

PRESS RELEASE
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Stockholm3 in NICE Medtech Innovation Briefing for the UK

NICE, the UK National Institute for Health and Care Excellence, has published a Medtech Innovation Briefing (MIB) on Stockholm3, where experts state that Stockholm3 has the potential of improving accuracy in prostate cancer diagnostics. The MIB report is not a recommendation, but generally seen as a first step towards diagnostic guidance in the UK.

NICE has been evaluating Stockholm3 as a means of improving prostate cancer diagnostics in the UK. The outcome of the evaluation is a MIB report providing a thorough external evaluation of Stockholm3, including comments by independent NICE experts and patient organization representatives.

The report highlights that the improved accuracy of Stockholm3 has the potential to reduce unnecessary MRIs and biopsies and that implementation of Stockholm3 could potentially reduce the overall costs of prostate cancer diagnosis in the UK. The clinical evidence is described as “adequate and of good methodological quality”. However, the report mentioned the lack of studies carried out in the UK, and the lack of data on non-Caucasian ethnicities, which are currently in progress.

Several of the experts noted that the use of Stockholm3 could lead to less or similar resource usage compared with current standards of care. A representative from the patient organization Prostate Cancer UK said that *“the benefits of Stockholm3 are that it is convenient and results in quick and accurate care provision”* and that *“Stockholm3 prevents harm from unnecessary biopsies. For people who are concerned about their prostate cancer risk, this technology could rule out any unnecessary worry of being referred into secondary care for an exploratory MRI scan or biopsy.”*

“The MIB report is a great initial step for us in the UK. Even though it is not a diagnostic guidance, it shows that the specific benefits of Stockholm3 are understood and appreciated. We are already conducting studies on non-Caucasian ethnicities, and we are planning to start a validation study in the UK”, says David Rosén, CEO of A3P Biomedical.

“While we realize that a diagnostic guidance from NICE will take more time, we can now start contacting private and NHS care providers, based on the findings of this report”, David Rosén concludes.

With more than 52,000 new cases per year, prostate cancer is the most common form of cancer in UK men and one of the deadliest with 12,000 fatalities every year.

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About A3P Biomedical

A3P Biomedical's mission is to improve quality of life of men by radically increasing the precision in prostate cancer diagnostics. The company's lead product is **Stockholm3**, a blood test for early detection of aggressive prostate cancer. Stockholm3 has been developed by scientists at Karolinska Institutet and validated in clinical studies including more than 75,000 men. A total of SEK 750 million has been invested in clinical research, product development and market validation activities of Stockholm3. A3P Biomedical is headquartered in Stockholm, Sweden. For more information, please visit www.a3p.com.

About Stockholm3

Stockholm3 is a blood test that combines protein markers, genetic markers, clinical data, and a proprietary algorithm, to predict the risk of aggressive prostate cancer at an early stage. In clinical practice, Stockholm3 finds 100 percent more aggressive prostate cancers and reduces 50 percent of unnecessary biopsies compared to current practice with PSA (1).

Stockholm3 has been evaluated in clinical studies with more than 75,000 men. Data from the latest pivotal study, a randomized study including 12,750 men, was published in The Lancet Oncology in 2021. The study was also awarded the European Association of Urology (EAU) "Prostate Cancer Research Award 2022". Multiple additional studies have been published in high-impact journals, including a previous study with 58,000 men, published in The Lancet Oncology in 2015 (1).

Based on robust peer-reviewed clinical data, leading Nordic healthcare providers such as Capio S:t Görans Hospital in Sweden and Stavanger University Hospital in Norway have replaced PSA with Stockholm3. Region Värmland has introduced general screening for prostate cancer with the help of Stockholm3 for men in the age category 50-75. Patients benefit from a more precise test (increasing sensitivity and specificity) and healthcare providers can reduce the direct costs by 17 to 28 percent (1).

(1) Publications, results and clinical validation.

About prostate cancer

Prostate cancer is the second most common male cancer, and the fifth leading cause of cancer related death in men worldwide. According to WHO, 1.4 million men were diagnosed with prostate cancer and 375,000 deaths were reported in 2020. Incidence of prostate cancer is expected to increase by 70 percent until 2040, driven by an aging population.

Attachments

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