laboratory testing in New Zealand.

2. The Government should consider limiting the practice of direct-to consumer clinical laboratory testing by methods available to them, including regulation / legislation. In particular, these measures should include restricting the marketing and promotion of such testing.

3. The Government should support cross-sectoral approaches towards improving health literacy that help ensure patients, doctors and other appropriate health practitioners make better informed shared decisions about screening and testing options.

4. The Government should support initiatives that increase the provision of independent, accurate and accessible sources of health information, including information about screening and diagnosis.

5. Doctors, other health practitioners and laboratories should take a more active role in educating the public and their patients about the risks of nonindicated direct-to-consumer laboratory tests.

[2] https://choosingwisely.org.nz/