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Anxiety and borderline PAP smear results

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ABSTRACT

Purpose: Low-grade abnormalities after cervical cancer screening, i.e. borderline (Pap 2) or mildly (Pap 3a1) dyskaryotic (BMD) smear results, are found in considerable numbers of women annually. We compared quality of life and anxiety in women with BMD and a reference group of screening participants who were awaiting smear taking.

Methods: Five hundred and fifty women with BMD in the preceding 6–24 months, identified through a regional screening organisation, were sent a questionnaire addressing generic quality of life (12-item Short-Form Health Survey [SF-12], EuroQol classification [EQ-5D]), generic anxiety (STAI-6) and screen-specific anxiety (Psychological Consequences Questionnaire [PCQ]).

Results: After adjustment for differences in background characteristics, women with BMD ($n = 270$) reported more generic anxiety (44.4 versus 32.6) and screen-specific anxiety (5.0 versus 1.4) than the reference group ($n = 352$). The differences indicated statistical ($p < 0.001$) and clinical significance. High anxiety (STAI-6 > 44) was reported by 49% of the BMD group. Mental quality of life was worse in the BMD than in the reference group (44.2 versus 52.0, $p < 0.001$). The BMD group considered screening more often frightening (27% versus 10%) and reported 'fear for cervical cancer' more frequently as their reason for having a (repeat) smear taken (62/270, 23% versus 12/346, 4%).

Conclusion/discussion: BMD smears were consistently associated with considerable excess anxiety in the period of 6–24 months after the original BMD Pap smears had been taken.

1. Introduction

Cervical cancer screening as a population-based prevention policy is organised in many European and other countries. Such programmes aim to reduce cervical cancer mortality by early detection and treatment of pre-invasive (i.e. cervical intraepithelial neoplasia, CIN) or early invasive disease. If high-grade abnormalities are found, i.e. moderately dyskaryotic smears or worse, women are referred for colposcopy and further gynaecological evaluation. However, low-grade abnormalities, i.e. borderline (Pap 2) or mild (Pap 3a1) dyskaryosis (BMD), are much more common. In the Netherlands in 2003, 0.5% of screen participants had high-grade cytological abnormalities while 1.8% of participating women had a BMD smear.[1,2] In Sweden, BMD smears also occur in about 2% of the participating women,[2] while BMD smear results occur in about 7% of the cases in the United Kingdom (UK) and in Finland.[2,3] In most countries these women are advised to have a repeat smear taken after 6 months. If BMD then persists, or the abnormality increases in severity, women are referred for a colposcopy. They are told that their smear showed 'minor' abnormalities that may or may not regress spontaneously

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and that a repeat smear is required. In an Australian qualitative study ($n = 29$) women experienced abnormal smear tests as alarming and often distressing.[4] In a Swedish study on 242 women who had had 2 consecutive Pap smears diagnosed with mild dysplasia 5 years earlier, 59% reported feelings of worry and anxiety. Five years after the atypical smear tests there were no signs of remaining anxiety, but 8% of women reported a remaining negative influence on their sexual life. For 30% of the respondents the abnormal smear affected everyday life between being informed of the result of the first Pap smear test and subsequent further investigation.[5]

In the UK the psychological impact of BMD smear test results was assessed in three groups of women whose BMD smears were HPV-positive, HPV-negative or untested for HPV, respectively, and a fourth group with normal smears. At 6-month follow-up concern about the smear results was found to be highest in the group of women that was untested for HPV ($n = 102$). The strongest predictor of concern across the three groups with BMD smear results was the perceived risk of developing cervical cancer, while other predictors were being HPV-positive or untested for HPV, sexual health and the smear test being a woman's first smear test.[3] Roughly half of the adult women in Europe are invited to have a smear test done at least once every 5 years. Because of the large numbers involved, even a small adverse effect per woman may result in a considerable negative impact.

We aimed to assess generic health-related quality of life (HRQoL), physical and mental health and (screen-specific) anxiety in women at 6–24 months after a BMD smear result. We assessed why these women agreed to have a repeat smear taken after a BMD smear and their opinions on the cervical cancer-screening programme. We compared the reported questionnaire outcomes to those of a reference group, consisting of women who recently participated in the screening programme. The smear results of the latter group were still unknown at the time they completed the questionnaire.

We hypothesised that the BMD group would have a similar physical health as the screen participants and a slightly worse mental health, and that they would experience more generic and screen-specific anxiety. We also hypothesised that the more recent a BMD smear had been taken the more anxiety and screen-specific anxiety would be reported.

2. Materials and methods

2.1. Selection of respondents

Between April and August 2006 we conducted a cross-sectional survey in cooperation with the regional screening organisation in Maastricht (The Netherlands). Two groups of respondents were addressed by the screening organisation: women with BMD smear results and a reference group.

2.2.1. Women with BMD smear results

Five hundred and fifty women who participated in the Dutch cervical cancer-screening programme with a borderline (Pap 2) or mildly (Pap 3a1) dyskaryotic (BMD) Pap smear result in the previous 6–24 months were sent a questionnaire. The overall response rate was 49% ($n = 270$).

2.2.2. Reference group

To enable an interpretation of the generic HRQoL, generic anxiety and screen-specific anxiety scores of the BMD group we included a reference group. A questionnaire was sent to a randomly selected group of women (aged 30–60 years, stratified in 10-year age groups) who were due for the next round in the screening programme, attached to their invitation for the Pap smear test. The overall response rate was 44%. When the women of the reference group completed the questionnaire, smear tests had not been carried out yet and smear results were still unknown. For reasons of comparability with the BMD group, only women who subsequently had a smear taken were eligible for inclusion in the present study ($n = 352$). This reference group will be referred to as 'screen participants'.

2.3. Sending of questionnaire

The screening organisation addressed women from both groups with a questionnaire (see below for further details) and an accompanying letter, asking women to complete and return the questionnaire. Women were assured that non-participation did not have any consequences for their follow-up care or treatment. If the questionnaire was not returned within a month, a reminder-letter was sent.

This study was part of a comprehensive evaluation of the Dutch cervical cancer-screening programme. The ethics review committee of the Erasmus MC, University Medical Center Rotterdam, approved the research protocol.

2.4. Respondents' characteristics

Information on marital status, education, comorbidity, job status and country of birth was obtained through the questionnaire. Educational level was classified as low (primary school or lower technical education), intermediate or high (college/university degree). Comorbid conditions at the time of the survey were assessed though a slightly adapted version of the Charlson comorbidity index. Data on the amount of time that had elapsed between the BMD smear and completion of the questionnaire were obtained through the regional screening organisation. To assess non-response bias we compared the average age of the respondents with that of the non-respondents.

2.5. Content of the questionnaire

The questionnaire included validated measures on generic HRQoL, generic anxiety and screen-specific anxiety.

Generic HRQoL was assessed through the EuroQol classification (EQ-5D) and the 12-item Short-Form Health Survey (SF-12). The EQ-5D classification consists of 5 items (mobility, self-care, usual activities, pain/discomfort and anxiety/depression). Classification scores can be linked to a utility score with 0 indicating 'death' and 1 indicating 'full health'.[6] The EQ-5D is complemented by a visual analogue scale on current health, the Valuation of Own Health, which is anchored at the lower end (0) by 'worst imaginable health state' and at the upper end (100) by 'best imaginable health state'. The SF-12 consists of 12 items in the physical and mental do-

mains. Information from all 12 items is used to construct physical and mental component summary measures (PCS-12 and MCS-12).[7] These measures are scored using norm-based methods, where the mean and standard deviation (SD) are 50 and 10 in the general US population. A one-point difference can be interpreted as one-tenth of a SD.[8] Age- and sex-adjusted SF-12 norm scores are available from Statistics Netherlands.[9]

Generic anxiety was assessed by the STAI-6, a validated short version of the State Trait Anxiety Inventory containing 6 items on, e.g. feeling at ease or upset. Higher scores (20–80) indicate higher levels of generic anxiety.[10,11] A STAI-state score of over 44 defines an individual as highly anxious.[12]

To measure the psychological impact of a BMD smear in women we used the Psychological Consequences Questionnaire (PCQ). The PCQ was developed to measure the consequences of breast screening on three dimensions, i.e. emotional, physical and social functioning. Corresponding subscales contain 5, 4 and 3 items, respectively.[13] Ratings for symptoms within each dimension vary from 0 (not at all) to 3 (quite a lot of time). The added ratings indicate the level of dysfunction with higher scores indicating more dysfunction. Since the three subscales are highly correlated and measure the same concept of adverse psychological consequences,[14] we also report an overall PCQ score (score range 0-36). We used the Dutch version as adapted by Rijnsburger and colleagues.[15]

We measured women's attitudes towards cervical cancer screening through an attitude scale, adapted from Marteau's multidimensional measure for informed choice.[16] The scale, consisting of 9 items with five response categories each, addressed cervical cancer screening being perceived as e.g. frightening versus reassuring, or important versus unimportant. To facilitate interpretation, results were transformed to 0–100 scores. Because we agree with Van den Berg and colleagues,[17] that mid-point scale responses do not reflect a positive or negative attitude, we classified the mid-point of the scale (45–55) as 'neutral attitude'. Scores below 45 were classified as negative attitude, and scores above 55 were classified as positive attitude.

Anticipated regret and worry in case a smear would not have been taken were assessed using 2 items with five response categories ranging from 'no, certainly not' to 'yes, certainly'.

Perceived risk of developing cervical cancer was assessed through an item on women's perceptions of their likelihood of ever being diagnosed with cervical cancer, with five response categories ranging from 'a very small risk' to 'a very big risk'.

Finally, the questionnaire included items on reasons for having or not having a (repeat) smear taken.

2.6. *Statistical analyses*

If respondents had completed at least 50% of the items per scale, missing items in the STAI-6, the PCQ and in the scale on attitude towards cervical cancer screening were imputed to maximise the use of the available data. This procedure is performed according to the guidelines of the SF-36 Health Survey Manual.[18]

Differences between the groups in background variables, in HRQoL, generic and screen-specific anxiety scores, and in general attitude towards preventive health care were assessed using Mann Whitney *U* tests for continuous variables and Chi-square tests for categorical ones. We conducted regression analyses including group, age at survey, job status, marital status, having children or not and country of birth in the analyses as covariates, since the differences between the two groups of respondents for these variables were statistically significant.

We tested the relationship between generic anxiety and screen-specific anxiety scores on the one hand and the time period that had elapsed since the BMD smear on the other hand by comparing scores of women who had a BMD smear 6–12 months before completion of the questionnaire versus 12–18 months versus 18–24 months. Furthermore, we compared HRQoL and anxiety scores between women whose first smear was BMD versus women who had at least one normal smear before their BMD smear result. The associations between perceived risk of cervical cancer and generic HRQoL, mental health, generic anxiety and screen-specific anxiety were assessed through ANOVA.

To indicate clinical significance we used the minimal important difference (MID), defined as the smallest change in a patient-reported outcome that is perceived by patients as beneficial or that would result in a change of treatment. MID was operationalised as a difference of at least half a standard deviation.[19]

Statistical analyses were performed using SPSS for Windows, version 15. A p-value less than 0.05 (referring to two-sided statistical tests) was considered significant.

3. Results

Background variables differed significantly between the BMD group and the reference group (Table 1). Women with a BMD smear ($n = 270$) were younger (43 versus 46 years), had a paid job more often and had children less often than the screen participants ($n = 352$). The average age of women from the BMD group who responded to the questionnaire did not differ significantly from that of women who did not respond (43.2 versus 41.9 years, respectively, $p = 0.07$).

The raw PCS-12 scores of women with a BMD smear were significantly higher, thus indicating better functioning, than the reference group (Table 2). They were also higher than the age-adjusted norm scores for the female Dutch population of 50.5 (Statistics Netherlands). The raw MCS-12 scores, however, were lower, indicating worse functioning, in women with a BMD than in the reference group (Table 2) and the general population, i.e. 51.8 (Statistics Netherlands).

Raw average STAI-6 and PCQ scores were higher in women with a BMD smear than in the screen participants, indicating more generic and more screen-specific anxiety, respectively, in the BMD group.

After adjustments for differences in age at survey, job and marital status, having children or not and country of birth, the differences between groups were still statistically significant, and in the same direction as unadjusted comparisons, considering physical health summary (PCS-12) scores, mental

Table 1 – Background characteristics of respondents, observed scores in numbers and percentages, unless otherwise indicated.

	Women with BMD (n = 270)		Screen participants (n=352)		p-Value
Age (years)					<0.001
Average (SD)	43.0 (7.9)		46.1 (9.3)		
Median	41.6		45.0		
Range	30–62		29–60		
Education					0.28
Low	39	16%	73	22%	
Medium	132	56%	177	53%	
High	67	28%	86	26%	
Job status					0.009
Paid job	168	74%	209	64%	
No job	26	11%	33	10%	
Retired	0		7	2%	
Housewife/unpaid job/student	34	15%	76	23%	
Marital status					0.003
Married/cohabiting	188	74%	285	85%	
Partner, but living alone	24	10%	13	4%	
No partner	41	16%	39	12%	
Children					0.008
No	69	26%	57	17%	
Yes	198	74%	278	83%	
Average no., range	2, 1–8		2, 1–4		
Country of birth					<0.001
The Netherlands	247	93%	321	99%	
Country of birth of parents					
Father born in the Netherlands	235	89%	313	99%	<0.001
Mother born in the Netherlands	243	91%	312	99%	<0.001
Both parents of non-Dutch origin	19	7%	4	1%	<0.001

BMD smear = borderline (Pap 2) or mild (Pap 3a1) dyskaryosis.

health summary (MCS-12) scores, STAI-6 and all 3 PCQ subscale scores and its overall scale score (all $p < 0.001$). Differences in MCS-12 scores, STAI scores, the overall PCQ score and one of the PCQ subscale scores exceeded the minimal important difference (MID), indicating clinical significance (Table 2). Forty-nine percent of the BMD group reported anxiety scores indicating high anxiety (STAI-6 > 44).

We found no statistically significant differences in generic anxiety, screen-specific anxiety and quality of life scores between women who had a BMD smear 6–12 months earlier versus 12–18 months versus 18–24 months (Table 3). When comparing women whose first smear was BMD to women who had had at least one normal smear before their BMD result, we found a significantly increased generic anxiety ($p = 0.04$) and decreased mental health ($p = 0.02$) in the first group. Other measures did not differ between these two groups (data not given in the table). Anxiety scores did not differ between age groups.

Both respondent groups reported positive attitudes towards the cervical cancer-screening programme (Table 4). However, 27% of women with BMD considered screening frightening versus 10% of the reference population and women with BMD reported fear for cervical cancer more often as their reason for having a (repeat) smear taken ($p < 0.001$). Both respondent groups reported benefit of early detection and the expected reassurance of a favourable screening result as their main reasons for having a Pap smear taken (Table 4).

The perceived risk to be ever diagnosed with cervical cancer was higher in women with BMD than in screen participants ($p < 0.001$); 12% of women with BMD considered their risk (very) large versus 3% of the screen participants (Table 4). Perceived risk of developing cervical cancer was found to be associated with generic HRQoL (EQ-5D) ($p = 0.004$) and with screen-specific anxiety ($p = 0.005$), but not with mental health (MCS-12) ($p = 0.12$) or generic anxiety ($p = 0.18$).

4. Discussion

Having had a BMD smear was found to be associated with excess generic anxiety, excess screen-specific anxiety and a worse mental health (MCS-12) at 6–24 months after the initial BMD smear. The differences in the scores exceeded the MID, suggesting clinical significance. The differences were consistently larger than expected and could not be attributed to differences in background variables between the groups.

Twelve percent of women with BMD versus 3% of the screen participants perceived their risk of developing cervical cancer as (very) big, indicating that the cervical cancer risk is perceived as a real threat in the BMD group. In reality, however, the a priori lifetime risk to develop cervical cancer is very low in the Netherlands, i.e. 0.6%.[20] In the first 12 months following a BMD smear, 1.3 per 1000 women were diagnosed with cervical cancer in the Netherlands.[21]

Table 2 – Mean scale scores (SD) of women with BMD and participants in cervical cancer screening (Pap smear). The first column of p-values indicates the significance level of differences in observed scores, and the second column of p-values indicates the significance level of differences between groups in scores after adjustment for differences in age at survey, job and marital status, having children or not and country of birth.

	Women with BMD (n = 270)	Screen participants (n = 352)	p-Value before adjustment	Differences between scores after adjustment	Meaning of result for women with BMD	p-Value after adjustment
Generic HRQoL						
EuroQoL						
EQ-5D (0–1)	0.87 (0.21)	0.89 (0.19)	0.10	–0.01	BMD group worse generic HRQoL	0.66
Rating of own heatlh (0–100)	78.8 (14.7)	81.7 (14.9)	0.002	–1.4	BMD group worse self-rated health	0.28
SF-12 (0–100)						
Physical health (PCS-12)	54.0 (9.0)	51.4 (9.7)	<0.001	+3.0	BMD group better physical health	<0.001
Mental health (MCS-12)	44.2 (8.0)	52.0 (9.5)	<0.001	–7.4[a]	BMD group worse mental health	<0.001
Generic anxiety						
STAI-6 (20-80)	44.3 (5.1)	32.6 (9.7)	<0.001	+ 12.1[a]	BMD group more generic anxiety	<0.001
Screen-specific anxiety						
PCQ						
Emotional scale (0–15)	2.6 (3.7)	0.9 (1.9)	<0.001	+1.4	BMD group	<0.001
Physical scale (0–12)	1.3 (2.4)	0.4 (1.2)	<0.001	+0.7	more screen	<0.001
Social scale (0–9)	1.1 (1.9)	0.2 (0.8)	<0.001	+0.7[a]	specific	<0.001
Total score (0–36)	5.0 (7.4)	1.4 (3.4)	<0.001	+3.0[a]	anxiety	<0.001

BMD = borderline (Pap 2) or mild (Pap 3a1) dyskaryosis.

a Differences exceed the minimal important difference (MID).

Table 3 – Observed generic quality of life scale scores (SD) of women with BMD, for the whole group and per time period passed between a BMD smear and completion of questionnaire. p-Values indicate the significance level of differences in observed scores between groups that had BMD 6–12 months, 12–18 months or 18–24 months previously.

	Women with BMD (n = 270)	6–12 months after BMD (n = 93)	12–18 months after BMD (n = 93)	18–24 months after BMD (n = 84)	p-Value
EuroQol					
EQ-5D (0–1)	0.87 (0.21)	0.87 (0.19)	0.89 (0.22)	0.84 (0.22)	0.11
Rating of own health (0–100)	78.8 (14.7)	80.1 (13.6)	78.5 (16.1)	77.8 (14.3)	0.47
SF-12 (0-100)					
Sumscore physical	54.0 (9.0)	53.2 (9.6)	54.6 (9.2)	54.4 (8.1)	0.58
Sumscore mental	44.2 (8.0)	43.9 (8.3)	44.5 (7.8)	44.1 (8.1)	0.72
STAI-6 (20-80)					
Mean (SD)	44.3 (5.1)	44.9 (4.8)	44.0 (5.3)	44.1 (5.1)	0.42
PCQ					
Emotional scale (0–15)	2.6 (3.7)	2.7 (3.5)	2.7 (3.6)	2.5 (3.9)	0.58
Physical scale (0–12)	1.3 (2.4)	1.4 (2.5)	1.3 (2.2)	1.2 (2.5)	0.74
Social scale (0–9)	1.1 (1.9)	1.2 (1.9)	1.0 (1.6)	1.2 (2.2)	0.91
Total score (0–36)	5.0 (7.4)	5.2 (7.2)	4.9 (6.8)	4.9 (8.3)	0.67

BMD smear = borderline (Pap 2) or mild (Pap 3a1) dyskaryosis.
EuroQol and SF-12: higher scores indicate *better* functioning; STAI-6 and PCQ: higher scores indicate *worse* functioning.

Table 4 – Attitude towards the cervical cancer-screening programme assessed through a 5-point scale, main reasons for having a smear taken, anticipated regret and worry in case no smear would have been taken, and perceived risk of cervical cancer among women with BMD and a reference group of screen participants.

	Women with BMD (n = 270)		Screen participants (n = 352)		p-Value
Attitude towards cervical cancer screening					0.26
Positive	245	97%	328	98%	
Neutral	6	2%	7	2%	
Negative	2	1%	–		
Reasons for having a smear taken					
Benefit of early detection	204	76%	299	86%	0.001
A good result is reassuring	169	63%	197	57%	0.16
Fear for cervical cancer	62	23%	12	4%	<0.001
To prevent regret	57	21%	68	20%	0.47
Belly problems	27	10%	10	3%	<0.001
Regret in case smear is not taken					0.012
Certainly/probably not	14	5%	16	5%	
Neutral	34	13%	21	6%	
Yes, probably/certainly	211	82%	307	89%	
Worried in case smear is not taken					0.15
Certainly/probably not	39	15%	59	17%	
Neutral	53	20%	53	16%	
Yes, probably/certainly	170	65%	229	67%	
Perceived own risk to be diagnosed with cervical cancer experienced as…					<0.001
(Very) small	59	22%	136	41%	
Small nor big	178	66%	191	57%	
(Very) big	31	12%	9	3%	

BMD smear = borderline (Pap 2) or mild (Pap 3a1) dyskaryosis.

We did not find an association between the time interval since the BMD smear had been taken and the level of adverse psychological consequences. This may have to do with the policy in the region. According to the Guidelines of the Dutch Pathology Association on cervical cancer screening a BMD smear has to be followed up by a repeat smear after 6 months at the most, and again after another 12 months. Consequently, most of the women with BMD in this study probably had had at least one repeat smear taken when they completed the questionnaire. Population-based data from 1999 showed that within 9 months after a BMD result 74% of women did have their advised repeat smear taken. These repeat smears led to a referral to the gynaecologist in at least 31% of the cases.[2] Unfortunately, the outcomes of the repeat smears

in the BMD group in our study are unknown to us. From the questionnaire data we learned that 40% of the women in the BMD group had been referred to a gynaecologist for further evaluation, probably after a repeat smear with a persistent BMD or worse result. We expect that only a small number of women had cervical cancer, since in the Netherlands, 1.3 per 1000 women are diagnosed with cervical cancer in the first year after a BMD result.[21]

Our results confirm findings from previous research that was often performed in small samples. Like Maissi and colleagues we found an association between increased generic anxiety and the BMD smear being a woman's first smear. Since HPV testing after abnormal smears was no current practice within the cervical cancer-screening programme in the Netherlands at the time of data collection, the majority of women with BMD in the current study were assumingly untested for HPV. This implies no reassurance because of a HPV-negative status, as found by Maissi and colleagues,[3] nor concern about a HPV-positive status.

The strengths of our study are the population-based unselected sample of women with BMD, the large number of respondents ($n = 270$) and the presence of a reference group of screen participants. Additional strengths are the use of standardised, valid measures, and the combination of generic and more specific measures.

Limitations of our study are the absence of data on repeat smears and the cross-sectional nature of our data. Although reported mental health, generic anxiety and screen-specific anxiety were consistently and significantly worse in women with BMD than in screen participants, the data do not allow causal inference on relations between having had a BMD smear and adverse psychological outcomes. Longitudinal data are needed to address these relationships. The response rate of 49% was rather low. We do know that the average age of non-responding women did not significantly differ from that of women who did respond. However, data on age of non-respondents are too limited to assess the presence or absence of a non-response bias, and therefore our results cannot necessarily be generalised to the whole group of women with BMD.

The results of this study show the extent of the burden of a BMD result plus its follow-up regimen on the subjected women. It shows the importance of weighing these effects against the possible benefits when issuing guidelines on the definition of a BMD smear, i.e. the cut-off between a negative and a positive smear. In the Dutch situation, for instance, a wider definition of a negative smear was adopted in the Guidelines of the Dutch Pathology Association on cervical cancer screening in 1996. This change resulted in a decrease from 10% to less than 2% in BMD rate and did not lead to an increased risk for cervical cancer in the first 6 years after a negative smear.[22] Based on the current results the question is raised whether the burden of screening can be reduced by informing women better on the meaning and the seriousness of their BMD smear result.

We showed that even Pap smear results that were borderline abnormal can be considerable burdensome for women. This burden of screening will grow after the introduction of HPV screening, since that will lead to increased numbers of abnormal screen results.

5. Conclusion/discussion

We conclude that a BMD smear result was associated with excess anxiety, even 6–24 months after the Pap smears had been taken.

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Conflicts of interest statement

One of the authors, Marjolein van Ballegooijen, was principal investigator in a project on cost effectiveness of HPV vaccination, financed by GSK (a pharmaceutical company that produces HPV vaccines).

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