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Meeting Abstract

# Systematic Review of the Clinical Effectiveness of Biomarkers as Cancer Screening Test offered as Self-Pay Service in Austria and Germany


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## Text

**Background:** Individual health services (IGeL) are medical self-pay services that are not under the liability of the German statutory health insurance. Up to 14% of IGeL are blood or laboratory and cancer screening tests, which are offered to asymptomatic individuals [1]. The aim was to investigate the clinical effectiveness of eleven biomarkers that are the most often offered biomarkers for cancer screening by physicians and laboratories on the internet in Germany (i.e., AFP, CA125, CA15-3, CA19-9, CEA, Cyfra21-1, β-HCG, NMP22, M2-PK, NSE and PCA3).

**Research Question:** What is the benefit-harm-balance regarding patient relevant outcomes (mortality, morbidity, quality of life) for using these biomarkers as cancer screening test in comparison to usual care?

**Methods:** Firstly, searches for Health Technology Assessment (HTA) reports and systematic reviews (SR) were performed in three different databases in spring 2012. Secondly, randomized controlled trials (RCT) that were published after the end of the research period of the most recent included secondary study were searched. We included publications in English or German which compared cancer screening with one of these biomarkers in asymptomatic persons to unscreened controls. References were independently screened by two reviewers. One reviewer extracted relevant characteristics from full text and evaluated the quality of included studies.

**Results:** Five HTA or SR dealing with CA125 (4) or NMP22 (1) and 2 RCTs (CA125) were included. For ten biomarkers, incl. NMP22, no direct evidence on patient relevant outcomes was available. One RCT combining CA125 and vaginal ultrasound for ovarian cancer screening provided results of interest [2]. Screening compared with usual care did not reduce ovarian cancer mortality (RR, 1.18; 95% CI, 0.82-1.71) [2]. Harms occurred through overdiagnosis and false-positive results, e.g., 20.6 complications occurred per 100 surgical procedures in women who underwent surgery after a false-positive result [2]. About 4.5 surgeries were performed per one case of invasive cancer identified through CA125 screening [3].

**Conclusion:** While ovarian cancer screening with CA125 showed no survival benefit, false-positive tests, overdiagnosis and -treatment resulted in harm. For ten biomarkers no sufficient evidence was available. When IGeL are offered, patients should get comprehensive information about the lack of evidence on patient-relevant outcomes and potential harm caused by biomarker screening.

## References

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