

# An Innovative Method for Specimen Autocollection in the Diagnosis of Vaginitis

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In 1983 there were almost 8 million office visits to physicians for vaginitis.<sup>1</sup> Using current charges paid by the North Carolina Blue Cross and Blue Shield Prepaid Care Plan, costs are estimated at more than \$300 million for these visits. While current textbook management of vaginitis suggests a careful history, pelvic examination, and laboratory tests, evidence indicates that primary care physicians often deviate from this protocol with techniques based on clinical experience, epidemiological findings, and personal knowledge of the patient and her environment.<sup>2</sup> Optimal therapy is dependent upon accurate diagnosis that requires microscopic examination of a vaginal specimen.<sup>3</sup>

A rational approach to the diagnosis and treatment of vaginitis should consider effectiveness, expense, comfort, and safety. To satisfy these conditions, The Family Practice Center of North Carolina Memorial Hospital has tested a method by which a patient can collect her own vaginal specimen. Immediate research questions were (1) would a specimen collected by the woman herself be equal on wet preparation analysis to one collected by the physician during a pelvic examination, and (2) would this self-collection technique be acceptable to patients?

## METHODS

Women who came to the Family Practice Center complaining of vaginal itching or discharge were candidates for the study if they were over 18 years old, not pregnant, physically capable of collecting their own specimen, and able to understand English.

Each consenting patient was given a set of illustrated instructions for the collection of the vaginal

specimen. For each patient, five specimens were submitted to the laboratory for examination: one patient collected, one physician collected, and three unrelated specimens, so that both physician and laboratory technician were blinded to the source of the specimens. Each specimen was labeled with a random five-digit code prior to submission to the laboratory. All specimens were analyzed by the same technician using the technique described by Fischer et al.<sup>4</sup> Before each woman left the Family Practice Center, she filled out a five-item questionnaire about the autocollection process.

Specimen pairs were compared on each of 15 biological characteristics. Those measured on an ordinal scale (ie, on a scale from 1 to 5 indicating none to heavy amounts) were analyzed using Kendall's tau. Where differences were found between specimens, the sign test was used to determine whether the direction of the difference was consistent or random.<sup>5</sup> Specimen characteristics that were coded as either present or absent were analyzed using Cohen's kappa statistic.<sup>6</sup>

## RESULTS

Of 21 successive patients approached, 20 agreed to participate. They ranged in age from 19 to 39 years, with a mean age of 28 years. All except two had some college education and eight had postgraduate degrees. There were 15 white and five black women. The single refusal was from a 26-year-old black college graduate who lacked the time. Table 1 shows results of the statistical analyses. Basal cells, leptothrix, and a clear mucus-like discharge were not observed in any of the 20 specimen pairs. Very good correlations (Kendall's tau 0.66 to 0.87) were found for six of the seven characteristics for which semiquantitative estimates of cellular material were made. For the remaining five characteristics (measured as either present or absent), high concordance was found with Cohen's kappa ranging from 0.76 to 1.00 ( $P < .001$ ). Only one characteristic, amount of squamous cells, showed a poor correlation between specimen pairs (Kendall's tau 0.06). Where differences in amount of cellular material were found,

Submitted, revised, July 22, 1986.

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TABLE 1. AMOUNT OF CONCORDANCE BETWEEN 20 PAIRS OF VAGINAL SPECIMENS ON EACH OF 15 SPECIMEN CHARACTERISTICS

Characteristics Observed	Frequency Observed		Statistical Analysis	
	Patient-Collected Specimen	Physician-Collected Specimen	Kendall's tau	Cohen's kappa
Squamous cells	20	20	.06	—
Sheets of squamous cells	9	9	.66	—
White blood cells	17	17	.71	—
Red blood cells	6	5	.68	—
Amount of bacteria	20	20	.72	—
Clue cells	9	8	.87	—
Parabasal cells	2	1	.72	—
Basal cells	0	0	—	—
Type of bacteria	20	20	—	.92
Pseudohyphae	6	6	—	.76
Buds	5	4	—	.86
Trichomonae	1	1	—	1.00
Leptothrix	0	0	—	—
Clear, mucus-like discharge	0	0	—	—
Fishy odor when potassium hydroxide added	8	8	—	1.00

a sign test indicated that the patient-collected specimens tended to contain greater amounts of cellular material than the physician-collected specimens (binomial  $P < .05$ ).

All patients (100 percent) reported that the instructions for specimen collection were clear or very clear and expressed positive attitudes toward the study. Ninety percent were comfortable with the autocollection technique vs 60 percent with physician collection. All but one woman felt positive about collecting their own vaginal specimens in the future; the remaining patient was indifferent.

## DISCUSSION

There was very good agreement between the results of laboratory analyses of patient-collected and physician-collected vaginal specimens, particularly for characteristics recorded as either present or absent. Correlations between specimen pairs were only slightly lower for characteristics that were estimated semiquantitatively (eg, none 0, few 1, light 2, moderate 3, heavy 4). These lower correlations may be due, in part, to the imprecision of the measurement scales. Close analysis of the difference using the sign test, however, shows that the patient-collected specimens contained more cellular material and that statistically this finding was not a chance occurrence. Two possible explanations are: (1) the patient collected her grounds reported high concordance between physi-vaginal discharge of cellular contents, or (2) the patient's vigor in rubbing the cotton swabs in her vagina resulted in greater abrasive force than that used by the physician, causing the patient-collected specimen to have more cells. In no case did an examining physician find evidence of mucosal injury.

This new technique was highly acceptable to patients. Only one patient was uncomfortable collecting her own specimen, while five were uncomfortable with the physician's collection.

Specimen comparability and patient satisfaction are the two variables addressed in this paper. Because of the small, nonrepresentative sample, results are not generalizable to women of all ages and socioeconomic groups. However, a recently published study using over 1,400 women from varied racial and social backgrounds, reported high concordance between physician-collected and patient-collected cervical smear. All were able to collect their own specimens.<sup>7</sup> Further research is needed to determine what percentage of women would risk having serious pelvic infection or pathology remain undetected with specimen autocollection and how this risk might be reduced or eliminated. Additional questions of patient and physician acceptance of the method remain to be answered.

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