Thieme

# First Results for the Evaluation of the Cervical Cancer Screening Carried Out in 2021 and 2022 in the Context of the Organized Cancer Screening Program (oKFE): Part 1 – Primary Screening

## Erste Ergebnisse der Evaluation des Zervixkarzinom-Screenings für die Jahre 2021 und 2022 im Rahmen des organisierten Krebsfrüherkennungsprogramms (oKFE): Teil 1 – Primärscreening

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**ABSTRACT**

Organized cancer screening programs (oKFE) aim to detect and treat various cancers in their early stages. The German oKFE Directive has set out the requirements for evaluating the efficacy, quality, and safety of such programs. The first evaluation report on the cervical cancer screening program in Germany was published in May 2024 and covers the years 2021 and 2022. Women with statutory health insurance who are above the age of 20 and live in Germany are entitled to be screened for cervical cancer. Between the ages of 20 and 34 years, women are offered an annual cytology-based examination. From the age of 35 years and above, screening consists of a cytology examination and an HPV test (co-testing). The current evaluable data consists of pseudonymized data obtained from statutory health insurance companies and service providers as defined by the specifications of the IQTIG.

The evaluation shows that around three million women between 20 and 34 years of age undergo cervical cancer screening every year, which corresponds to a response rate of 45%. As regards the co-testing carried out in women aged 35 years and above, around 2.3 million women with statutory health insurance had cytological examinations and co-testing in 2021 and 1.3 million women were similarly examined in 2022. The participation rate for this cohort cannot yet be determined as the three-year interval for persons eligible for this type of screening cannot be depicted using only two years of data. 97% of cytology smears were unremarkable. Fewer than 0.1% of smears resulted in cytological findings indicating precancerous cervical lesions or cervical malignancies. The average positive rate for HPV tests carried out as part of co-testing was 8.56%. The high-risk human papilloma viruses 16/18 were identified in 30% of cases with positive HPV tests, and the presence of these high-risk viruses increased in parallel with an increase in the severity of cytological findings. More than 30% of insured women aged between 20 and 34 years have been fully vaccinated against HPV.

The limitations of this evaluation are the short observation period, some data gaps, and the not yet implemented combi-

nation of screening data with data from the cancer registries of the German federal states. It is not yet possible to make valid statements about the acceptance of the screening program and the long-term impact of this program.

**ZUSAMMENFASSUNG**

Organisierte Krebsfrüherkennung (oKFE) zielt auf frühzeitige Erkennung und Behandlung von Krebserkrankungen ab. Die oKFE-Richtlinie definiert Vorgaben zur Evaluation von Wirksamkeit, Qualität und Sicherheit der Programme. Der erste Evaluationsbericht zum Zervixkarzinom-Screening wurde im Mai 2024 veröffentlicht und umfasst die Datenjahre 2021 und 2022. Anspruchsberechtigt sind gesetzlich versicherte Frauen ab 20 Jahren. Zwischen 20 und 34 Jahren wird jährlich eine zytologiebasierte Untersuchung angeboten, ab 35 Jahren alle 3 Jahre eine Kombinationsuntersuchung aus Zytologie und HPV-Test (Ko-Testung). Die auszuwertende Datenbasis setzt sich aktuell aus pseudonymisierten Daten von Krankenkassen und Leistungserbringern zusammen, definiert durch die Spezifikationen des IQTIGs.

Die Auswertung zeigt, dass jährlich etwa 3 Millionen Frauen zwischen 20 und 34 Jahren am Screening teilnahmen, entsprechend einer Teilnahmerate von 45 %. Bei der Ko-Testung ab 35 Jahren nahmen 2021 rund 2,3 Millionen und 2022 etwa 1,3 Millionen weibliche Versicherte teil. Eine Teilnahmerate ist für diese Untersuchungsgruppe noch nicht bestimmbar, da das 3-Jahres-Intervall der Anspruchsberechtigung mit 2 Datenjahren nicht abgebildet werden kann. 97 % der Zytologieabstriche waren unauffällig. Die zytologischen Befundgruppen der unmittelbaren Vorstadien des Zervixkarzinoms und Malignome wurden in weniger als 0,1 % Abstrichen festgestellt. Der HPV-Test im Rahmen der Ko-Testung war durchschnittlich zu 8,56 % positiv. Bei 30 % der positiven HPV-Tests wurden die High-Risk-Viren 16/18 nachgewiesen, deren Präsenz mit steigendem Schweregrad der zytologischen Befunde zunimmt. Über 30 % der versicherten Personen im Alter von 20 bis 34 Jahren sind vollständig gegen HPV geimpft.

Limitationen dieser Evaluation sind der kurze Betrachtungszeitraum, noch fehlende Daten und die ausstehende Einbindung der Landeskrebsregister. Valide Aussagen zur Akzeptanz des Screening-Programms und zu Langzeiteffekten sind derzeit noch nicht möglich.

## Introduction

If detected early, cervical cancer is almost entirely avoidable and curable. The Papanicolaou smear (Pap smear) is the first precautionary screening procedure and has been used in Germany since 1971 as part of a statutory opportunistic cancer screening program (CS program) [1, 2]. The incidence and mortality for cervical cancer has decreased significantly since the introduction of this CS procedure [3].

The organized cancer screen program (oKFE) now used in Germany was introduced as a consequence of some historical decisions. In January 2019, the Federal Research Ministry of Germany (*Bundesforschungsministerium*, BMBF) initiated a National Decade Against Cancer (NDC) as a countermeasure against the predicted continuous increase in the number of new cases with cancer in Germany [4]. This resulted in changes to the previous process used for the early detection of cervical cancer in Germany, as it was felt that further action was still needed despite the drop in the number of new cases with cervical cancer [5]. Every year, just under 4500 women are still diagnosed with cervical cancer in Germany (Center for Cancer Registry Data, as at 2022) [6]. Since 2020, an organized cancer screening program (oKFE) has been implemented in Germany, based on the relevant directive issued by the Federal Joint Committee (*Gemeinsamer Bundesausschuss*, G-BA) [5]. The directive defines the invitation process, the examination methods, the intervals between examinations, the algorithms used to evaluate findings as well as processes for quality assurance, evaluation and safety of the program. Gesundheitsforen Leipzig GmbH was commissioned by the G-BA to be the independent review office which would accept, manage and evaluate the data collected in the context of the program.

Screening is generally carried out in people who probably do not have cancer. False-positive findings which then involve further examinations to clarify the results are associated with high levels of emotional stress until the final result is available [7, 8]. But the risks of the examination methods themselves must also be carefully weighed up against the desired benefit [9]. For this reason, a detailed evaluation report is compiled every two years for the G-BA. The report provides a continuous assessment of the program and suggests necessary optimizations [5, 10]. The report focuses on the questions specified in the directive regarding the acceptance of screening, its implementation, and the results of the different examinations. The existing framework conditions for screening such as the target population, data sources, analyzed parameters, and the validation of data are described in detail [10].

The first evaluation report on the cervical cancer screening program was published in May 2024 [10]. The report covers the data years 2021 and 2022 and represents an important milestone since the introduction of organized cancer screening.

This paper analyzes the first Germany-wide results of primary screening presented in the evaluation report. The existing limitations with regards to the collection and evaluation of data have been considered. This publication has three main goals. It aims to provide a concise overview of the comprehensive results obtained with both screening methods in the context of the organized cancer screening program for the early detection of cervical cancer: cytology-based primary screening (PSZ) of eligible women aged 20–34 years and primary screening combined with co-testing (PSK) of eligible women aged 35 years and above. It also aims to identify initial trends and key findings in the collected data and to attempt, based on these results, to provide a perspective for fu-

ture developments and possible implications with regards to cervical cancer screening.

## Material and Methods

### Legal basis for data collection

The legal basis for the Directive for Organized Cancer Screening Programs (*Richtlinie für organisierte Krebsfrüherkennungsprogramme*, oKFE-RL) was included in the German Social Security Code (SGB) in the form of Sec. 25a of Book V of the SGB. It was based on the law on the development of cancer screening and quality assurance and the use of clinical cancer registries (the Cancer Screening and Registries Act [*Krebsfrüherkennungs- und -registergesetz* [KFRG]] of 09.04.2013) [11]. The purpose was to address key recommendations of the German National Cancer Plan regarding the further development of cancer screening and to prepare the way for their implementation [12]. The organized cancer screening program for the detection of cervical cancer, which is based on the directive, started on January 1 st, 2020 [5].

### Database

The results of the primary screening carried out in the context of the organized cancer screening program presented here are from a database which uses two data sources. The first source are data from statutory health insurance companies which collect and store data in accordance with Sec. 284 para. 1 of the SGB V. This source also includes data from the facilities which issue invitations to attend screening. The data includes the insurance numbers of insured women (Sec. 290 of the SGB V), the date of issuing the invitation, the date of birth, the date of death, and possibly the date of any objections raised against being invited for screening. This data is then combined with data from the second source, which consists of data from service providers which has been pseudonymized. The data from service providers offers information about and results for the examinations carried out by gynecologists as well as the findings of the cytology laboratories. The third data source required by the oKFE Directive is data from the clinical cancer registries of the German federal states. This third source had not yet been linked to the other two at the time of compiling the results for the evaluation report and will only be available for assessment in the next evaluation report. For the period from 1 January 2020 to 30 September 2020, the documentation obligation was suspended following a decision of the G-BA which was approved by the German Ministry of Health (*Bundesministerium für Gesundheit*, BMG) [13]. This means that for 2020, only data from the 4 th quarter is available, making it impossible to provide a detailed look at the first data year of this newly initiated program. The data described in the following pages covers the data years 2021 and 2022. To ensure that the data in the database can be evaluated and is valid, data transfers from the above described data sources are carried out in accordance with binding specifications. The professional and technical specifications for the transfer of data used to evaluate the program in accordance with the oKFE-RL are developed by the Institute for Quality Assurance and Transparency in Healthcare (IQTIG). IQTIG was commissioned to develop them by the G-BA and they are published annually [14, 15]. How relevant data of the primary screening examinations is collected and transferred is specified by IQTIG. The data obtained using the screening methods specified by the oKFE-RL are recorded using documentation forms which are defined in the annual specifications of IQTIG [14, 15].

### Population

In accordance with the oKFE-RL, two cancer screening methods for primary screening are used to identify suspicious changes, cancers, and precancerous lesions. The aim is to detect and treat lesions as early and as best as possible [10, 16]. The entitlement to primary screening depends on the age of the woman [10, 16]. Women entitled to have screening examinations in accordance with the oKFE include all women insured by statutory healthcare companies (GKV) above the age of 20 years. This publication only reviews results obtained from primary screening examinations. The investigated population is divided into two age groups in accordance with the requirements of the oKFE Directive. For the group aged from 20 to 34 years, the results of cytology-based primary screening (PSZ) are reviewed, with all persons in this group entitled to have annual screening. For the group aged 35 years and above, the results of primary screening with co-testing (PSK) are reviewed, with all persons in this group entitled to have screening every three years. The test results for this group also include the results of HPV testing in addition to the findings of the Pap test [10, 16].

### Parameters

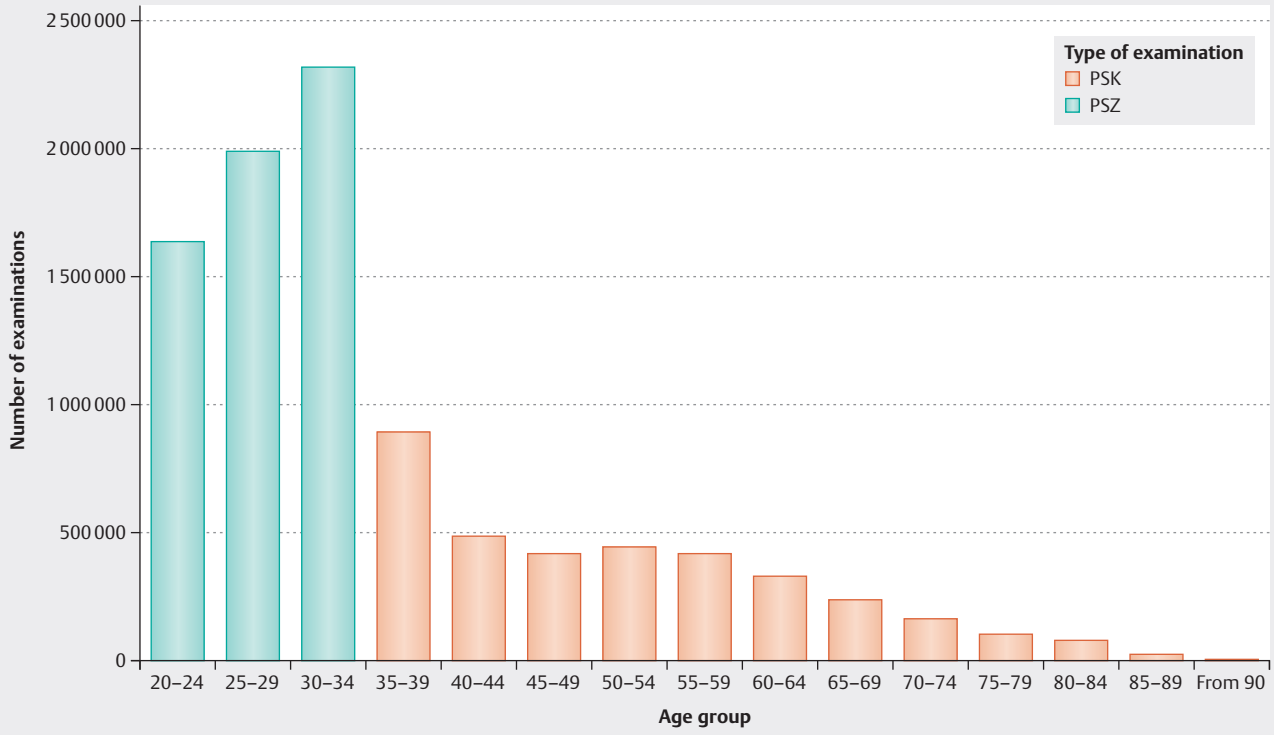
For this evaluation, the following parameters collected during primary screening examinations are presented descriptively: cytology results classified using the Munich Nomenclature III (MNK III) [17]; the results of HPV testing; the vaccination status. Data processing, the creation of tables, and the graphic representations of results were carried out using programming language R [18], Version 4.4.1. All graphics in the *Results* and *Discussion* chapters were created with ggplot2 [19].

Depending on the specific question, the analysis of results uses either data from the insurance companies or data from the type of examination.

## Results

The presented results were obtained from the comprehensive evaluation report on the organized cancer screening program for cervical cancer provided by the independent oKFE review office in 2023.

To evaluate the program, the oKFE-RL defined questions which could be answered using the collected data [16]. This *Results* chapter examines a few selected aspects which focus on primary screening. Key figures are the participation rates of persons who underwent screening and the number and distribution of the examination results from cytology and HPV testing. The data on HPV vaccinations in the context of primary screening is also considered.




▶ **Fig. 1** Number of persons entitled to screening above the age of 20 years investigated using primary screening (PSZ and PSK) in the years 2021 and 2022.

## Participation in primary screening: PSZ and PSK

In 2021 and 2022, just under 9.6 million (n = 9 565 414) entitled persons underwent primary screening in the context of the oKFE. Of these persons, around 5.2 million (n = 5 243 321) were screened in 2021 and 4.3 million (n = 4 322 093) were screened in 2022. This figure is based on data from insurance companies. This means that in this period, more than one screening examination (PSZ or PSK) may be recorded for a person insured with a statutory health insurance company (GKV).

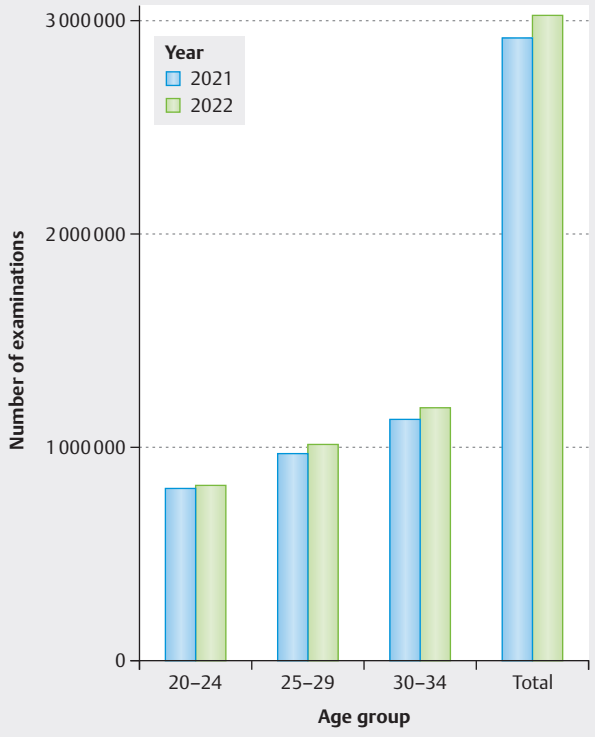
In the group of persons aged 20–34 years entitled to have screening, the number of women who had cytology-based screening (PSZ) increased with increasing age (▶ **Fig. 1**, turquoise bar). While 1.6 million women (n = 1 634 868) in the group aged from 20 to 24 years of age had cytology-based screening (PSZ), the figure for women aged from 25 to 29 years was just under 2 million (n = 1 989 109). About 2.3 million (n = 2 319 433) persons in the group aged 30 to 34 years had cytology-based screening (PSZ). The highest number of primary screening examinations using cytology and co-testing (PSK) carried out in the group aged 35 years and above was recorded for the group aged between 35 and 39 years, with more than 800 000 (n = 894 625) examinations carried out. The figures remained relatively constant for the group aged between 40 and 59 years with an average of 440 000 examinations carried out annually and then decreased with increasing age in the group above the age of 60 years (n = 332 063). The recorded figure for persons aged 90 and above who had screening was only just above 5000 (n = 5255) (▶ **Fig. 1**, red bar).

▶ **Fig. 2** presents the number of cytology-based cervical screening (PSZ) examinations per reporting year and age group and shows that about 3 million persons entitled to screening in the group aged from 20 to 34 years made use of the annual cytology-based primary screening they were entitled to each year. This corresponds to an approximate annual participation rate of 45 % of insured persons entitled to screening based on the KM 6 statistics (statistics about the number of persons insured by statutory insurance companies in Germany) [20]. It is currently difficult to calculate the annual participation rate for the cohort aged 35 years and above entitled to have PSK (screening with co-testing) because their participation cycle covers three years. Around 2.3 million women had screening with co-testing in 2021 and around 1.3 million women underwent screening with co-testing in 2022 (▶ **Fig. 3**). The participation rates (in percent) will only be available for this group of persons after data has been collected and reviewed for several years.

## Results of cytology-based primary screening for persons entitled to screening aged 20–34 years

Just under 6 million (n = 5 943 410) persons entitled to have screening had PSZ (cytology-based screening) in 2021 and 2022 (insurance-based data). Of these, 2.9 million (n = 2 918 836) insured persons were screened in 2021 and 3.0 million (n = 3 024 574) insured persons were screened in 2022 (▶ **Fig. 3**).

Over the two years, around 6.0 million (n = 6 062 254) Pap smears were taken for cytological examination (examination-




▶ **Fig. 2** Annual number of persons entitled to screening (aged 20–34 years) who had PSZ (cytology-based screening) in the years 2021 and 2022.

based data). In 228 149 cases, primary screening was recorded but no information about the results of the Pap smear was documented, meaning that there are no results available for 3.76 % of examinations. Of the 6.0 million samples, 0.38 % (n = 23 130) were classified as group 0. This category is used to describe technically unsatisfactory material which cannot be assessed. According to MNK III, the Pap smear is repeated in these cases.

After the number of results for all documented cytological examinations carried out in the context of PSZ (n = 6 062 254) was adjusted by subtracting the smears for which no findings were reported (n = 228 149, cytological findings "not reported"), a total of 5.8 million (n = 5 834 105) findings from cytology smears were available for evaluation for the years 2021 and 2022. Of these, 97 % (n = 5 650 042) were found to be unremarkable; 0.4 % (n = 26 375) were unremarkable but the medical history was suspicious; 2.3 % (n = 134 558) of findings were suspicious, and 0.4 % (n = 23 130) could not be assessed. Overall, 95.86 % of the documented PSZ smears could be evaluated.

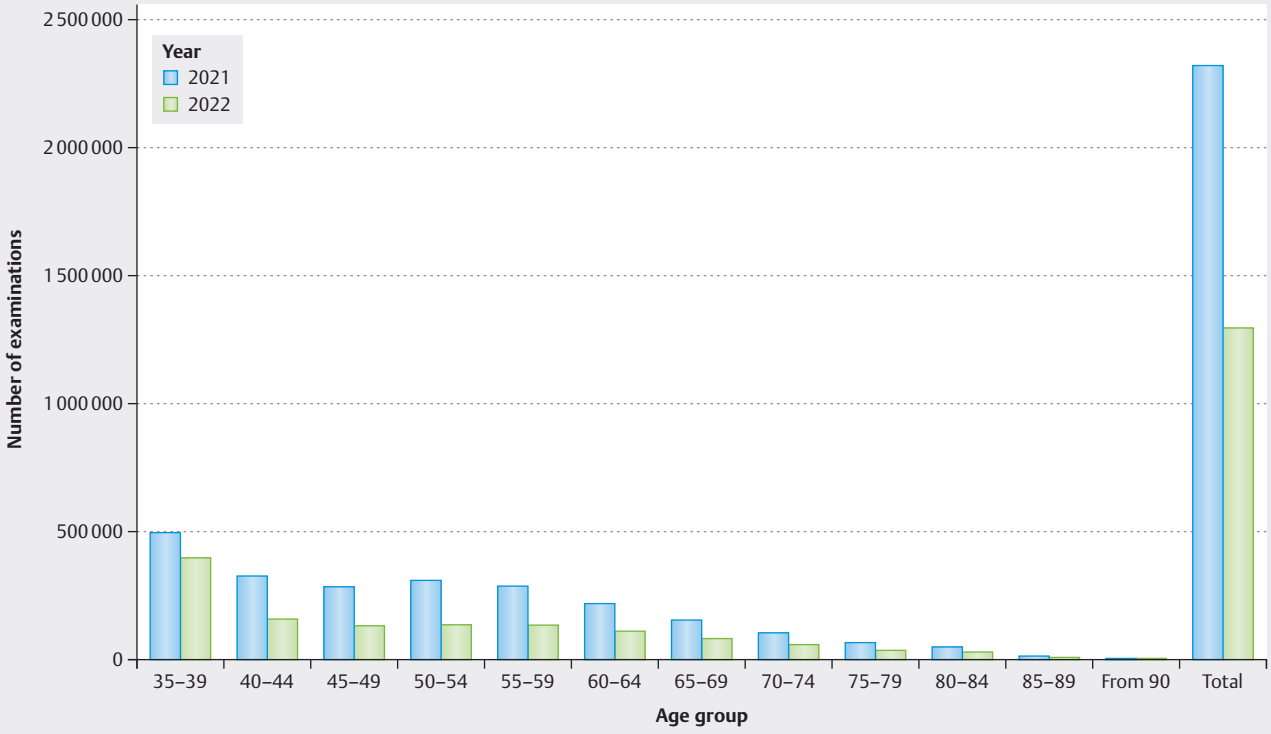
▶ **Table 1** provides an overview of all documented results for the cytological examinations carried out in the context of PSZ. Findings were classified as follows using the MNK III:

The majority of findings (93.20 %) were classified as group I (n = 5 650 042 smears), which means they were categorized as unremarkable. 2.23 % (n = 134 558) of findings were identified as suspicious and included precancerous lesions and malignancies. A very small percentage (0.44 %) were classified as II-a (n = 26 375 smears). This means that the findings were unremarkable but the medical history was suspicious.

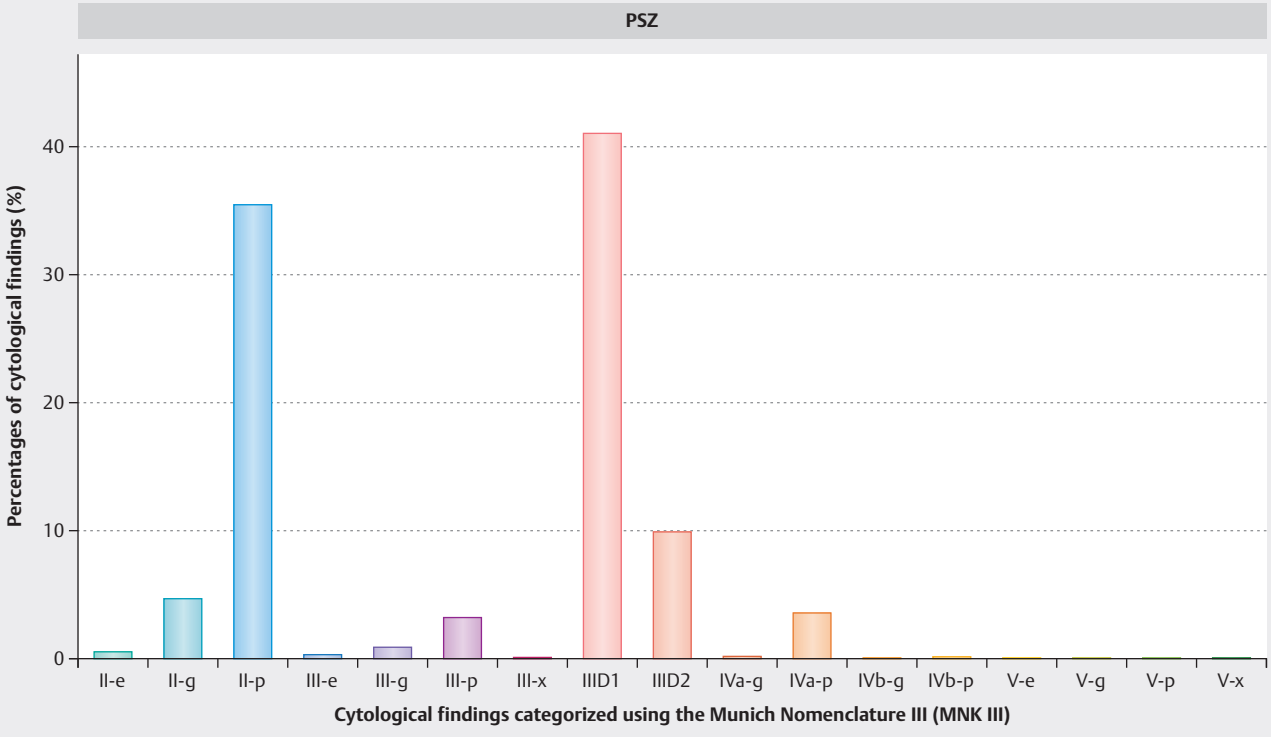
▶ **Fig. 4** shows the distribution of the different subgroup categories, given as percentages, for the group of suspicious findings detected in the context of cytology-based primary screening. Of the 134 558 suspicious findings, 41 % (n = 54 675) were categorized as having limited protective value (II-p, II-g and II-e). A further 41 % (n = 55 193) of smears were categorized as dysplastic findings with a greater tendency to regression and cell formation indicating slight dysplasia (IIID1, analogous to CIN 1). Just under 10 % (n = 13 338) were classified as dysplasia with a greater tendency to regression and cell formation indicating moderate dysplasia (IIID2, analogous to CIN 2). 4.46 % (n = 6006) of the smears were classified as unclear or doubtful findings (III-e, III-g, III-p and III-x). Precancerous stages of cervical cancer (IVa-g: adenocarcinoma in situ; IVa-p: severe dysplasia/carcinoma in situ, analogous to CIN 3; IVb-g: adenocarcinoma in situ, invasion cannot be excluded) or IVb-p (CIN 3, invasion cannot be excluded) were detected in 3.91 % (n = 5260) of suspicious smears. A total of 0.06 % (n = 86) of findings obtained during cytology-based primary screening were

▶ **Table 1** Results of the cytological examinations carried out in the context of PSZ (cytology-based screening) in 2021 and 2022 in persons aged from 20 to 34 years, classified using the Munich Nomenclature III.

| Cytological findings | Number | In percent |
|---|---|---|
| 0 | 23 130 | 0.38 154 % |
| I | 5 650 042 | 93.20 035 % |
| II-a | 26 375 | 0.43 507 % |
| II-e | 721 | 0.01 189 % |
| II-g | 6 281 | 0.10 361 % |
| II-p | 47 673 | 0.78 639 % |
| III-e | 435 | 0.00 718 % |
| III-g | 1 191 | 0.01 965 % |
| III-p | 4 294 | 0.07 083 % |
| III-x | 86 | 0.00 142 % |
| IIID1 | 55 193 | 0.91 044 % |
| IIID2 | 13 338 | 0.22 002 % |
| IVa-g | 270 | 0.00 445 % |
| IVa-p | 4 834 | 0.07 974 % |
| IVb-g | 28 | 0.00 046 % |
| IVb-p | 128 | 0.00 211 % |
| V-e | 5 | 0.00 008 % |
| V-g | 10 | 0.00 016 % |
| V-p | 35 | 0.00 058 % |
| V-x | 36 | 0.00 059 % |
| Not reported | 228 149 | 3.76 344 % |
| Total | 6 062 254 | 100.00 000 % |




▶ **Fig. 3** Annual number of persons entitled to screening (aged 35 years and above) who had PSK (screening with co-testing) in the years 2021 and 2022.




▶ **Fig. 4** Suspicious findings detected in cytological examinations carried out in persons aged from 20 to 34 years in the context of PSZ (cytology-based screening) in 2021 and 2022 and categorized using the Munich Nomenclature III (II-a to V-x). Results are given as percentages.

categorized as group V (malignancies) in both observation years. They included 35 findings classified as V-p (squamous cell carcinoma), 10 findings categorized as V-g (endocervical adenocarcinoma), 5 findings classified as V-e (endometrial adenocarcinoma) and 36 findings classified as V-x (other malignancies).

## Results of primary screening with co-testing in persons aged 35 years and above: part 1 – cytology

A total of more than 3.6 million (n = 3 622 004) insured women entitled to have screening were investigated in the years 2021 and 2022 using screening with co-testing (insurance-based data). Around 2.3 million (n = 2 324 485) women were examined in 2021 and just under 1.3 million (n = 1 297 519) were examined in 2022 (▶ **Fig. 3**).

Around 3.6 million (n = 3 656 645) smears were taken over the two years in the context of PSK (screening with co-testing) for cytological investigation in laboratories (examination-based data). No information was provided in 4.77 % (n = 174 536) of documented PSK examinations, meaning that no results were available for these cases. Of the 3.6 million samples, 0.45 % (n = 16 289) were classified as group 0 (inadequate material, recommendation to repeat the smear). Smears in this group are categorized as technically unsatisfactory and the smear must be repeated.

After the number of results for all documented cytological examinations carried out in the context of PSK (n = 3 656 645) was adjusted by subtracting the smears for which no findings were reported (n = 174 536, cytological finding "not reported"), a total of 3.4 million (n = 3 482 109) findings from cytology smears were available for evaluation for the years 2021 and 2022. Of these, 95 % (n = 3 323 303) were unremarkable; 1.0 % (n = 35 005) were unremarkable but the medical history was suspicious; 3.0 % (n = 107 512) of smears were suspicious, and 0.5 % (n = 16 289) could not be assessed technically. 94.78 % of all documented smears could be evaluated.

▶ **Table 2** provides an overview of all documented results of the cytological examinations carried out in the context of PSK (screening with co-testing). Findings were classified as follows using the MNK III:

The majority (90.88 %) of findings were categorized as group I (n = 3 323 303) and were therefore considered unremarkable. 2.94 % (n = 107 512) of smears carried out in the context of PSK (screening with co-testing) were identified as suspicious. A small percentage (0.95 %; n = 35 005 smears) were categorized as II-a, meaning that the findings were unremarkable but the medical history was suspicious.

▶ **Fig. 5** shows the distribution of the different subgroups, given as percentages, for the group of suspicious findings obtained in the context of primary screening with co-testing. Of the smears with suspicious findings (from II-e and findings "not reported", n = 107 512), 42 % (n = 45 140) were categorized as having limited protective value (II-p, II-g and II-e). About 28 % (n = 30 491) of suspicious smears were categorized as dysplastic findings with a greater tendency to regression and cell formation indicating slight dysplasia (IIID1, analogous to CIN 1). Just over 9 % (n = 9818) of suspicious findings were categorized as dysplasia with a greater tendency to regression and cell formation indicating moderate dysplasia (IIID2, analogous to CIN 2). Unclear or doubtful findings (III-e, III-g, III-p III-x) were detected in 12 % (n = 12 803) of suspicious cases. Precancerous stages of cervical cancer were detected in 7 % (n = 7638) of suspicious smears (IVa-g: adenocarcinoma in situ; IVa-p: severe dysplasia/carcinoma in situ, analogous to CIN 3; IVb-g: adenocarcinoma in situ, invasion cannot be excluded, and IVb-p: CIN 3, invasion cannot be excluded).

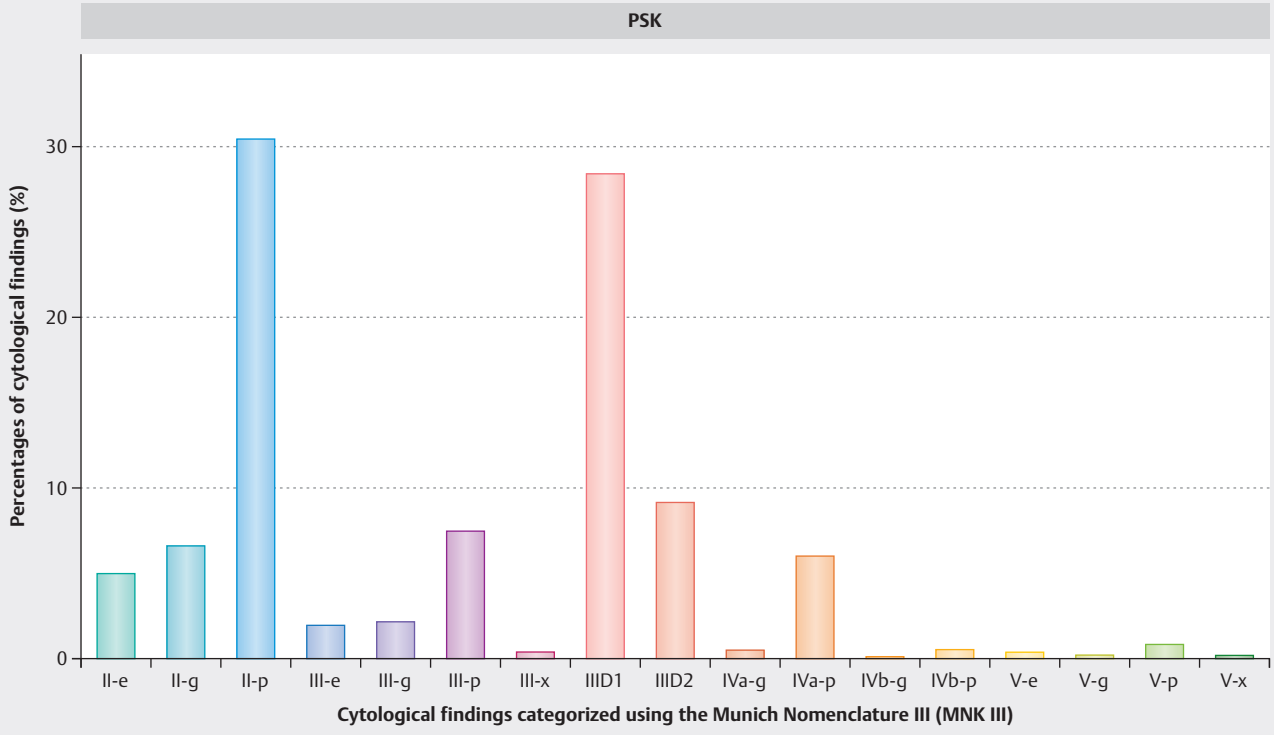
▶ **Table 2** Results of the cytological examinations carried out in persons aged 35 and above in the context of PSK in 2021 and 2022, classified using the Munich Nomenclature III.

| Cytological findings | Number | In percent |
|---|---|---|
| 0 | 16 289 | 0.44 546 % |
| I | 3 323 303 | 90.88 394 % |
| II-a | 35 005 | 0.95 730 % |
| II-e | 5 363 | 0.14 666 % |
| II-g | 7 094 | 0.19 400 % |
| II-p | 32 683 | 0.89 380 % |
| III-e | 2 073 | 0.05669 % |
| III-g | 2 278 | 0.06230 % |
| III-p | 8 014 | 0.21 916 % |
| III-x | 438 | 0.01198 % |
| IIID1 | 30 491 | 0.83 385 % |
| IIID2 | 9 818 | 0.26 850 % |
| IVa-g | 527 | 0.01441 % |
| IVa-p | 6 453 | 0.17 647 % |
| IVb-g | 97 | 0.00265 % |
| IVb-p | 561 | 0.01534 % |
| V-e | 379 | 0.01036 % |
| V-g | 202 | 0.00552 % |
| V-p | 888 | 0.02428 % |
| V-x | 153 | 0.00418 % |
| Not reported | 174 536 | 4.77 312 % |
| Total | 3 656 645 | 100.00000 % |

In both observation years, a total of 1.5 % (n = 1622) of cytological smears taken during primary testing using co-testing were identified as group V (malignancies). This included 888 findings classified as V-p (squamous cell carcinoma), 202 results categorized as V-g (endocervical adenocarcinoma), 379 findings classified as V-e (endometrial adenocarcinoma) and 153 findings categorized as V-x (other malignancies).

## Results of primary screening with co-testing in persons aged 35 years and above: part 2 – HPV tests

Testing for human papillomavirus (HPV) is part of cervical cancer screening with co-testing (PSK). All in all, around 3.6 million (n = 3 656 645) HPV tests were carried out and documented dur-




▶ **Fig. 5** Suspicious findings detected in cytological examinations carried out in persons aged 35 years and above in the context of PSK (screening with co-testing) in 2021 and 2022 categorized using the Munich Nomenclature III (II-a to V-x). Results are given as percentages.

▶**Table 3** Results of HPV testing carried out in the context of PSK in women aged 35 years and above (2021 and 2022)

| HPV test result | Number |
|---|---|
| Positive | 312878 (8.56%) |
| Negative | 3317553 (90.73%) |
| Cannot be evaluated | 25316 (0.69%) |
| Not reported | 898 (0.02%) |
| Total | 3656645 (100.00%) |

ing the two observation years of 2021 and 2022. Of these tests, 0.69% (n = 25316) could not be evaluated, and no information was provided for 0.02% (n = 898) of the tests (▶ **Table 3**).

A negative test result was reported for 90.73% (n = 3317553) of HPV tests carried out in the context of PSK and a positive test result was detected in 8.56% (n = 312878) of HPV tests (▶ **Table 3**). This means that out of 3.6 million documented HPV tests carried out in 2021 and 2022 in the context of PSK, infection with HPV was detected in fewer than 9%.

▶ **Table 4** presents the results of the cytological examinations carried out in the context of PSK. These results are juxtaposed with the relevant results from the related HPV tests. Of all the HPV tests carried out in the context of PSK, no information about the results of cytological screening was available for 174536 (4.77%) of tests. Of these tests, 89.78% (n = 156697) of tests were negative and 7.34% (n = 12815) were positive.

The results of around 3.3 million evaluable HPV tests (n = 3338991) are available for the groups with unremarkable and unsuspicious findings (I and II-a), excluding non-evaluable findings and cases where there is no information about the cytological findings or the HPV test result. 93.04% (3106621 of 3338991) of HPV tests were negative and 6.96% (232370 of 3338991) were positive when groups I and II-a were taken together. However, when group II-a was considered separately, it was very noticeable that more than half of the HPV tests of this group were positive (▶ **Fig. 6**). The HP virus was confirmed in 60.17% of cases (20665 of 34344), and the test result was negative in 39.83% (13679 of 34344) of cases.

The results of 106735 evaluable HPV tests (excluding findings which cannot be evaluated and cases where there is no information about the cytological findings or the HPV test) were available for all groups with suspicious cytological findings (IIe–IIp, III, IIID, IV, V). 62.21% (66400 of 106735) of these tests were positive and 37.79% (40335 of 106735) were negative. This means that the HPV-positive rate was about 10 times higher in cases with suspicious cytological findings compared to cases where the cytological findings were unremarkable (combined result for groups I and II-a).

▶**Table 4** Overview of the results of HPV testing for different groups of cytological findings identified during cervical cancer screening with co-testing (PSK) in 2021 and 2022 in women aged 35 years and above.

| **Cytological finding** Test result | **Positive** | **Negative** | **Cannot be evaluated** | **Not reported** | **Total** |
|---|---|---|---|---|---|
| 0 | 1293 | 13900 | 994 | 102 | 16289 (0.45%) |
| I | 211705 | 3092942 | 18143 | 513 | 3323303 (90.88%) |
| II-a | 20665 | 13679 | 658 | 3 | 35005 (0.96%) |
| II-e | 404 | 4910 | 49 | 0 | 5363 (0.15%) |
| II-g | 2446 | 4582 | 66 | 0 | 7094 (0.19%) |
| II-p | 18045 | 14378 | 258 | 2 | 32683 (0.89%) |
| III-e | 315 | 1725 | 22 | 11 | 2073 (0.06%) |
| III-g | 1262 | 1005 | 11 | 0 | 2278 (0.06%) |
| III-p | 6193 | 1775 | 46 | 0 | 8014 (0.22%) |
| III-x | 111 | 319 | 8 | 0 | 438 (0.01%) |
| IIID1 | 20958 | 9358 | 174 | 1 | 30491 (0.83%) |
| IIID2 | 8577 | 1186 | 54 | 1 | 9818 (0.27%) |
| IVa-g | 460 | 62 | 5 | 0 | 527 (0.01%) |
| IVa-p | 6136 | 290 | 26 | 1 | 6453 (0.18%) |
| IVb-g | 79 | 18 | 0 | 0 | 97 (0.00%) |
| IVb-p | 507 | 50 | 4 | 0 | 561 (0.02%) |
| V-e | 49 | 319 | 11 | 0 | 379 (0.01%) |
| V-g | 97 | 98 | 7 | 0 | 202 (0.01%) |
| V-p | 717 | 155 | 15 | 1 | 888 (0.02%) |
| V-x | 44 | 105 | 4 | 0 | 153 (0.00%) |
| Not reported | 12815 | 156697 | 4761 | 263 | 174536 (4.77%) |
| Total | 312878 (8.56%) | 3317553 (90.73%) | 25316 (0.69%) | 898 (0.02%) | 3656645 (100.00%) |

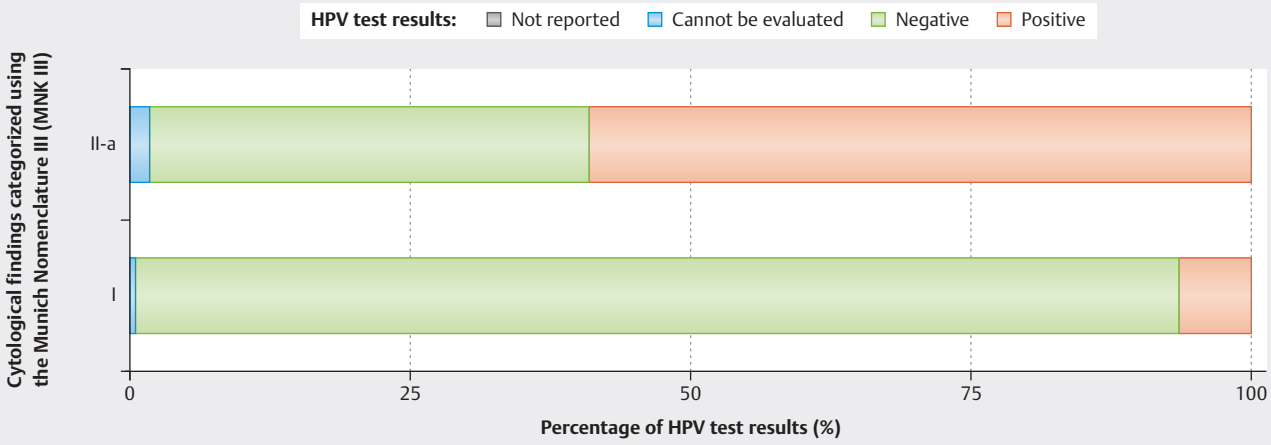
In the groups with cytology findings with limited protective value or unclear or doubtful findings (II and III) we noted that percentages of positive test results were recorded for the respective p-subgroups (▶ **Table 4**, ▶ **Fig. 7**). Positive results were recorded less often for the subgroups e, g and x. This did not apply to group III-g. About half of the tests in this group were negative (1005 of 2267 tests) and half were positive (1262 of 2267 tests), excluding findings which could not be evaluated and cases where information about the cytological results or the HPV test results was missing.

The results of 40079 evaluable HPV tests carried out in the context of PSK were available for the IIID group with dysplasia and a greater tendency to regression (this figure excludes non-evaluable findings and cases where information about the cytological findings or the HPV test result are missing). 30316 results of HPV tests were available for group IIID1 and 9763 were available for group IIID2. The HPV-positive rate for IIID1 was 69% (20958 of 30316). In the IIID2 group, the percentage of positive test results was significantly higher with 88% (8577 of 9763) (▶ **Fig. 7**).

The results of 7602 evaluable HPV tests were available for the group with cytological results showing precancerous cervical lesions (IV according to the MNK III). This figure excludes non-evaluable findings and cases where information about the cytological findings or the HPV test results are missing. An HPV infection was detected in 94.48% (7182 of 7602) of tests from all four subgroups. 5.52% (420 of 7602) of tests were negative (▶ **Table 4**). Again, a particularly high percentage of positive HPV test results was identified in the p subgroups (IVa-p and IVb-p) (▶ **Fig. 7**).

The results of 1584 evaluable HPV tests were available for the group with cytological findings classified as malignancies (V) according to the Munich Nomenclature III. When all four subgroups (V-e, V-g, V-p, V-x) were taken together, HPV infection was identified in 57.26% (907 von 1584) of tests, while 42.74% (677 of 1584) of tests were negative for HPV. When the cytological findings of the subgroups were considered separately, the percentage of positive HPV tests was only higher in the V-p subgroup (▶ **Fig. 7**), with HPV confirmed in 82.22% of tests (717 of 872). The subgroups V-g, V-e and V-x had more negative test results (< 50%) (▶ **Table 4**).

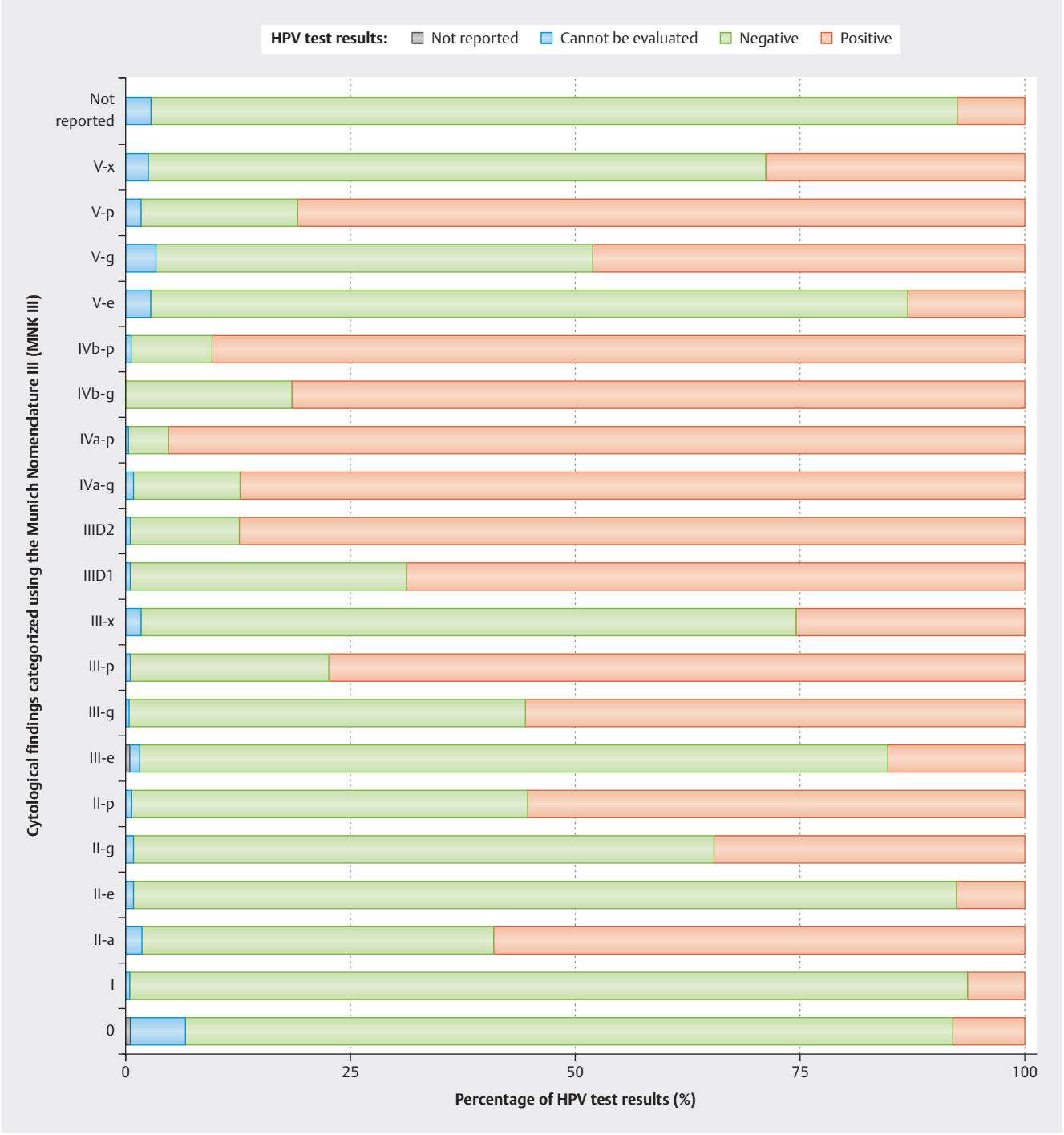
When all positive HPV samples were examined for the high-risk HPV types 16/18, HPV types 16/18 were confirmed in around one third of samples (32.38%; 101320 of 312878) (▶ **Table 5**). HPV




▶ **Fig. 6** Graphical comparison of cytological findings and HPV test results for groups I and II-a in % (cervical screening with co-testing [PSK] carried out in 2021 and 2022 in women aged 35 years and above).

▶**Table 5** HPV types 16/18 detected in positive HPV tests carried out in the context of cervical screening with co-testing (PSK) in women aged 35 years and above (2021/2022).

| Cytological findings | HPV type 16/18 yes | HPV type 16/18 no | Virus type cannot be differentiated | Total |
|---|---|---|---|---|
| 0 | 390 | 786 | 117 | 1293 |
| I | 63690 | 125263 | 22752 | 211705 |
| II-a | 5480 | 12780 | 2405 | 20665 |
| II-e | 113 | 246 | 45 | 404 |
| II-g | 998 | 1237 | 211 | 2446 |
| II-p | 6211 | 9833 | 2001 | 18045 |
| III-e | 144 | 140 | 31 | 315 |
| III-g | 677 | 488 | 97 | 1262 |
| III-p | 3006 | 2688 | 499 | 6193 |
| III-x | 60 | 42 | 9 | 111 |
| IIID1 | 7161 | 11631 | 2166 | 20958 |
| IIID2 | 3940 | 3846 | 791 | 8577 |
| IVa-g | 303 | 128 | 29 | 460 |
| IVa-p | 3757 | 1945 | 434 | 6136 |
| IVb-g | 57 | 17 | 5 | 79 |
| IVb-p | 340 | 127 | 40 | 507 |
| V-e | 30 | 18 | 1 | 49 |
| V-g | 63 | 29 | 5 | 97 |
| V-p | 495 | 182 | 40 | 717 |
| V-x | 24 | 17 | 3 | 44 |
| Not reported | 4381 | 6869 | 1565 | 12815 |
| Total | 101320 (32.38%) | 178312 (56.99%) | 33246 (10.63%) | 312878 (100.00%) |




▶ **Fig. 7** Graphical comparison of cytological findings and HPV test results for groups 0 to V in % (cervical screening with co-testing [PSK] carried out in 2021 and 2022 in women aged 35 years and above).

types 16/18 were not detected in around 60% (n = 138 043) of cases in the groups with unremarkable cytological findings (I and II-a). Both high-risk variants were identified in just under 30% (69 170 of 232 370) of investigated samples from these groups. The percentage of HPV types 16/18 increased when cytological abnormalities classified as group III or above increased (▶ **Table 5**). The only exception was subgroup IIID1 in which only around 38% (7161 of 118 792) of smears were positive for the high-risk HPV types 16/18 with the two high-risk viruses not found in more than 60% (11 631 of 18 792) samples. HPV types 16/18 were present in just over half of the samples categorized as IIID2 (50%, 3940 of 7786) and were not detected in just under half (49%, 3846 of 7786).

▶**Table 6** Documented HPV vaccination status for different cytological groups categorized using the MNK III. Data were collected in 2021/2022 in the context of PSZ (cervical cancer screening carried out in women aged 20–34 years).

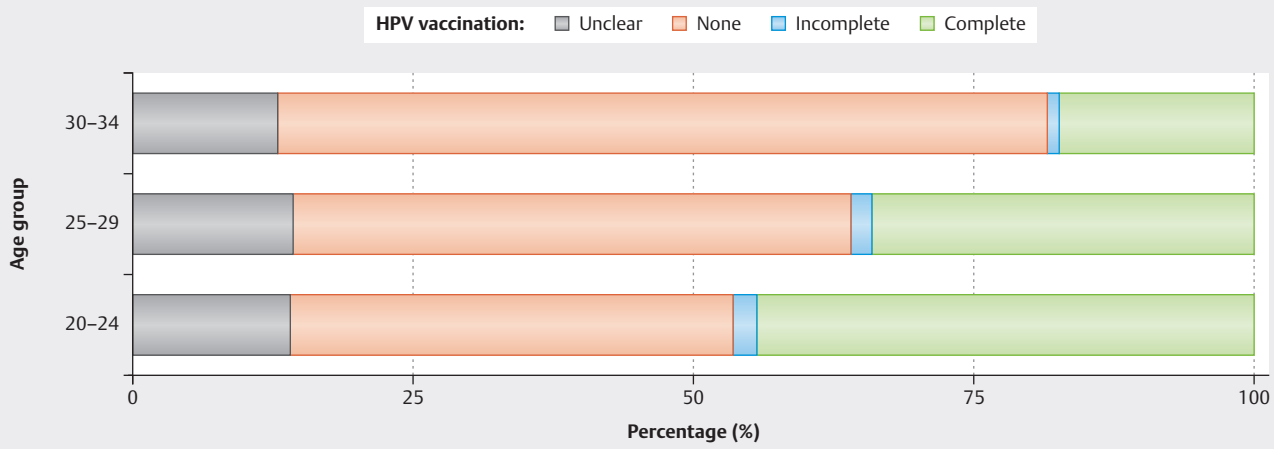
| Cytological findings – vacc. status | Complete | Incomplete | None | Unclear | Not reported | Total |
|---|---|---|---|---|---|---|
| 0 | 5587 (0.30%) | 296 (0.29%) | 12712 (0.39%) | 4520 (0.54%) | 15 (28.85%) | 23130 (0.38%) |
| I | 1723611 (94.01%) | 94690 (92.75%) | 3058417 (92.97%) | 773301 (92.37%) | 23 (44.23%) | 5650042 (93.20%) |
| II-a | 7531 (0.41%) | 810 (0.79%) | 14444 (0.44%) | 3590 (0.43%) | 0 (0.00%) | 26375 (0.44%) |
| II-e | 183 (0.01%) | 16 (0.02%) | 408 (0.01%) | 114 (0.01%) | 0 (0.00%) | 721 (0.01%) |
| II-g | 1542 (0.08%) | 104 (0.10%) | 3814 (0.12%) | 821 (0.10%) | 0 (0.00%) | 6281 (0.10%) |
| II-p | 14108 (0.77%) | 924 (0.91%) | 25837 (0.79%) | 6804 (0.81%) | 0 (0.00%) | 47673 (0.79%) |
| III-e | 119 (0.01%) | 9 (0.01%) | 245 (0.01%) | 60 (0.01%) | 2 (3.85%) | 435 (0.01%) |
| III-g | 225 (0.01%) | 11 (0.01%) | 783 (0.02%) | 172 (0.02%) | 0 (0.00%) | 1191 (0.02%) |
| III-p | 759 (0.04%) | 75 (0.07%) | 2814 (0.09%) | 646 (0.08%) | 0 (0.00%) | 4294 (0.07%) |
| III-x | 19 (0.00%) | 1 (0.00%) | 56 (0.00%) | 10 (0.00%) | 0 (0.00%) | 86 (0.00%) |
| IIID1 | 16058 (0.88%) | 1071 (1.05%) | 30025 (0.91%) | 8039 (0.96%) | 0 (0.00%) | 55193 (0.91%) |
| IIID2 | 2924 (0.16%) | 255 (0.25%) | 8212 (0.25%) | 1947 (0.23%) | 0 (0.00%) | 13338 (0.22%) |
| IVa-g | 25 (0.00%) | 5 (0.00%) | 201 (0.01%) | 39 (0.00%) | 0 (0.00%) | 270 (0.00%) |
| IVa-p | 579 (0.03%) | 57 (0.06%) | 3436 (0.10%) | 762 (0.09%) | 0 (0.00%) | 4834 (0.08%) |
| IVb-g | 2 (0.00%) | 0 (0.00%) | 24 (0.00%) | 2 (0.00%) | 0 (0.00%) | 28 (0.00%) |
| IVb-p | 9 (0.00%) | 1 (0.00%) | 93 (0.00%) | 25 (0.00%) | 0 (0.00%) | 128 (0.00%) |
| V-e | 1 (0.00%) | 1 (0.00%) | 2 (0.00%) | 1 (0.00%) | 0 (0.00%) | 5 (0.00%) |
| V-g | 3 (0.00%) | 0 (0.00%) | 4 (0.00%) | 3 (0.00%) | 0 (0.00%) | 10 (0.00%) |
| V-p | 2 (0.00%) | 0 (0.00%) | 26 (0.00%) | 7 (0.00%) | 0 (0.00%) | 35 (0.00%) |
| V-x | 9 (0.00%) | 1 (0.00%) | 22 (0.00%) | 4 (0.00%) | 0 (0.00%) | 36 (0.00%) |
| Not reported | 60095 (3.28%) | 3768 (3.69%) | 127938 (3.89%) | 36336 (4.34%) | 12 (23.08%) | 228149 (3.76%) |
| Total | 1833391 (100.00%) | 102095 (100.00%) | 3289513 (100.00%) | 837203 (100.00%) | 52 (100.00%) | 6062254 (100.00%) |

## HPV vaccination status in the group of women entitled to have screening aged 20–34 years

Considering when the vaccines were first approved and the availability of vaccinations, the HPV vaccination status in the group of women aged between 20 and 34 years is particularly interesting. The birth cohort of 1990 is the first age group in which a significant number of insured women could already be vaccinated. The vaccination status was determined in the context of the oKFE and was confirmed by a certificate of vaccination or was based on information voluntarily disclosed by the insured women. There are no detailed scientifically collected data on HPV vaccination status in Germany.

When all of the 6062254 recorded primary screenings of the group aged from 20 to 34 years (PSZ) were reviewed, no information about their vaccination status was available for < 0.01% (52 of 6062254). The vaccination status was not clear for 13.81% (837203 of 6062254) of screenings. No information about the cytological results was available for 3.76% (228147 of 6062254) of the documented examinations. These cases are not included in the further evaluation below, as they cannot be categorized in accordance with MNK III. This leaves 5834105 examination results for which possible connections between cytological findings and vaccination status can be reviewed. More than half (54.19%) of the women for whom cytological findings were available (3161575 of 5834105) had not been vaccinated against HPV. About 30.40% (1773296 of 5834105) of women screened in the context of PSZ aged between 20 and 34 years had been fully vaccinated against HPV. Incomplete vaccination status was recorded for 1.69% (98327 of 5834105) of women screened in the context of PSZ (▶ **Table 6**).

When the group of women entitled to have PSZ screening were divided into three age groups, an increasing trend to vaccination was found in the younger age groups. In the youngest group, aged 20 to 24 years, 44% had already been fully vaccinated. In the group of women aged 30 to 34 years only 17% of examined women were fully vaccinated (▶ **Fig. 8**). It became clear that if women were vaccinated, they were almost always fully vaccinated. Only a very small percentage of investigated women (< 2% in all three age groups) had only had a single vaccination and were therefore not fully vaccinated and lacked full vaccination protection.




▶ **Fig. 8** HPV vaccination status of women who underwent PSZ screening in 2021 and 2022 (aged between 20 and 34 years), grouped according to age. Data are given in percent.

## Discussion

It is important to ensure that the gratifying decline in the number of new cases with cervical cancer is not merely maintained but reduced even further [21]. This was why the structured cancer screening program for the early detection of cervical cancer was set up in 2020. The aim of establishing qualitative monitoring using data-driven assessments of the available measures is to ensure that the program will be developed further at a professional and organizational level.

The decisive part is participation in screening. As outlined in the oKFE-RL, persons entitled to be screened are invited to attend a screening appointment and provided with information about the screening. The aim is to motivate persons entitled to have screening to make full use of the available screening and significantly increase screening rates. The participation rates for cytology-based primary screening in the group of women aged from 20 to 34 years was about 45 % for both of the investigated data years (2021 und 2022), based on the KM 6 statistics. Because of the new data pool and changes in screening entitlement, a direct comparison with data collected in the years prior to 2020 is possible only to a limited extent. A study using healthcare data from the German federal state of Lower Saxony revealed an annual participation rate for cervical cancer screening of about 50 % for the period from 2006 to 2011 [22]. However, this rate can only serve as a rough orientation because participation rates vary across the different German federal states in this period and not all federal states had set up organized screening programs in the period under review. If we look at an organized cancer screening program in Germany where participants are invited to attend and which has existed for a long time such as the mammography screening program, the participation rates are similar. In 2021, 3 031 022 women out of 5 887 028 invited women participated in the mammography screening program. When women who self-request screening are included in the assessment, then 51.5 % of all invited women participated [23]. In the period from 2005 to 2021, when the mammography screening program was implemented in its current form, the participation rate levelled off at around 50 % after some initial fluctuations. The somewhat lower participation rates reported for the first two years of the newly established organized screening program for cervical cancer does not necessarily indicate that participation rates are actually decreasing. This was borne out when the billing figures provided by the National Association of Statutory Health Insurance Physicians in Germany (*Kassenärztliche Bundesvereinigung*, KBV) for cytology-based primary screening for the year 2019 (Physicians Fee Schedule [*EBM*] code 01730: 4 076 811) were compared with those of 2021 (*EBM* codes 01760 and 01761: 3 748 074). Instead, it must be assumed that participation was underestimated, as the data for 2020 which was the year of the changeover could not be included in the analysis. Whether the reorganization and the switch to issuing invitations for screening will result in a gradual increase in participation rates will only be clear in the coming years when longer measurement periods will be available for analysis. At the moment, the figures indicate that the focus with regards to women entitled to have cervical screening in the context of PSZ should be on motivating younger women to take part.

An assessment of the participation rates for primary screening with co-testing of women aged 35 and above is currently not possible, as they are only entitled to have screening every three years and the data for 2020 could not be included in this analysis. The second cycle of invitations issued to attend cervical cancer screening appointments will cover the period from 2023 to 2025. When this data is evaluated, it will be possible to start interpreting the data on the participation rates of women aged 35 years and above and to consider whether measures to increase participation rates would be feasible, and if so, which ones.

The findings of just under 96 % of the around 6 million Pap smears obtained in the context of PSZ screening could be evaluated. No information on the findings was available for just over 3 % of examinations. 0.4 % of samples were categorized as 0, which

means that they were considered technically unsatisfactory, non-evaluable samples. This low percentage is similar to the figures reported for the years 2017 to 2019 [24]. About 97% of evaluable smears obtained in the context of PSZ, excluding findings for which no information was provided, were categorized as unremarkable or not suspicious (group I according to MNK III). These results correspond to reference data from 2019 where about 97% of cytological findings were classified as group I according to MNK III [24]. All other cytology subgroups identified in the context of cervical cancer screening were under 1%, respectively. The percentage of findings obtained in 2021 and 2022 in the context of cytology-based screening which were categorized as group IV or V (MNK III) was less than 0.01% for each subgroup, with the exception of subgroup IVa-p (0.08%) (▶ **Fig. 9**). Again, these results are similar to the reference data for 2019 presented by Schenck et al. in 2023, in which all subgroups (with the exception of subgroup IVa-p which was 0.15%) were recorded as < 0.01% in the annual statistics. The focus in the coming years will be on findings classified as group IV and V. When the data from the newly introduced general screening program is compared with the reference data, it is important to be aware of the scope of the data used in the annual statistics for 2019 [24]. In addition to the cytological results obtained from primary screening and from examinations carried out to investigate suspicious findings, the statistics for 2019 also include findings obtained in the context of birth control as well as the results of curative cytological examinations.

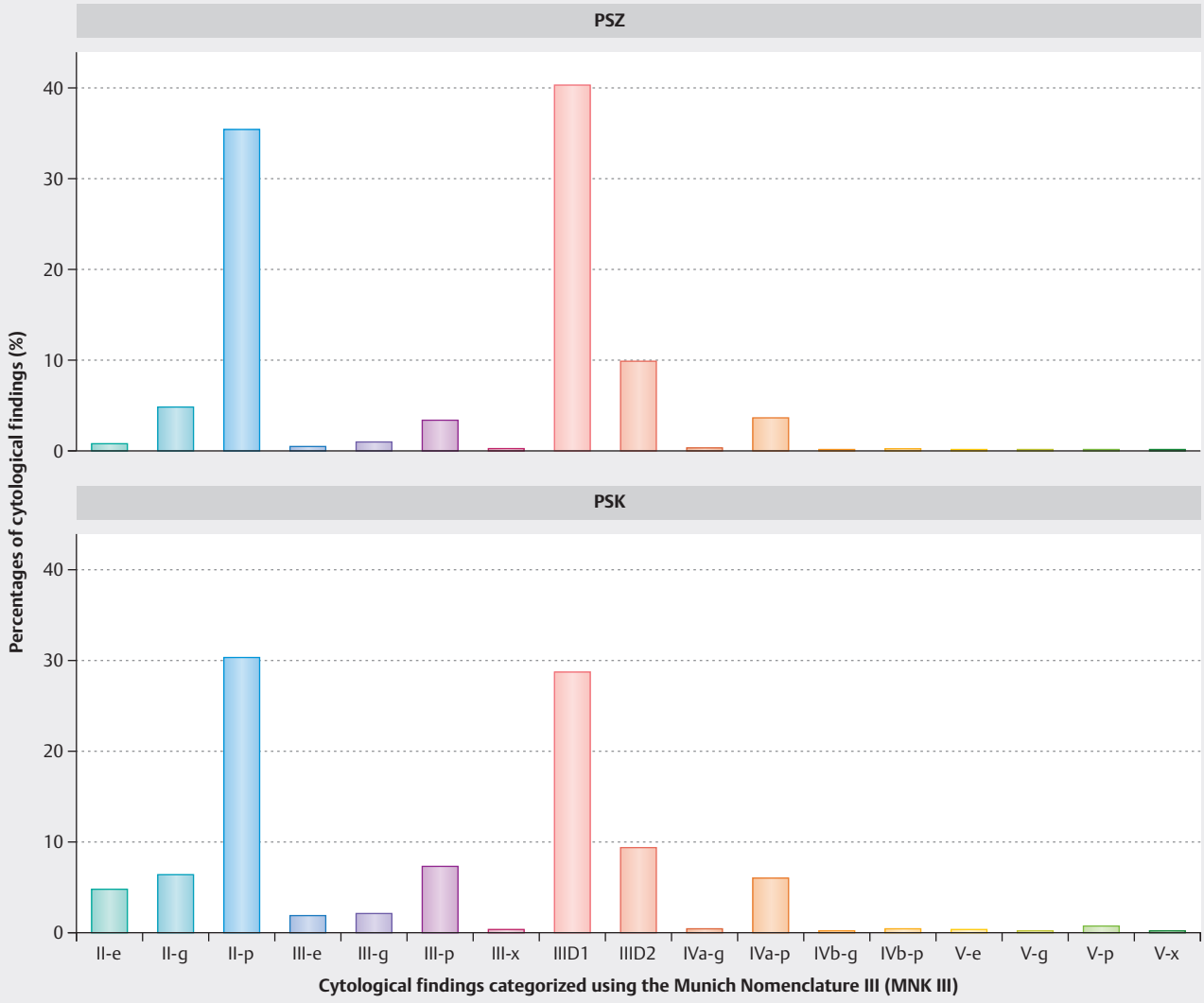
The evaluation report includes just under 3.6 million cytological examinations carried out in 2021 and 2022 in women aged 35 and above in the context of primary screening with co-testing (PSK). Similar to the data obtained from screening carried out in the context of cytology-based screening (PSZ), about 95% of smears could be evaluated. No information on findings was available for about 5% of examinations. 0.4% of samples were categorized as 0, which means they were technically unsatisfactory, non-evaluable samples. Again, the majority (95%) of the examinations carried out in the context of PSK were unremarkable or not suspicious (group I according to MNK III) after the findings for which no information was available had been subtracted. A comparison with the reference data from 2019 [24] showed similar trends. All other subgroups identified during screening examinations carried out in the context of PSK were less than 1%, and only a few cytological findings of precancerous lesions and cervical malignancies were detected. The highest percentage of any subgroup in groups IV and V were findings categorized as IVa-p (0.176%). A comparison with the reference data (IVa-p: 0.146%) shows that the figures for 2019 were similar [24]. Findings classified as group IV or V were found more often in the group of women aged 35 and above investigated in the context of PSK compared to women aged 20 to 34 years investigated in the context of PSZ. The higher percentage of findings categorized as IV-p in the group of women aged 35 years and above is particularly noticeable (▶ **Fig. 9**). This development will need to be monitored in future.

The percentage of positive HPV tests increased as the severity of cytological findings increased from group II to group IV (MNK III). The highest positive rate in all groups was recorded for p-type findings. This trend increased significantly from group II to group V. However, findings categorized as V-g and V-p where the HPV test results were negative need to be examined more closely. Around 50% of HPV tests for the subgroup classified as V-g and about 20% of HPV tests for the subgroup categorized as V-p were negative. These suspicious findings were discovered through combined screening. This will need to be monitored and critically reviewed when the data is analyzed in the years to come.

Out of 6.0 million examinations carried out in the context of PSZ (cytology-based screening) 86 findings were identified and categorized as V-g (endocervical carcinoma). Out of 3.7 million examinations carried out in the context of PSK (screening with co-testing), 1622 findings were identified and categorized as V-g (endocervical carcinoma). The clear difference between these figures showing cytological evidence of carcinoma in the two cohorts can be largely explained by the age difference between the two groups. In general, cervical cancer occurs less often in younger women below the age of 35 years. The incidence of cervical cancer increases with increasing age and peaks between the ages of 35 and 55 years [25, 26].

In almost all cases, cervical cancer is caused by HPV [27]. According to the RKI guideline on the human papillomavirus, the currently available HPV vaccines provide almost 100% protection against infection with the HPV types contained in the vaccines [28]. This means that recording the vaccination status when documenting cytology results is relevant. It is important to be aware that this data is based on information obtained from vaccination cards or from self-disclosure by the insured woman herself and is therefore neither comprehensive nor was it collected scientifically. The fact that more than 30% of insured persons between 20 and 34 years are fully vaccinated against HPV is positive. In view of the data on the severity of cytological findings and the number of positive HPV tests, the importance of HPV vaccinations must be stressed, and further evaluation of this data in the coming years will be useful. Conclusions with regards to possible correlations are currently not meaningful because of the small number of cases and the limitations of the data.

The first assessment of the effectiveness of the newly developed screening program for the early detection of cervical cancer faces a number of challenges. The transition year 2020 was not included in the data collection, some of the data on the results of examinations was incomplete, and not all cancer registries of the German federal states had been linked to the program at the time of the first data evaluation for the years 2021 and 2022. Because of these limitations, it is currently not possible to make reliable statements about key issues. The coronavirus pandemic in 2020–2022 also had an impact. In Germany, the effects were appreciable, but the extent of the impact varied. Adults were more affected by cancellations and postponements of appointments. In contrast, screening examinations and vaccination rates of children remained largely stable with only slight delays [29, 30]. Questions about the acceptance of the screening program by the target group and the effect of issuing invitations to attend screening on participation rates can therefore only be answered after a longer observation period. An informed assessment of the organized screening program will only be possible when the data basis has been completed and data from the cancer registries of the federal states has also been included in the evaluation. Until then, this first evaluation of the new program must be viewed with caution.




▶ **Fig. 9** Comparison of the distribution of unclear and suspicious smears categorized according to MNK III for findings obtained with cytology-based screening (PSZ) and findings obtained from primary screening with co-testing (PSK) collected in 2021 and 2022. Data are presented in percent.

## Conclusions and Outlook

The process of setting up the conditions to merge data from different sources for the oKFE program and this first evaluation has highlighted some areas where data is still missing as well as certain limitations.

The implementation and initial evaluation of the oKFE program show that there are still some gaps in the data and some methodological limitations. But it has provided valuable starting points which can be used to improve the program further and achieve its objectives. It will be necessary to identify the causes of data discrepancies as this will improve the comprehensiveness and quality of the data. But the focus in the coming years will also be on developing more essential questions to advance the program and bring it closer to its goals. The successful integration with the cancer registries of the federal states, completed in June 2024, is another milestone of the oKFE program.

The results show that a comprehensive and meaningful data basis has been established. This will make it possible to answer key questions in future and to potentially investigate other important aspects. The constant increase in data will reinforce this trend. All parties involved cooperated constructively and were highly committed. The common goal was to ensure that future analyses will be targeted and effective and to optimize the program.

## Note

The Federal Joint Committee (G-BA) provided the framework for the screening program for the early detection of cervical cancer in its directive on organized cancer screening programs (*Richtlinie für organisierte Krebsfrüherkennungsprogramme*, oKFE-RL). The service provider Gesundheitsforen Leipzig GmbH was commissioned by the G-BA with setting up, operating and developing the oKFE review office (oKFE-AS) to evaluate the quality of the oKFE programs.

The authors have no material or immaterial conflicts of interest. The authors acted entirely autonomously during the preparation and writing of this article. All authors are employees of Gesundheitsforen Leipzig GmbH, an independent healthcare service provider.

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## Conflict of Interest

The authors declare that they have no conflict of interest.

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