

## PP33 Molecular Markers For The Detection Of Clinically Significant Prostate Cancer

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**Introduction.** It is estimated that approximately 1.1 million cases of prostate cancer (PCa) are diagnosed in the world every year. In general, PCa is a slow-onset cancer and less than 10 percent of cases are detected in the metastatic phase. In order to identify patients at risk of suffering from clinically significant prostate cancer (csPCa), as well as to avoid unnecessary biopsies, overdiagnosis and overtreatment, a variety of molecular biomarker detection tests have been developed.

**Methods.** We undertook a systematic review with meta-analyses on the effectiveness of diagnostic tests based on biomarkers in blood or urine samples for the identification of men at risk of csPCa. A cost-effectiveness analysis was conducted using a decision tree model for the short term and a Markov model for the long term, both from the social and the National Health System perspectives. The effectiveness measure was quality-adjusted life years (QALYs). We ran extensive sensitivity analyses, including a probabilistic sensitivity analysis.

**Results.** Sixty-five studies were included with a total of 34,287 participants. The diagnostic tests analyzed were: PHI, Progenesa<sup>®</sup> PCA3, SelectMDx, MyProstateScore, 4Kscore<sup>®</sup>, TMPRSS2: ERG, Stockholm3, ExoDx Prostate IntelliScore and Proclarix<sup>®</sup>. All studies included biopsy as comparator. The sensitivity and specificity of diagnostic tests depended on the test itself and the threshold chosen, and ranged from 42 percent to 99 percent and from 13 percent to 87 percent, respectively. In the cost-effectiveness analysis, the alternative that includes the biomarker, specifically the SelectMDx, led to higher QALYs and healthcare costs with an estimated incremental cost-effectiveness ratio (ICER) of 6,640.21 EUR per QALY. The sensitivity analyses confirmed that the results were robust.

**Conclusions.** Biomarker testing to select men at risk of csPCa who should undergo prostate biopsy can be a cost-effective strategy depending on its cost per determination and its sensitivity/specificity. The analyses carried out indicate that the SelectMDx biomarker is cost-effective at a cost of EUR 375 per determination.

## PP34 Next Generation Sequencing For Informing Lung Cancer Therapy In Europe – Hospital Impact With A Lifecycle Perspective

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**Introduction.** Next-generation sequencing (NGS) can be run in-house or outsourced to an independent laboratory. It has enabled wider use of deoxyribonucleic acid/ribonucleic acid (DNA + RNA) sequencing in clinical practice. Within oncology, NGS has paved the way for more effective treatment, including personalized medicine. There are, however, large variations in access and reimbursement across Europe. The aim is to understand the European NGS landscape and barriers to access.

**Methods.** Structured telephone interviews covered topics on NGS perception, guidelines, use-cases, benefits, costs, and future expectations. Twelve experts per country (France, Germany, Italy, Spain): two payers, five oncologists, and five pathologists were interviewed between June and August 2021. Responses were translated into English for qualitative analysis.

**Results.** NGS was considered most useful when there were approved, targeted treatments. Although often noted that there was a lack of published evidence to support a beneficial link, respondents perceived that NGS has the potential to improve patient quality of life (QoL) and reduce resource use through avoiding suboptimal treatment. All of the payer respondents expected the role of NGS to increase, though it may be held back by lack of reimbursement. Respondents favored in-house NGS over outsourcing in terms of clinical benefit: “Advantages of in-house NGS are turnaround time, results and lean processes” ... “you build the expertise in-house. If you have urgent samples, it’s easy to prioritize them”. Reasons for not having in-house NGS included “costs, lack of personnel. Basically, organizational and financial issues.” In-house NGS was perceived to be associated with high setup-costs (acquisition, setup, training), but lower running costs (per-test costs). There was a view that in-house solutions are mainly suitable in larger centers undertaking many tests.

**Conclusions.** NGS can save costs and provide QoL benefit through enabling optimized, personalized therapy, but published evidence establishing the outcomes link is lacking. From the hospital perspective, investing in NGS requires understanding the cost of NGS over its entire lifecycle, likely entailing a health-technology assessment including health-economic analysis.