Researchers zero in on molecular fingerprint for prostate cancer

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Credit: University of South Australia

Six cancers that claim more than 23,000 Australian lives each year1 should be prioritised for research that makes it possible to identify the molecular fingerprint of the tumour and improve survival, according to a landmark report launched today.

"Cancer Biomarkers in Australia" by the Sansom Institute for Health Research at the University of South Australia (UniSA) found that the most common cancers, prostate, breast, colorectal and Australia's biggest cancer killer, lung cancer – as well as rarer but deadly pancreatic and ovarian cancers – should be the focus of biomarker research in order to fast-track new diagnostic, prognostic and predictive tests for use with cancer patients. This finding was based on a survey of 116 Australian oncologists and researchers.

Director of UniSA's Sansom Institute, Professor Ian Olver said that fast-tracking research into biomarkers over the next five years "has the potential to transform cancer care more than anything seen over the past 50 years."

"It's not an exaggeration to say that biomarkers are the silver bullet that can speed up diagnosis and pinpoint the best treatment approach for the patient, maximising the response while minimising toxicities," he said.

However, Professor Olver said that Australia must streamline regulatory and reimbursement processes "to ensure bureaucratic red-tape doesn't stand in the way of matching medicines to biomarkers and seizing a new era in precision medicine."

The report authors warn that Australia is lagging behind other countries in making cancer medicines available that are matched to a biomarker test, with a number of medicines paired to biomarkers widely available in Canada, England and France, but not funded in Australia.

Cancer medicines matched to a biomarker test that requires a Medicare Item Number take on average twice as long to be added to the Pharmaceutical Benefits Scheme, compared to cancer medicines without a biomarker.

Pointing to an example of a colon cancer medicine that saves $600 million a year by being restricted to patients tested for a specific biomarker, Professor Olver said that biomarker-led treatment will save millions of dollars for the public purse.

"Research and reimbursement of biomarker-driven treatments should be a top priority for Government. This is key to improving cancer survival and ensuring we get the best bang for buck," he said.

"Gone are the days of a 'one size fits all' approach where treatment decisions were based solely on tumour type or location. We can now gauge the molecular fingerprint of many cancers, allowing the right treatment to be given to the right patient, at the right time."

A cancer biomarker is a molecule produced by the cancer or the body in response to the cancer that can be measured in blood, body fluid or tissues. Biomarker tests can inform diagnosis and prognosis, as well as predict treatment response.

Existing cancer biomarkers include ALK, EGFR and PD-L1 in lung cancer, KRAS/NRAS in bowel cancer, PSA in prostate cancer, HER2 in lung, breast and gastric cancer, BRCA1 or 2 in breast cancer, BRAF in melanoma and DRG mutations in ovarian cancer.

The report calls for the Federal Government to approve and reimburse medicines based on the molecular characteristics of the cancer rather than where the cancer originates in the body, and to align the reimbursement of medicines with their accompanying biomarkers, ideally so this is handled by one agency. Currently, medicines are reviewed by the Pharmaceutical Benefits Committee and biomarkers are reviewed by the Medical Services Advisory Committee.

Co-author of the report, UniSA's Professor Doug Brooks said strict guidelines are needed for biomarker development, validation and implementation.

Professor Brooks is involved in ground-breaking research to develop a new biomarker in prostate cancer that may replace the PSA test, which is known to give false-positive and false-negative results.

"There is a clear need to replace the PSA test, which can show elevated levels not just in men with prostate cancer but in response to benign

conditions, as well as recent sexual activity or even having just ridden a bicycle," he said.

"This leads to unnecessary biopsies and treatment in men who are well, as well as missed diagnosis in around 15 per cent of men with prostate cancer.

"Our research has revealed that the entire cellular pathway is altered in prostate cancer with changes in more than 20 genes and proteins. This gives us a large panel of biomarkers which we hope will eventually replace PSA," said Professor Brooks.

"The new biomarkers we are developing will enable us to not only better diagnose prostate cancer but predict how severe the disease is and guide treatment timing – a win-win for patients and the health system," he concluded.

"Cancer Biomarkers in Australia" reviews the body of evidence for the efficacy of biomarkers and examines overseas precedents for their regulation and the Australian context. It also reports on the opinions of Australian oncologists and researchers in the biomarker field who are ultimately responsible for their measurement being translated into improved patient care and outcomes. The report was written independently of MSD and Janssen who commissioned the report.

Provided by University of South Australia