ORIGINAL ARTICLE

Self-Testing of Vaginal pH to Prevent Preterm Delivery

A Controlled Trial

Eva-Maria Bitzer, Andrea Schneider, Paul Wenzlaff, Udo B. Hoyme, Elisabeth Siegmund-Schultze

SUMMARY

Background: From 2004 to 2006, in a model project carried out by four German health insurers, expectant mothers were offered self-testing of vaginal pH in order to prevent preterm delivery. They were given pH test gloves on request so that they could measure their vaginal pH twice a week from the 12th to the 32nd week of gestation. They were instructed to consult with a gynecologist after any positive result. All further diagnostic or therapeutic decisions were at the discretion of the treating gynecologist. We assessed the effectiveness of the screening intervention, using delivery before the 37th week of gestation as the primary endpoint.

Methods: In this prospective, controlled trial, we collected data on deliveries from 2004 to 2006 that were covered by the four participating insurers in five German federal states. We compared the outcomes of pregnancy in women who did and did not request test gloves (intervention group, [IG], and control group, [CG]). The data were derived from claims data of the participating insurers, as well as from a nationwide quality assurance auditing program for obstetrics and perinatal care. Propensity score matching and multivariate adjustment were used to control for the expected self-selection bias.

Results: The study sample comprised 149 082 deliveries. 13% of the expectant mothers requested test gloves, about half of them up to the 16th week of gestation. As expected, women with an elevated risk of preterm birth requested test gloves more often. Delivery before the 37th week of gestation was slightly more common in the intervention group than in the control group (IG 7.97%, CG 7.52%, relative risk 1.06, 95% confidence interval 1.00–1.12). This result was of borderline statistical significance in the propensity score matched analysis, but it was not statistically significant in the multivariate model.

Conclusion: This trial did not demonstrate the efficacy of self-testing of vaginal pH for the prevention of preterm delivery (< 37 weeks of gestation).

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Bacterial vaginosis (disturbance of the micro-biological balance of the flora of the female genital tract) is regarded as a risk factor for a multitude of obstetric, gynecological, and neonatal complications. Prospective studies have shown significant correlations with preterm delivery, spontaneous abortion in the second trimester, and low birthweight. Review articles on this topic have produced similar results (1, 2): they show that bacterial vaginosis is associated with a higher risk of birth before the 37th week of gestation (< 37 + 0 gestational week, GW) with odds ratios (OR) = 1.85 and OR = 2.05 (95% confidence interval [CI]: 1.62–2.11 and 1.67–2.50 respectively) (1) or 2.40 (95% CI: 1.63–3.54) (2).

The effectiveness of annual screening by a (specialist) physician for bacterial vaginosis is under debate. A prospective, randomized, controlled study (3) on the usefulness of screening by a general practitioner, and the Cochrane Report that was based on this study (4), demonstrate a risk reduction (RR 0.6; 95% CI: 0.41–0.75). However, there are methodological limitations, for example in the comparability of the study groups (4, 5), and international institutions recommend against the screening of asymptomatic pregnant women with an average risk profile (6, 7).

In terms of self-testing of pH, two German studies (Erfurt and Thuringia Campaign Against Premature Delivery) came to the conclusion that the incidence of preterm births before the 32nd GW and deliveries of low-birthweight babies (<2500 g) can be significantly reduced (8–10). The results of these two studies, however, are based on study samples restricted to one region. In addition, confounding factors such as risk factors for preterm delivery were not adequately taken into account, so that it is possible that the effects have been overestimated.

Bacterial vaginosis, unlike other known risk factors for preterm delivery (e.g., older age of the mother, multiple pregnancies), is a risk factor that can potentially be modified. The prevalence of bacterial vaginosis in pregnant women varies between 10% and 20%, depending on the underlying sample group (population versus clinical sample) and the diagnostic techniques used (1, 11, 12). The so-called maternity guidelines (13) do not at present include general screening for bacterial vaginosis during pregnancy.

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TABLE 1

Distribution of selected risk factors in the intervention and control group before and after matching

Risk factors	Observed = before matching			After 1:4 matching		
	Control group (n = 130 225)	Intervention group (n = 18 857)	p	Control group (n = 69 432)	Intervention group (n = 17 358)	p
Mean maternal age (in years)* ¹	30.99	32.3	0	31.68	32.28	0
Multiple pregnancies* ²	1.50%	2.40%	0	1.90%	2.10%	0.0757
Marital status single* ²	11.90%	9.60%	0	10.00%	10.00%	0.8204
Primigravida* ²	47.60%	54.70%	0	53.10%	53.80%	0.0955
Previous preterm deliveries* ²	1.60%	2.40%	0	2.00%	2.10%	0.7194
Previous abortions/terminations* ²	23.10%	23.70%	0.0709	23.00%	23.50%	0.1852
In vitro fertilization* ²	2.30%	4.70%	0	3.30%	3.60%	0.0479
Smokers* ²	9.10%	3.80%	0	3.60%	4.00%	0.0396

*¹ t-Test; *² chi-square test

In an attempt to make pregnant women take an active part in early discovery of bacterial vaginosis—a risk factor that can be medically treated—four health insurers (KKH-Allianz, Barmer, Techniker Krankenkasse, Hamburg Münchener Krankenkasse) in five federal German states (Bavaria, Hesse, Lower Saxony, North Rhine–Westphalia, Thuringia) have been carrying out a model project in accordance with §63 SGB V (German Social Code, Book V). The implicit assumption was that screening would lead to early diagnosis and treatment of bacterial vaginosis and thus achieve a “reduction in the premature birth rate” and a “reduction in healthcare costs related to delivery and the first year after delivery.”

From 2004 to 2006, in a model project carried out by four German health insurers, expectant mothers were offered self-testing of vaginal pH in order to prevent preterm delivery. They were given pH test gloves on request so that they could measure their vaginal pH twice a week from the 12th to the 32nd week of gestation. They were instructed to consult with a gynecologist after any positive result. All further diagnostic or therapeutic decisions were at the discretion of the treating gynecologist.

Since insurers usually only find out about a pregnancy towards its end, they are not in a position to approach those they insure early during the pregnancy. The model project was therefore publicized via traditional media (e.g., membership magazines, company home page) (14).

Methods

Study design, outcomes, and power calculation

The evaluation of pH self-testing was carried out as a prospective controlled study. The central outcome parameter for evaluation of the efficacy of pH self-testing was the rate of preterm delivery < 37 + 0 GW (i.e., proportion of pregnant women who gave birth

before the 37th GW as a proportion of all pregnant women). The hypothesis was that pH self-testing would lead to a reduction in preterm deliveries as defined above from 8.4% to 7.8%.

Estimates of the preterm delivery rate were based on information from the quality assurance process in the obstetric/perinatal data records of several federal states (including Thuringia, Hesse, and Brandenburg) from 1995 to 2001, while the expected effect was estimated by reference to the results of Hoyme et al. (10).

To detect the expected reduction by 0.6 points with a power of 80% and confidence of 95%, two equally sized test groups of 32 000 births each are required. Secondary outcomes were premature births <32 + 0 GW and birthweight (<2500 g, <2000 g, <1500 g).

Data base

The data on the birth outcomes “duration of pregnancy” and “birthweight” and on maternal risk factors based on the mother’s history were provided by the obstetric/perinatal data quality assurance offices of the participating federal states. Since 1980 these offices have been collecting comprehensive data for the purposes of external quality assurance. From 2004 to 2006 these data included information about marital status, previous preterm deliveries, and bodyweight (15). These data were linked with claims data of the insurers on health care utilization. A 97% rate of linkage of mother–child data with health insurer data was achieved.

In addition to the analyses largely based on routine data, the test results returned by the participating women were assessed. All data had been pseudonymized. Processing the data was complicated; in particular, collating it with the data from the obstetric/perinatal data quality assurance took much longer than planned, for both technical and organizational reasons. However, through repeated harmonization procedures, a considerably improved set of base data was achieved.

TABLE 2

Preterm delivery rate (<37th GW and <32th GW) and proportion of low birthweight babies in the two study groups before and after matching

		Observed = before matching			After 1:4 matching		
		Control group (n = 130 225)	Intervention group (n = 18 857)	p	Control group (n = 69 432)	Intervention group (n = 17 358)	p
Preterm delivery (<37 + 0 GW)	Proportion in %	7.28	8.23	0.0000	7.52	7.97	0.0480
	Relative risk (95% CI)	1.13 (1.07 – 1.19)			1.06 (1.00 – 1.12)		
Early preterm delivery (<32 + 0 GW)	Proportion in %	0.93	0.87	0.4246	0.93	0.84	0.2611
	Relative risk (95% CI)	0.94 (0.80–1.10)			0.90 (0.76–1.08)		
Low birthweight (<2500 g)	Proportion in %	5.34	5.55	0.2232	5.49	5.32	0.3740
	Relative risk (95% CI)	1.04 (0.98–1.11)			0.97 (0.90–1.04)		
Very low birthweight (<2000 g)	Proportion in %	1.89	1.86	0.8108	1.97	1.78	0.1088
	Relative risk (95% CI)	0.98 (0.88–1.10)			0.90 (0.80–1.02)		
Extremely low birthweight (<1500 g)	Proportion in %	0.89	0.80	0.2040	0.91	0.77	0.0668
	Relative risk (95% CI)	0.86 (0.74–1.01)			0.87 (0.74–1.04)		

CI, confidence interval

Statistics

Because of the lack of randomization, it was anticipated that participating women would differ in central characteristics from non-participating women. Self-selection bias (significantly more risk factors for preterm delivery in the study group) was taken into account using Propensity Score Matching (16–18) and by means of multivariate adjustment (19, 20).

To control for the anticipated self-selection bias, we included:

Age and marital status of the mother, number of previous pregnancies and their outcome (e.g., preterm delivery, abortion), potentially modifiable risk factors (e.g., smoking, body mass index) and risk factors of the current pregnancy that were not potentially modifiable (e.g., multiple fetuses, in vitro fertilization).

We will report on evaluations of effectiveness made by comparing pregnant women who requested a test kit with a control group of pregnant women who did not request a test kit (intention-to-treat approach). The significance tests for differences in birth outcomes between the matched study groups used the chi-square test. Significant group differences within the framework of the multivariate adjustment (logistic regression) are presented in the form of the odds ratio together with the corresponding 95% confidence interval. No correction was made for multiple testing.

The health insurers' prescription data were closely examined for any information about medical drug treatment during pregnancy concerning bacterial vaginosis. For a subgroup of participants, we have additional documented information about test compliance,

diagnostic confirmation or medical (drug) treatment, which were also analyzed in detail. We made use of the bacterial vaginosis guideline of the German Society for Obstetrics and Gynecology (*Deutsche Gesellschaft für Gynäkologie und Geburtshilfe*) (11), according to which medical therapy for bacterial vaginosis after the first trimester should be with locally or systemically administered metronidazole or clindamycin. The corresponding ATC codes were taken from the drug data of those women who had at least one relevant prescription during their pregnancy.

The study design was approved by the German Federal (Social) Insurance Office (*Bundesversicherungsamt*) as a § 63 SGB V model project.

Results

Study sample

In the 28-month recruiting period, initial data on a total of 203 183 women with completed pregnancies from the years 2004 to 2006 were collected from the health insurers. Only births for which definite matching of mother with child was possible, and for which information about both mother and child was available from both data sources, were analyzed. Data on a total of 149 082 births were included in the analyses (73.4%).

18 857 women requested test gloves from their health insurer, corresponding to 12.6% of the study population. Of these, 7469 pregnant women returned the documentation of their test results (39.6% of those who requested test kits, i.e., 5.0% of the overall study group). The unselected control group consisted of 130 225 pregnant women.

TABLE 3

Contribution of the characteristic "Belongs to the intervention group" in the multivariate modeling of the outcome measures "duration of pregnancy" and "birthweight"

	Odds ratio (95% CI)
Preterm delivery (<37 + 0 GW)	1.05 (0.99–1.12)
Early preterm delivery (<32 + 0 GW)	0.85 (0.72–1.02)
Low birthweight (<2500 g)	0.92 (0.85–0.99)
Very low birthweight (<2000 g)	0.85 (0.75–0.96)
Extremely low birthweight (<1500 g)	0.79 (0.66–0.95)

GW, gestational week; CI, confidence interval

Before matching, as expected, significantly more nonmodifiable risk factors for preterm births were seen in the intervention group, e.g., more multiple pregnancies or previous preterm deliveries, than in the control group (Table 1). Similarly, modifiable risk factors were more common in the control group, e.g., the proportion of smokers (Table 1). After matching, the two study groups differed significantly only in respect of maternal age, proportion of smokers, and in vitro fertilization (Table 1).

Primary outcome: early birth rate (<37 + 0 GW): no positive effect of the intervention can be demonstrated

In neither of the two statistical evaluation methods used did the intervention show a positive effect on the primary outcome "preterm delivery before the 37th GW."

Table 2 shows the preterm delivery rate in the two study groups before and after matching (row 1). Before matching, the preterm delivery rate (<37 + 0 GW) in the intervention group is nearly one point higher, and thus significantly higher than in the control group (8.23% versus 7.28%, $p < 0.0001$). After matching—with improved comparability between the study groups (Table 1)—the difference between the two groups is halved, but the preterm delivery rate (<37 + 0 GW) is still about 0.45 points higher than in the control group (7.97% versus 7.52%, $p = 0.048$). The relative risk of preterm delivery <37 + 0 GW in the intervention group was 1.13 (95% CI: 1.07–1.19) before matching and 1.06 (95% CI: 1.00–1.12) after matching.

In multivariate modeling, belonging to the intervention group with simultaneous control for the other parameters that went into the model calculation was associated with a slight, statistically nonsignificant risk of preterm delivery <37 + 0 GW (odds ratio [OR] 1.05, 95% CI: 0.99–1.12, Table 3).

Early preterm deliveries (<32 + 0 GW): positive tendency but no statistically significant effect

If one looks at the early preterm delivery rate (<32 + 0 GW), women in the intervention group have a slightly but not significantly lower risk before matching (0.87% versus 0.93%, difference: 0.06 points). After matching, the difference between the two groups increases slightly (0.84% versus 0.93%), becoming 0.1%, but remains statistically nonsignificant. The relative risk of an early preterm delivery (<32 + 0 GW) is 0.94 before matching and 0.90 after matching (Table 2).

The results of the multivariate modeling show a 15% lower risk of early preterm delivery (<32 + 0 GW) for women taking part in the intervention, but this difference too is not statistically significant (OR 0.85, 95% CI: 0.72–1.02; Table 3).

Low birthweight babies: multivariate analyses indicate a positive effect

After matching, the proportion of babies with a low birthweight in the intervention group is in all low birthweight groups about 0.2 points lower than in the control group (e.g.: birthweight <1500 g: 0.77% versus 0.91%—relative risk 0.87, 95% CI: 0.74–1.04). The differences between the two study groups, however, are statistically nonsignificant in all birthweight groups (Table 2).

In the logistic regression, belonging to the intervention group showed a protective effect for all three birthweight related outcomes: the odds ratios are smaller than 1 in all low birthweight groups, and in no case does the 95% confidence interval contain the number 1, i.e., they are statistically significant. The protective effect of pH self-testing is, as expected, smallest in relation to the outcome "birthweight <2500 g" (8% reduction, OR = 0.92, 95%CI: 0.85–0.99), and strongest for "birthweight <1500 g" (21% reduction, OR = 0.79, 95%CI 0.66–0.95; Table 3).

Analysis of influencing factors

For the intervention to be effective, it is important to start self-testing of pH early in pregnancy. About half of the pregnant women interested in self-testing started early enough in their pregnancy (up to the 16th GW). Another important element for the intervention to be effective is appropriate medical treatment if bacterial vaginosis does occur. From the prescription data of the participating health insurers, however, it could be seen that, irrespective of whether a test kit had been requested, it was relatively rare that drugs approved in the guidelines (metronidazole or clindamycin, ATC codes G01AA10, G01AF01, J01FF01 and J01XD01) were prescribed to treat bacterial vaginosis during pregnancy (with test request versus without test request: 1.6% versus 1.3%, $p = 0.0038$) (eTable 1).

For a subgroup of participating women we have documentation of the pH test series over time. Many of these women carried out the tests regularly, a quarter of these did so over a period that would have been long enough to allow early discovery and treatment of

bacterial vaginosis during their pregnancy. One in every four pregnant women with test series documentation had at least one abnormal pH value. About 43% went to their physician to have these abnormal pH values confirmed, and in four out of five cases the physician confirmed the abnormal pH value. Of the women who had at least one abnormal pH value, 36% received drug treatment (*eTable 2*).

Detailed analyses of the prescriptions show that pregnant women with documentation who had abnormal pH values confirmed by their physician were much more frequently treated with medications recommended for bacterial vaginosis than were pregnant women without physician confirmation of a self-tested abnormal pH value or who had only normal pH values (6% versus 1.1% versus 0.5%).

Discussion

Overall, all the effects on preterm delivery rates and birthweight identified in this study proved to be smaller than was assumed at the outset, and smaller than would be expected on the basis of other, previously published studies.

Although we were unable entirely to reach the intended sample size for the intervention group required for the intention-to-treat approach, the statistical power of a study (within certain limits) is maintained if a smaller intervention group is compared with a larger control group (21). According to currently accepted calculation formulae, the sample sizes achieved in the study were sufficient to have shown the desired effect with adequate power and confidence at a statistically significant level.

We believe that the (slightly) increased risk of preterm delivery $<37 + 0$ GW in the intervention group is to be interpreted as showing that it was not possible to take into account all potential confounding factors (such as social status, level of education, individual health behavior) on the basis of the data at our disposal. This interpretation is also supported by the fact that the negative effect was only shown to be of (borderline) significance in one of the two evaluation approaches employed (Propensity Score Matching), whereas for all the other outcomes considered, both of the statistical methods employed indicated a similar, slightly protective effect of the intervention.

The reason for the lack of proof of efficacy is either that self-testing of pH is not effective or that self-testing of pH as implemented and practiced in the model project could not be effective.

There are some grounds for believing that the intervention could not be effective under current conditions. These are:

- Only a small proportion of women requested the test kit early enough
- The self-testing did not bring forward the diagnosis in time, as was the intention
- Even where abnormal test results were confirmed by a physician, treatment according to current guidelines was carried out in only very few cases.

As long as the health insurers are unable to contact pregnant women insured with them early in the pregnancy and make them aware of pH testing, and as long as the recommendations regarding treatment of bacterial vaginosis are only partially implemented in outpatient obstetric care, an intervention in which test kits for self-testing of pH are distributed by the health insurers will be ineffective.

Future studies might attempt to make contact with the pregnant women earlier, e.g., by involving their physicians. Generally, it would be desirable to carry out a randomized, controlled study with an adequate sample size.

Conflict of interest statement

Professor Hoyme receives consultancy and lecture fees from the health insurers participating in this study and was scientific adviser to the study reported here. He has received consultancy fees and travel expenses from Inverness Medical (glove manufacturer).

The other authors declare that no conflict of interest exists according to the guidelines of the International Committee of Medical Journal Editors.

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REFERENCES

1. Flynn CA, Helwig AL, Meurer LN: Bacterial vaginosis in pregnancy and the risk of prematurity: a meta-analysis. *J Fam Pract* 1999; 48: 885–92.
2. Leitch H, Bodner-Adler B, Brunbauer M, et al.: Bacterial vaginosis as a risk factor for preterm delivery: a meta-analysis. *Am J Obstet Gynecol* 2003; 189: 139–47.
3. Kiss H, Petricevic L, Husslein P: Prospective randomised controlled trial of an infection screening programme to reduce the rate of preterm delivery. *BMJ* 2004; 329: 371.
4. Swadpanich U, Lumbiganon P, Prasertcharoensook W, et al.: Antenatal lower genital tract infection screening and treatment programs for preventing preterm delivery. *Cochrane Database of Systematic Reviews* 2008.
5. Stokes-Lampard HJ, Mant J, Newnham A, Daley A, MacLeod J, Mc Manus R: The value of CONSORT in interpreting dramatic findings. <http://bmj.bmjournals.com/cgi/eletters/329/7462/371> 27–4–2006.
6. Nygren P, Fu R, Freeman M, Bougatsos C, Klebanoff M, Guise JM: Evidence on the benefits and harms of screening and treating pregnant women who are asymptomatic for bacterial vaginosis: An update review for the U.S. Preventive Services Task Force. *Ann Intern Med* 2008; 148: 220–33.
7. NCCWCH – National Collaborating Centre for Women's and Children's Health Antenatal Care. Routine Care for the healthy pregnant women 2008.
8. Hoyme UB, Grosch A, Roemer VM, et al.: Erste Resultate der Erfurter Frühgeburten-Vermeidungs-Aktion, *Z Geburtshilfe Neonatol* 1998; 202: 247–50.
9. Hoyme UB, Grosch A, Roemer VM, et al.: Die Bakterielle Vaginose als Risikofaktor – Ergebnisse der Erfurter Frühgeburtenvermeidungsaktion. *Gynäkologie* 2000; 33: 331–3.
10. Hoyme UB, Möller U, Saling E: Ergebnisse und mögliche Konsequenzen der Thüringer Frühgeburtenvermeidungsaktion 2000, *Geburtshilfe Frauenheilkd* 2002; 62: 257–63.
11. Deutsche Gesellschaft für Gynäkologie und Geburtshilfe (DGGG), Arbeitsgemeinschaft für Infektionen und Infektionsimmunologie in der Gynäkologie und Geburtshilfe (AG II): Empfehlungen zur bakteriellen Vaginose in Gynäkologie und Geburtshilfe, AWMF-Leitlinien-Register Nr.015/028 (S1), August 2008. http://www.dggg.de/fileadmin/public_docs/Leitlinien/g_01_04_03_bakterielle_vaginose_gynaekologie_geburtshilfe.pdf
12. Sobel JD: What's new in bacterial vaginosis and trichomoniasis? *Infect Dis Clin North Am* 2005; 19: 387–406.

13. Bundesausschuss Ärzte und Krankenkassen: Richtlinien des Bundesausschusses der Ärzte und Krankenkassen über die ärztliche Betreuung während der Schwangerschaft und nach der Entbindung („Mutterschafts-Richtlinien“) in der Fassung vom 10. Dezember 1985, zuletzt geändert am 22. Januar 2009, in: Bundesanzeiger 2009; 98: 23301.
14. Siegmund-Schultze E, Hoyne UB, Bitzer E, et al.: pH-Selbstmessung mit dem Ziel der Reduktion des Risikos für Frühgeburtslichkeit – Das Pilotprojekt der Kaufmännischen Krankenkasse wird zum Modellvorhaben. Geburtshilfe Und Frauenheilkunde 2005; 65: 80–3.
15. Zentrum für Qualität und Management im Gesundheitswesen: NPEXtra 2007 – Niedersächsische Perinatal- und Neonatalerhebung 2009, p. 17.
16. Rosenbaum PR, Rubin DB: Assessing sensitivity to an unobserved binary covariate in an observational study with binary outcome. Journal of the Royal Statistical Society, Series B, 1983; 45: 212–8.
17. Rosenbaum PR, Rubin DB: Reducing bias in observational studies using sub-classification on the propensity score. Journal of the American Statistical Association 1984; 79: 516–24.
18. D’Agostino RB Jr: Propensity score methods for bias reduction in the comparison of a treatment to a non-randomized control group. Statistics in Medicine 1998; 17: 2265–81.
19. Nelder JA, Wedderburn RWM: Generalized linear models. Journal of the Royal Statistical Society. Series A, 1972, A 135: 370–84.
20. McCullagh P, Nelder JA: Generalized linear models. 2nd Edition. London: Chapman and Hall. 1989.
21. Bortz J, Döring N: Optimale Stichprobenumfänge für die wichtigsten Signifikanztestvergleiche. In Bortz J, Döring N: Forschungsmethode und Evaluation: für Human- und Sozialwissenschaftler, 2nd edition. Berlin: Springer 1995; 577.

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eTABLE 1

Medical prescriptions during the 12th and 34th weeks of gestation^{*1}

Pregnant women with at least one ...	After 1:4 matching		
	Control group (n = 69 432)	Intervention group (n = 17 358)	p
... medical prescription	42.3%	42.7%	0.3830
... antibiotic prescription ^{*2}	16.4%	17.0%	0.0843
... medical prescription in accordance with the guidelines ^{*3}	1.3%	1.6%	0.0038

^{*1} Source: routine data

^{*2} At least one antibiotic prescription; ATC code G01—gynecological anti-infectives and antiseptics, or J01—antibacterials for systemic use

^{*3} At least one prescription of metronidazole or clindamycin, the drugs recommended in the guidelines for treatment of bacterial vaginosis, ATC codes G01AA10, G01AF01, J01FF01, or J01XD01

eTABLE 2

Analysis of the documented tests: test behavior, frequency of confirmation requests, and treatment carried out^{*1}

Characteristic	Average / n
Average start of self-testing (median, range)	15 th GW (15; 1 st –32 nd GW)
Average number of documented tests (SD, range)	28 (11; 1–57)
Average interval between two documented tests (SD, range)	4.1 days (1.8; 1–53)
Pregnant women with at least one raised test value (%)	n = 1848 (24.7%)
Average number of raised test values (median, range)	4 (2; 1–42) ^{*2}
Pregnant women who visited their physicians because of test results	n = 807 (43.7%) ^{*2}
Pregnant women whose test results were confirmed by their physician	n = 633 (34.3%) ^{*2}
Pregnant women who started medical treatment	n = 667 (36.1%) ^{*2}
—of these, those with at least one ...	
... medical prescription (as shown by routine data ^{*3})	n = 344 (51.6%) ^{*4}
... antibiotic prescription ^{*5} (as shown by routine data ^{*3})	n = 234 (35.1%) ^{*4}
... medical treatment in accordance with the guidelines ^{*6} (as shown by routine data ^{*3})	n = 40 (6.0%) ^{*4}

^{*1} Source: documentation sheet; GW, gestational week; SD, standard deviation

^{*2} Percentages shown relate to the number of pregnant women with at least one raised test value.

^{*3} The time taken into account was the period from the 70th to the 240th day of pregnancy = desired pH testing period (12th to 32nd GW) plus an estimated 14 days for visit to physician and start of medication.

^{*4} Percentages shown relate to the number of pregnant women who started medical treatment (self-reported in the documentation sheet).

^{*5} At least one prescription of antibiotics; ATC code G01—gynecological anti-infectives and antiseptics, or J01—antibacterials for systemic use.

^{*6} At least one prescription of metronidazole or clindamycin, the drugs recommended in the guidelines for treatment of bacterial vaginosis, ATC codes G01AA10, G01AF01, J01FF01, or J01XD01