Minomic International
Transforming clinically significant prostate cancer detection: An exclusive interview with Minomic's CEO

Prostate cancer is the second most common cancer among men after skin cancer and the fourth most commonly diagnosed cancer globally. In 2020, an estimated 1.4 million people were diagnosed with prostate cancer, and over 375,000 people died from the disease worldwide.

Although prostate cancer survival has tripled in the last 50 years in the UK, in part due to greater awareness and better treatment, there are considerable doubts about the veracity of the widely used PSA test and its usefulness as a screening tool in prostate cancer. In some developed countries, for example, these doubts have resulted in health authorities specifically recommending PSA not be used as a screening tool because they believe it does not reduce mortality and may be harmful. These concerns result from, in part, the high false positive rate associated with the test and the resulting overdiagnosis of cancer and consequent unnecessary biopsies, an invasive, expensive, painful and potentially risky medical intervention. With prostate cancer incidence growing by 5% per annum, reflecting the developed economy's ageing population, there is an urgent need for a better, more accurate prostate cancer test that doesn't result in overdiagnosis but leads to better patient outcomes and survival rates.

Minomic International, an Australian pathology company specialising in developing cancer tests, has spent the last seven years developing the solution, MiCheck® Prostate.

In 2016, during a clinical study, the Minomic team saw interesting results, which led them to develop a new, more accurate prostate cancer test.

Dr Brad Walsh, CEO of Minomic International, said, "Clinicians were at the time no longer looking at getting better prostate cancer tests as they had PSA, which works for getting an indication that a man may have cancer, with the next step being diagnosis through a prostate biopsy."

However, 50% of men sent for biopsies following a PSA test should not be sent at all. Clinicians want to know which patients are at risk of having clinically significant prostate cancer as opposed to indications of cancers that don't pose a risk at all, a common issue with PSA testing.

50%
of biopsies following a PSA test are avoidable

"A strong case for improving testing from PSA is that many patients show an elevated PSA; this is called a false positive. Those false positives are a big problem as these patients are sent for a biopsy when they don't need one", Walsh explains.

When you have a prostate biopsy, your results are marked on a scale called the Gleason Score. The scores range from about one to ten. About 50% of men have no cancer following biopsy, and there are those scoring Six - the lowest-grade cancer (termed clinically insignificant). Anything over seven is classified as a clinically significant cancer.

Minomic was most interested in a new test that could accurately distinguish between the patient group with either no cancer or clinically insignificant cancer and the group scoring seven and above. While all these patients have elevated PSA, MiCheck® Prostate can differentiate the groups. The at-risk patients would then be sent for a biopsy, while those with elevated PSA would be put into active surveillance, returning in six to twelve months for further tests.

"This is more appropriate than sending them off for a biopsy, which frequently is futile", says Walsh. To resolve this issue, Minomic developed an algorithm to accurately determine the patient's risk level without needing a biopsy.

The Minomic test measures three types of proteins from a patient blood sample, alongside clinical factors - such as the patient's age - recorded by the doctor facilitating the test.

The MiCheck® Prostate algorithm delivers the patient's clinically significant prostate cancer risk level as a percentage on a temperature bar. Those below a certain cut-off level can be excluded from an unnecessary biopsy and put into active surveillance instead.

"Over half of all PSA test patients that show an elevated PSA are actually false positives, so it is a significant number of men", Walsh says. "They're the ones we don't want to pull into having a prostate biopsy".

Walsh explains that there are several benign reasons why men may have elevated PSA. One of those is prostatitis, a transient inflammation that a man might have because of an activity like riding a bike. Another activity resulting in elevated PSA is sex, and so if a patient were to have sex or had been cycling in the morning before a PSA test, they could present as having a high prostate cancer risk when that may not be the case.

Another problem that MiCheck® Prostate could resolve concerning prostate cancer is what clinicians call the 'worried well patient'.

“This may be a patient who hasn't had elevated PSA before, but they've gone to their doctor as they might have had a family history of prostate cancer. Often, they take a PSA test, and the results show PSA is over a certain level, so the doctor refers the patient to the urologist.”

To avoid an unnecessary biopsy, this is where the urologist would use MiCheck® Prostate. If the patient’s blood test showed elevated PSA, the next step would be the Minomic test. The MiCheck® Prostate result will separate those men with elevated PSA from those at risk of clinically significant prostate cancer.”

“Without MiCheck® Prostate, those men with a high PSA are all sent for a biopsy or an MRI”, says Walsh.

Commercialising MiCheck® Prostate
Given the prevalence of prostate cancer worldwide, MiCheck® Prostate has catalysed interest in the United States, United Kingdom, Europe, Australia and South Africa and could generate global sales of up to USD 2 billion.

$2 billion
global sales potential of MiCheck® Prostate

The different approaches to healthcare delivery in each region mean that the journey to commercialise the product will be specific to each geography. Walsh says this is predominantly related to regulation, especially regarding cancer testing.

“As far as the regulator sees it, there’s an element of risk. The biggest concern is a patient receiving a false negative test result and not taking action.”

“For the US, the regulatory pathway is quite amenable to cancer testing, and the US healthcare system sees the benefit of early cancer detection. So, there we’ve rolled out testing in CLIA labs - which stands for Clinical Laboratory Improvement Amendments - under Medicare and Medicaid.”

The test is reimbursed if you’re under the Medicare/Medicaid system at $760 per test, while Minomic’s cost of goods is low.

“The US is a strong focus for us. With an addressable market of around two million men per year, there is a very attractive revenue opportunity there”, Walsh says, “the next step is FDA clearance as a precursor to offering the test more broadly.”

“While we are getting traction in the US, we recognise the need to add additional marketing resources to exploit the opportunity fully.”

Walsh adds, “Because Minomic uses blood pathology machines that aren’t expensive and because our data is stored in the cloud, our test is affordable but also very profitable. Other companies like Exact Sciences, Genomic Health and Guardant Health have done the same very effectively, all in CLIA labs.”

“That's how they do their testing and offer their product. And they've built companies with very significant market capitalisations.”

In Australia, Minomic has partnered with Sonic Healthcare, the largest pathology provider in the country and the third largest in the world. Sonic has a considerable presence in Europe, especially in Germany, and owns Doctor’s Laboratories in the United Kingdom, an extensive network of laboratories and pathology services.

Sonic has helped Minomic in several areas since the beginning of their partnership. In Australia, Sonic provides testing services for Minomic, which in turn provides Sonic with the risk score calculations.

Once the test achieves its CE Mark, Sonic could use its considerable presence in the United Kingdom to help Minomic navigate the approval pathway with the National Health Service and National Institute for Health Care Excellence. This could, in time, see MiCheck® Prostate become the leading clinically significant prostate cancer test in the UK, where projections suggest there will be over 85,000 new cases of prostate cancer every year, according to Cancer Research UK.

Minomic and Sonic Healthcare
The partnership between the two companies “began in 2017 with the championing of Minomic by Sonic’s Chief Medical Officer, Dr Stephen Fairy. Sonic was looking to see how it could deploy a prostate test, and once we developed it (MiCheck) to a point where it was commercially viable, it became quite an appeal to them.

SONIC HEALTHCARE

Sonic saw the huge potential of MiCheck® Prostate and could deliver it to the market.

“Sonic asked to see the test’s performance in an Australian cohort, and once we had completed that, we began deploying the test. That process that took around 18 months,” Walsh says.

The regulatory challenge is one aspect of bringing the MiCheck Prostate Test to the global market, but technology transfer is another challenge. This is where Sonic and Minomic’s dynamic relationship has again proven extremely useful and synergistic.

“Our team and Sonic’s team have done a fantastic job of technology transfer. Sonic has

also given strong support through facilitating introductions in other countries they operate in, and we've now completed US testing and also have a UK cohort," says Walsh. "Sonic is helping us to understand how to approach the urologists and where the low-hanging fruit is within the oncology and urology landscape."

"There are quite a few touch points with urologists before they say yes to a product, but for Sonic, urologists are already customers. They're already doing PSA testing and biopsies, so they've got an integrated view of the area," says Walsh.

Reception from oncologists and urologists to MiCheck® Prostate
Getting oncologists and urologists on board with the MiCheck Prostate Test has been a relatively straightforward process for Minomic and has relied on its ability to respond to three key questions, says Walsh.

"The first question is always the performance of the test, and it's far more sensitive and specific than what is available in the marketplace today, with PSA or other tests. Secondly, they want to know about the negative predictive value. How confident can they be that if they get a low-risk result for a patient that rules him out of having prostate cancer?"

This concern has been addressed within the MiCheck® Prostate protocol, which places men scoring a low-risk result into active surveillance, where they are tested again in six to twelve months."

"The third question is 'who's using the MiCheck test? The answer to that one is our key opinion leaders", says Walsh. MiCheck® Prostate was developed with substantial input from high-profile urologists and oncologists worldwide: Professor Mark Emberton in the UK, in Australia, Professor Manish Patel and Professor David Gillat, and in the US, Dr. Neil Shore.

These key opinion leaders for Minomic are well-recognised in their fields, and their endorsement of MiCheck® Prostate is reassuring for the wider oncology and urology community. "They're all respected researcher clinicians, so they have taken part in many studies. So other oncologists and urologists know it's backed up by professionals they trust," says Walsh.

Getting MiCheck® Prostate to at-risk men
Minomic has been working hard to ensure that men most at risk of developing prostate cancer can access MiCheck® Prostate globally. Data from the Global Cancer Observatory shows that Black males are more likely to develop prostate cancer, particularly African American men in the US and across the Caribbean.

As Walsh explains, it is not that the incidence rate is much higher among these groups but that the incidences of clinically significant cancer are much higher.

"We're looking closely at a particular African American cohort that will be of interest not just to this community but also to the government in the US. Often, these patients are in socio-economic groups that struggle to gain access to healthcare. We think this is very important, so we will soon be looking at a cohort of patients available to us through the Medical University of South Carolina."

One of the concerning issues with Black men and prostate cancer is the hesitancy to undertake the traditional digital rectal examination, a vital starting point for detecting signs of cancer. However, Minomic has found a way around this issue that addresses the concerns of patients reluctant to undergo this examination.

"We have developed an algorithm that uses the prostate volume - the size of the prostate - rather than the digital rectal exam. We set the digital rectal exam result to zero for the patient, and it doesn't have a big effect on the performance of the test. So, if a patient refuses a digital rectal exam, we can still run MiCheck® Prostate and get an accurate estimate from the blood test itself."

MiCheck® Prostate to be the leading test for clinically significant prostate cancer
Key to Sonic and opinion leaders' endorsement of the Minomic MiCheck® Prostate is its superior performance compared to any other test in the market. This superior performance is both in terms of specificity and sensitivity. This clear advantage over existing tests gives us the confidence that MiCheck® Prostate will become the world's leading clinically significant prostate cancer test, leading to better patient outcomes and significant reductions in wasteful healthcare spending on unnecessary, expensive and risky biopsies.

As Walsh explains, "key to successful performance is the test's specificity, meaning the reduction of the false positive rate. That has always been the issue with PSA, where specificity is about 25%. MiCheck® Prostate delivers about 50%, so we've doubled specificity."

The other side of a prostate test's performance is sensitivity. If sensitivity is high, more cancers will be found; however, many of these will not develop into the kind of clinically significant cancer clinicians are looking for. "Crucially, we've increased sensitivity without compromising our specificity. Doctors told us they wanted 95% sensitivity, which is where we're at, but we deliver a specificity of 50%. This is far higher than other prostate cancer tests."

"Doctors told us they wanted 95% sensitivity, which is where we're at, but we deliver a specificity of 50% – double other prostate cancer tests."

Dr Brad Walsh, CEO Minomic

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