# New Screening Proposals: the Federal Joint Commission Defines the Parameters for Cervical Cancer Screening from 2018

Statement of the Gynecology Oncology Working Group (AGO)

Neues zur Vorsorge: Der G-BA definiert die Eckdaten für die Zervixkarzinom-Krebsfrüherkennung ab 2018 Stellungnahme der AGO

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#### **Key words**

- cervical cancer screening in Germany
- HPV screening
- national screening program

#### Schlüsselwörter

- Krebsvorsorge in Deutschland
- HPV-Screening
- organisiertes Screening

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#### **Bibliography**

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# **Abstract**

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The Gynecology Oncology Working Group (AGO e.V.) unequivocally welcomes the decision taken by the German Federal Joint Commission (Gemeinsamer Bundesausschuss, G-BA) on March 19, 2015 regarding screening for cervical cancer. AGO is convinced that, in view of recent medical advances, this evidence-based decision will improve screening for cervical cancer.

The Law on the Screening and Registration of Cancer (Krebsfrüherkennungs- und -registergesetz, KFRG), which is based on the German National Cancer Plan and became effective in 2013, will require changes in the current approach to cervical screening and the implementation of an organized screening program for cervical cancer. The German Federal Joint Commission (Gemeinsamer Bundesausschuss, G-BA) is working on developing an organized program for cervical screening which will take account of the new legal requirements. In its session held on March 19th, 2015, the G-BA decided to commission the Institute for Quality and Efficiency in Healthcare (Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen, IQWiG) to prepare a letter of invitation for women with healthcare insurance along with information about the new organized screening program for cervical cancer. The G-BA also defined the parameters for the nationwide introduction of HPV testing as part of cervical screening from the year 2018 [1].

The current program of clinical examinations to screen women for genital and breast cancer will continue.

According to the proposals of the G-BA, from 2018 women aged between 20–60 years will receive a letter from their health insurance company every 5 years inviting them to be screened for cervical cancer. In future, women above the

# Zusammenfassung

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Die Arbeitsgemeinschaft Gynäkologische Onkologie (AGO e.V.) begrüßt ausdrücklich den Beschluss des Gemeinsamen Bundesausschusses (G-BA) vom 19. März 2015 zum Zervixkarzinomscreening und ist überzeugt, dass diese evidenzbasierte Entscheidung angesichts des medizinischen Fortschritts zu einer Verbesserung in der Vorsorge führen kann.

age of 30 years can request an HPV test every 5 years. Cytology is then only done if the findings of the HPV test are abnormal (cytology triage). Women can continue with the existing annual Pap-based screening as an alternative to the new screening strategy (optional model). Combining both screening strategies or switching from one to the other before the screening interval has expired will not be possible. To monitor the strategy, data on both strategies will be collected during a transition period which is expected to last at least 6 years (or until sufficient data is available from the 2nd round of screenings). The data will then be assessed based on performance indicators previously established by the G-BA to see whether there are any indications which would point to the superiority or inferiority of the screening strategy and would require this optional screening model to be changed.

# Reasons given by the G-BA for introducing HPV testing

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The reasons given by the G-BA for its decision is that opting for an HPV-based screening strategy complies with currently existing evidence and international recommendations: "the existing IQ-WiG report assessing the benefits of HPV testing in primary screening (January 2012, updated

May 2014) came to the conclusion that there is evidence that HPV testing in primary screening can reduce the incidence of invasive cervical cancer even more. It is not possible to recommend a specific screening strategy based on studies into the assessment of benefits, as different studies used a number of different strategies. After including further studies and considering current international recommendations it is possible to reach a reasoned decision justifying an HPV-based screening strategy. The HPV test is simpler, more reliable and less subjective than cytology. Provided there are extensive quality assurance and assessment measures in place, the higher sensitivity (approximately 90–98% for CIN2+) and the high negative predictive value of an HPV test will allow the interval between examinations to be extended."

The **Gynecology Oncology Working Group** (Arbeitsgemeinschaft Gynecologische Oncology, AGO e.V.) unequivocally welcomes the decision on cervical screening taken by the Federal Joint Commission (G-BA) on March 19th, 2015. AGO is convinced that, given recent medical advances, this evidence-based decision will improve screening for cervical cancer.

This decision is in accordance with the new EU guidelines currently in press and anticipates the update of the S3-guideline on screening for cervical cancer. Following the results of randomized controlled studies, countries such as the Netherlands, Belgium, Sweden, Spain, Italy, Estonia, Turkey, and Australia are switching to HPV testing while other countries are awaiting the results of ongoing pilot studies (England, Norway, Finland, Canada, and others). Such an organized and quality controlled concept is essential in preventive healthcare programs, and can contribute to the spread of HPV vaccination.

The AGO also welcomes the fact that clinical examinations to screen for breast and genital cancer are still being continued, as this will also ensure a high participation rate in the HPV tests done every 5 years. WOLPHSCREEN (Wolfsburg Primary HPV Screening Pilot Project), an innovative screening project rolled out by the insurance company Deutsche BKK, consists of an annual clinical examination and an HPV test done every 5 years; the take-up rate in the municipal area of Wolfsburg has been

more than 90% and it is very popular with insured women and gynecologists. In the period 2006–2011 the cumulative rate for CIN3+ was 0.9%; in the second round of screening, from 2011, this dropped to 0.05% [3].

The Gynecology Oncology Working Group (AGO e.V.) would like to point out that, based on the experience obtained with screening mammograms, organized screening with a population-based invitation to attend screening sessions results in socially balanced participation – which is currently not the case with screening for cervical cancer; this approach could be an opportunity to increase participation rates in screening [4].

## **Conflict of Interest**



P. H. received research grants from GSK, Abbott, and lecture fees from SPMSD, Roche, Hologic.

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