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Fausto Gondo

Prevalência das infecções do trato genital inferior em gestantes de baixo risco da Estratégia de Saúde da Família da Atenção Primária em Saúde.

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Prevalência das infecções do trato genital inferior em gestantes de baixo risco da Estratégia de Saúde da Família de Serviços de Atenção Primária em Saúde.

Dissertação apresentada ao Programa de Pós-graduação em Ginecologia, Obstetrícia e Mastologia, Faculdade de Medicina de Botucatu, Universidade Estadual Paulista “Júlio de Mesquita Filho” UNESP, para obtenção do título de Mestre.

Orientadora: Profa. Titular Marilza Vieira da Cunha Rudge
Co-Orientadora: Profa. Dra. Márcia Guimarães da Silva

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Resumo

Objetivos: A proposta do presente estudo foi estabelecer a prevalência de infecções do trato genital inferior em gestantes de baixo risco da Estratégia de Saúde da Família da Atenção Primária em Saúde em Botucatu, Estado de São Paulo-Brasil, e avaliar a relação de sinais e sintomas em infecções no trato genital inferior.

Pacientes e Métodos: Um total de 245 gestantes foi selecionado neste estudo, e durante o exame, o aspecto do corrimento e pH vaginal foram observados. Swabs foram utilizados para coletar secreções vaginais das paredes laterais da vagina para um esfregaço vaginal. O diagnóstico clínico foi baseado na combinação de sintomas e sinais, aferição de pH vaginal, realização do teste de aminas e exames laboratoriais.

Resultados: A taxa geral de infecção de diagnósticos clínicos foi de 45,7%. Vaginose bacteriana foi diagnosticada em 53 mulheres grávidas (21,6%), candidíase vaginal em 25 (10,2%), flora intermediária em 13 (5,2%), vaginite aeróbia em sete (2,9%), infecção mista em sete (2,9%) e outros achados em 2,9%. Entre as mulheres com sintomas e/ou sinais de infecções no trato genital inferior, 22,3% das mulheres foram diagnosticadas com vaginose bacteriana; 14,6% como candidíase vaginal; 5,7% como flora intermediária; 1,9% como vaginite aeróbia, 3,8% como infecção mista e 3,2% com outros achados, mas em 48,4% não foram identificadas infecções.

Conclusão: A prevalência de infecções do trato genital inferior em mulheres grávidas de baixo risco na Estratégia de Saúde da Família da Atenção Primária em Saúde é alta e nossos resultados sugerem que somente sintomas não deveriam ser utilizados para tratamento direto. A melhor prática para as infecções do trato genital inferior em gestantes deveria combinar os sinais ou sintomas e exames laboratoriais.

Palavras chaves: infecção genital inferior; gestantes de baixo risco; Estratégia de Saúde da Família da Atenção Primária em Saúde.

Abstract

Objective: The purpose of the present study was to establish the prevalence of lower genital tract infection in low risk pregnant women of the Family Health Strategy of the Primary Care Services in Botucatu, São Paulo State, Brazil, and to evaluate the correlation of signs and symptoms to lower genital tract infections. **Patients and Methods:** A total of 245 pregnant women were enrolled in this study and during the exam, the appearance and pH of the vaginal discharge were noted. Swabs were used to obtain vaginal secretion from the upper lateral vaginal vault for a vaginal smear. The clinical diagnosis were based by combining the symptoms and signs with office-based testing and laboratory exams. **Results:** The overall infection rate by clinical diagnosis was 45.7%. Bacterial vaginosis was diagnosis in 53 pregnant women (21.6%), vaginal candidiasis in 25 (10.2%), intermediate vaginal flora in 13 (5.2%), aerobic vaginitis in 7 (2.9%), mixed infection in 7 (2.9%) and another findings in 2.9%. Among women with symptoms and/or signals of the lower genital tract infection, 22.3% of the women were diagnosed as having bacterial vaginosis; 14.6% as vaginal candidiasis; 5.7% as having intermediate vaginal flora; 1.9% as aerobic vaginitis, 3.8% as having mixed infection, 3.2% another infection but in 48.4% no infection was identified. **Conclusion:** The prevalence of lower genital tract infection in low-income pregnant women attended in the Family Health Strategy of the Primary Care Services is high and our results suggest that symptoms alone should not be used to direct treatment. The best practice guideline to lower genital tract infections in pregnant women should take the combining symptoms or signs and laboratory exams.

Key words: lower genital infection; low risk pregnancy women; Family Health Strategy of the Primary Care Services.

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Lista de abreviaturas

et al. = co-authors

KOH = Potassium Hydroxide

USPSTF = United States Preventive Services Task Force

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Prevalence of lower genital tract infection in low risk pregnant women of the Family Health Strategy of the Primary Care Services

Gondo, F¹, Silva, MG², Polettini J², Tristão AR¹, Peraçoli JC¹, Rudge, MVC¹.

¹Departamento de Ginecologia e Obstetrícia, Faculdade de Medicina de Botucatu, UNESP.

²Departamento de Patologia, Faculdade de Medicina de Botucatu, UNESP.

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INTRODUCTION

The genital infections during pregnancy have been very neglectful in practice obstetric routine, mainly in the low risk public services (Brazilian Unified Healthcare System - SUS). Very little is researched in these sections that assist, most of the Brazilian pregnant women^{1,2}.

Lower genital tract complaints among women account for more outpatient visits than any other reason that women seek health care in the United States. It has been estimated that vaginal infections alone account for >10% of outpatients to providers of women's health care³. It would be expected that the diagnostic approach to such a common occurrence would have a major research focus over the years; it would be further expected that this area of medical practice would be influenced highly by evidence-based approaches that produced accurate diagnostic and very effective treatment regimens⁴.

There is evidence that screening of the genital infection for asymptomatic pregnancies may reduce the rate of preterm delivery (PTD). Evidence for screening and selective treatment exists for bacterial vaginosis in low-risk group⁵. A meta-analysis⁶ of 19 studies concluded that there was a 60% increased risk of PTD in the presence of bacterial vaginosis. However, according by Meis et al.⁷ neither *Trichomonas vaginalis* nor candidiasis, detected by microscopy, had significant association with preterm birth.

The genital infections may be asymptomatic needing vaginal evaluation protocol to firm the diagnoses and to establish prevalence, treatment, improving the maternal-fetal prognosis⁷⁻¹¹. Symptoms alone showed not be used in the diagnostic of the genital infection and in treatment which resources permit more

complete evaluation including microscopic analyses⁴. Landers et al.⁴ showed the poor predictive value of symptoms in the diagnosis of lower genital tract infection.

The purpose of the present study was to establish the prevalence of lower genital tract infection in low risk pregnant women of the Family Health Strategy of the Primary Care Services in Botucatu, São Paulo State, Brazil, and to evaluate the correlation of signs and symptoms to lower genital tract infections. Our hypothesis was that the current practice of using combinations of clinical signs and symptoms with office-based tests and microscopy is superior to symptom-direct approaches to predict correct diagnoses in pregnant women with lower genital tract infection.

PATIENTS AND METHODS

We conducted a study at eight Family Health Strategy of the Primary Care Services in Botucatu-(Brazilian Unified Healthcare System-SUS) and the pregnant population at each service was one of convenience with no attempt to select participants based on any specific criteria. Botucatu is a city of 130,000 people, located in the middle of Sao Paulo State-Brazil The population in general were of low income and reflect the ethnic distribution of the country. The Institution's Research and Ethical Committees of the Botucatu Medical School approved the study and all women gave written informed consent.

We enrolled pregnant women between 5 and 40 weeks of gestation receiving routine antenatal care at 8 study sites after screening for eligibility from September 2006 to February 2007. A total of 245 pregnant women were enrolled in this study. The sample was calculated considering the confidence interval of 95%, a precision of 5% and general prevalence of genital infections esteemed in 20%. A standardized medical, obstetric, sexual and social history was obtained. Women were excluded from the study for the following reasons: vaginal bleeding; current antibiotics use or vaginally medication in the preceding 3 days to sample collection or sexual intercourse in the preceding 72 hours to examination.

Specimen collection: a clean, unlubricated speculum was placed into the vagina, and the appearance and pH of the vaginal discharge were noted. Sterile cotton swabs were used to obtain vaginal material from the upper lateral vaginal vault for a vaginal smear. Combining the symptoms and signs with office-based testing and laboratory exams based the clinical diagnosis: 1) Gram stain; 2) wet mount; 3) vaginal pH; 4) Whiff test (detection of the amine odor after exposure of vaginal

secretions of KOH); 5) identification of > 20% of vaginal epithelial cells as clue cells. Vaginal discharges, changes in the characteristics of vaginal discharge, abnormal vaginal odor, vaginal itching or lower genital burning were considered as symptoms of lower genital tract infections. The characteristics considered as signals of lower genital tract infections included color, viscosity and homogeneity of vaginal secretion.

It was used standardized methods for collection of the samples in the 8 Family Health Strategy Units, with dedicated, trained staff and all slides stained were read at a central, experienced observers at the Botucatu Medical School, UNESP, Brazil, who were blinded to the clinical data.

The diagnosis of the vaginal candidiasis was based on the presence of yeast blast spores or pseudohyphae¹². Bacterial vaginosis and intermediate vaginal flora were diagnosed by Nugent's criteria¹³ and aerobic vaginitis was diagnosed if smears were deficient in lactobacilli, positive for cocci or coarse bacilli, positive for parabasal epithelial cells, and/or positive for vaginal leucocytes¹⁴.

The results of these exams were used to determine the definitive diagnosis of the following infections: vaginal candidiasis (VC), bacterial vaginosis (BV), aerobic vaginitis (AV), intermediate vaginal flora (IVF) and mixed infections characterized by the association between BV and VC.

Data were analyzed through descriptive tables of the variables studied, establishing the prevalence of the infections and were entered into a database and analyzed with SPSS (version 12.0; SPSS Inc., Chicago, IL) and R (version 2.4.1; R Development Core Team) statistical software. Fisher exact test and χ^2 were used to analyze classified data and Mann-Whitney test to numeric data. A p value less than 0.05 was considered significant.

RESULTS

The complete demographics characteristics among the 245 enrolled pregnant women are on Table 1. The median age of the pregnant women enrolled in this study was 24.4 years (13-44), 81.2% were white, 4.5% were black and 14.3% were another ethnicity. The median number of gestation was 2 (1-10) and more than two third (68.6%) were multiparous. Forty five (18.4%) had history of one or more abortions, 57.1% were married at the moment of the study and 72.2% had a low level of formal education. No difference in these characteristics was detected between groups with and without genital infections (Table 1).

The overall infection rate by clinical diagnosis among 245 pregnant women from the Family Strategy of the Primary Care Services was 45.7% (Table 2) and 7 patients had more than one infection for a total of 119 (48.6%) positive tests. Bacterial vaginosis was diagnosed in 53 pregnant women (21.6%), vaginal candidiasis in 25 (10.2%), intermediate vaginal flora in 13 (5.2%), aerobic vaginitis in 7 (2.9%), mixed infection in 7 (2.9%) and another findings in 2.9% (Table 2).

The prevalence of BV, intermediate vaginal flora, aerobic vaginitis, mixed infection and another findings in pregnant women with and without symptoms of lower genital tract infection were similar. Pregnant women with symptoms of lower genital tract infections showed high prevalence of vaginal candidiasis and pregnant women without vaginal discharge showed high prevalence of normal vaginal flora (Table 3).

DISCUSSION

The prevalence of 45.7% of lower genital infection observed in this low income population, of the pregnant women attended at Family Health Strategy of the Primary Care Services in Botucatu, São Paulo State-Brazil, may be considered high. However this prevalence was similar to the observed by others authors^{4, 15, 16}.

Bacterial vaginosis(BV), a polymicrobial clinical syndrome resulting from the replacement of the normal hydrogen peroxide-producing *Lactobacillus* species in the vagina with a mixture of anaerobic bacteria, *Gardnerella vaginalis* and *Mycoplasma hominis*, without signs of vaginal inflammation, was the most prevalent infection in this study, being present in 21.6% of the pregnant women. This result is similar to that found in Zimbabwe¹⁷. The infection rate of BV is variable in the literature from 9% to 28%¹⁷ and Carey & Klebanoff¹⁸ described that BV was found in 16.2% of 13.357 pregnant women.

For women with a history of preterm delivery the screening for BV is an option and the USPSTF¹⁹ recommends against routinely screening average risk asymptomatic pregnant women for BV. Although there is evidence that screening and treating BV in unselected low-risk population groups, rather than a heterogeneous combination of high-risk population groups, is effective at reducing the rate of preterm delivery⁸. Our results are in agreement with this critical appraisal of the literature since it was demonstrated that symptoms and or signals did not predict clinical diagnosis.

Vaginal candidiasis was the second more prevalent lower genital infection in this study, being present in almost 10% of the pregnant women. This result did not agree with the literature, where the most frequent genital infection during the

pregnancy is candidiasis¹⁴. Vaginal candidiasis was the unique form of lower genital infection where the symptoms and or signals were related to clinical diagnosis. On the other side, in 48.4% of the pregnant women, with symptoms, the clinical diagnosis was normal flora.

No cases of *T. vaginalis* were observed, however the methodology used was not the gold standard. Using the same methodology of this study, Simões et al.¹⁶ observed infection rate of 2.1% of the vaginal trichomoniasis in Brazilian pregnant women, at the beginning of the third trimester.

In our study, the prevalence of the intermediate vaginal flora (5.2%) was similar to described for Brazilian women and it is relatively high (6.7%) compared to Simões et al.¹⁶. These authors recommended that pregnant women with intermediate vaginal flora need to be followed during the prenatal care, due to the higher risk of maternal and perinatal complications.

Although the USPSTF²⁰ recommends against routinely providing the service to asymptomatic patients, the balance of benefits and harms cannot be determined.

Our data are in agreement with the conclusion described by Landers et al.⁴ that over the phone or in-office diagnosis and treatment that is based on symptoms is highly inaccurate and should be abandoned where resources permit.

At an estimated cost of U\$ 10.00 per Gram stain smear can solve the lower genital tract infections diagnosis that continues to be the major problem of the women's health care²¹. The cost of drug treatment ranging from U\$ 1.39 to U\$ 2.00 for pregnant women²², depending on the genital infection type, dosage and route of administration of the drug²³ is low and the approach to incorporate clinical diagnosis

and treatment based, may be considered a good practice in lower genital tract infections.

In summary, the prevalence of lower genital tract infection in low-income pregnant women attended at the Family Health Strategy of the Primary Care Services is high and low-cost and easy-to-carry out clinical diagnosis such wet mount and Gram stain smear should be routine in prenatal care, due to the high prevalence of genital infection and to the maternal and perinatal complications. Our results strongly suggest that symptoms alone should not be used to direct treatment. The best practice guideline to lower genital tract infections diagnosis in pregnant women should take the combination of symptoms / signs with office-based testing and laboratory exam (Gram stain; wet mount; vaginal pH; Whiff test (detection of the amine odor after exposure of vaginal secretions of KOH) and identification of > 20% of vaginal epithelial cells as clue cells) named here as clinical diagnosis.

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Table 1. Characteristics of study population

Characteristics	N (%)		Women without genital infection (%)		Women with genital infection (%)		P value
Age (median /range)	24.4 (13-44)		25.7 (15-44)		23.8 (14-44)		0.060 ⁽¹⁾
Race/ethnicity							
White	199	81.2	98	80.3	101	82.1	0.846 ⁽²⁾
Black	11	4.5	4	3.3	7	5.7	0.546 ⁽²⁾
Other	35	14.3	20	16.4	15	12.2	0.449 ⁽²⁾
Marital status							
Single	92	38.0	41	33.1	52	43.0	0.142 ⁽²⁾
Married	139	57.1	78	62.9	62	51.2	0.086 ⁽²⁾
Other	11	4.9	5	4.0	7	5.8	0.734 ⁽²⁾
Education							
< 8 years	177	72.2	89	71.2	88	73.3	0.818 ⁽²⁾
≥ 8 years	68	27.8	36	28.8	32	26.7	0.818 ⁽²⁾
Nulliparous	77	31.4	32	28.6	45	36.6	0.242 ⁽²⁾
Multiparous	168	68.6	90	71.4	78	63.4	0.242 ⁽²⁾
Abortion	45	18.4	26	74.3	9	25.7	
Trimester							
Gestational							
First	78	32.1	38	31.4	40	32.8	0.925 ⁽²⁾
Second	97	39.9	48	39.6	49	40.2	1.000 ⁽²⁾
Third	68	28.0	35	28.9	33	27.0	0.859 ⁽²⁾

(1) Mann-Whitney test for independent samples at significance level $\alpha = 0,05$.

(2) Test statistic Z between two proportions at significance level $\alpha = 0,05$.

Table 2. Prevalence of the different types of genital infection

Diagnosis of infection	N	%
Bacterial Vaginosis	53	21.6
Vaginal Candidiasis	25	10.2
Intermediate Vaginal Flora	13	5.2
Aerobic Vaginitis	7	2.9
Mixed Infection	7	2.9
Another findings	7	2.9
TOTAL	112	45.7

Table 3. Prevalence of the clinical diagnosis of genital tract infections in pregnant women with or without symptoms

Clinical Diagnosis	With symptoms (%)		Without symptoms (%)		p value
Bacterial Vaginosis	35	22.3	18	20.5	0.231 ⁽¹⁾
Vaginal Candidiasis	23	14.6	2	2.3	0.011 ⁽²⁾
Intermediate Vaginal Flora	9	5.7	4	4.5	0.751 ⁽²⁾
Aerobic Vaginitis	3	1.9	4	4.5	0.091 ⁽²⁾
Mixed Infection ⁽³⁾	6	3.8	1	1.1	0.671 ⁽²⁾
Another findings	5	3.2	2	2.3	1.000 ⁽²⁾
Normal Flora	76	48.4	57	64.8	0,019 ⁽¹⁾
TOTAL	157	100.0	88	100.0	

(1) Chi Square test at significance level $\alpha = 0,05$

(2) Fisher's exact test at significance level $\alpha = 0,05$

(3) Mixed infection between bacterial vaginosis and vaginal candidiasis

Anexas

Departamento de Ginecologia e Obstetrícia

BOTUCATU, SP-Rubião Júnior - Cep18.618-970 - ☎ (14) 3811-6227 / 6090 - Caixa Postal 530 - FAX (14) 6822-1933 - e-mail: gineco@fmb.unesp.br

TERMO DE CONSENTIMENTO LIVRE E ESCLARECIDO

Fui convidada pelo Dr. Fausto Gondo para participar da pesquisa **“Importância da rotina diagnóstica das vulvovaginites no acompanhamento pré-natal no Programa de Saúde da Família do Município de Botucatu”**.

Fui informada que será colhido material da vagina na consulta de pré-natal para exame. Fui esclarecida que na vagina existem muitas bactérias e conforme a que for encontrada posso ter algumas complicações na gravidez, como infecções, o bebê nascer antes do tempo e romper a bolsa das águas antes do parto. Se for diagnosticada qualquer alteração, será realizado tratamento específico para evitar essas complicações.

Eu,,
após ser devidamente esclarecida, aceito participar do projeto de pesquisa, podendo a qualquer momento esclarecer dúvidas e desistir de participar do mesmo, sem prejuízo do atendimento que eu necessitar. Sei que minha participação no estudo não será paga e que os resultados desse estudo serão utilizados apenas cientificamente e minha identidade será mantida em sigilo.

Botucatu, de de

Assinatura da Paciente: _____

Assinatura do pesquisador

Fausto Gondo
Rua Plácido Rodrigues Venegas, 1136
Jd. Paraíso II, Botucatu, SP
CEP 18610-180
Telefone: (14) 3814-1387

Orientadora

Profa. Titular Marilza Vieira Cunha Rudge
Rua General Teles, 1396 Apto 81
Centro, Botucatu, SP
CEP 18602-120
Tel: (14) 3811-6227

Departamento de Ginecologia e Obstetrícia

BOTUCATU, SP-Rubião Júnior - Cep18.618-970 - ☎ (14) 3811-6227 / 6090 - Caixa Postal 530 - FAX (14) 6822-1933 - e-mail:

gineco@fmb.unesp.br

Rotina Diagnóstica das Infecções do Trato Genital Inferior

Nome: _____

Matrícula: _____ Idade: _____ USF: _____

Última RS ____/____/____ G ____ P ____ A ____ C ____

DUM: ____/____/____ Idade Gestacional ____ semanas ____ dias

Solicitante: _____ Data do Atendimento ____/____/____

1. Queixas

Corrimento	<input type="checkbox"/> Sim	<input type="checkbox"/> Não		
Tempo de evolução	<input type="checkbox"/> Até 7 dias	<input type="checkbox"/> De 08 a 30 dias	<input type="checkbox"/> Mais de 30 dias	<input type="checkbox"/> Não sabe
Intensidade	<input type="checkbox"/> Pouco	<input type="checkbox"/> Moderado	<input type="checkbox"/> Muito	<input type="checkbox"/> Não sabe
Aspecto	<input type="checkbox"/> Fluido	<input type="checkbox"/> Pastoso	<input type="checkbox"/> Não sabe	
Cor	<input type="checkbox"/> Branco	<input type="checkbox"/> Amarelo	<input type="checkbox"/> Esverdeado	<input type="checkbox"/> Não sabe
Odor	<input type="checkbox"/> Sim	<input type="checkbox"/> Não	<input type="checkbox"/> Às vezes	<input type="checkbox"/> Não sabe
Prurido	<input type="checkbox"/> Sim	<input type="checkbox"/> Não	<input type="checkbox"/> Às vezes	<input type="checkbox"/> Não sabe

2. Exame Físico

Corrimento	<input type="checkbox"/> Sim	<input type="checkbox"/> Não		
Intensidade	<input type="checkbox"/> Pouco	<input type="checkbox"/> Moderado	<input type="checkbox"/> Muito	
Aspecto	<input type="checkbox"/> Fluido	<input type="checkbox"/> Pastoso	<input type="checkbox"/> Bifásico	<input type="checkbox"/> Outros: _____
Cor	<input type="checkbox"/> Branco	<input type="checkbox"/> Amarelo	<input type="checkbox"/> Acinzentado	<input type="checkbox"/> Outros: _____
Whiff Test	<input type="checkbox"/> Presente	<input type="checkbox"/> Ausente	<input type="checkbox"/> Duvidoso	
Achados	<input type="checkbox"/> Vulvite	<input type="checkbox"/> Endocervicite	<input type="checkbox"/> Ectopia	<input type="checkbox"/> Outros: _____
pH vaginal: _____	<input type="checkbox"/> Não realizado	JEC: _____		

Exame Microscópico Direto do Conteúdo Vaginal (GRAM):

Data ____/____/____



Universidade Estadual Paulista
Faculdade de Medicina de Botucatu



Distrito Rubião Junior, s/nº - Botucatu - S.P.
CEP: 18.618-970
Fone/Fax: (0xx14) 3811-6143
e-mail secretaria: capellup@fmb.unesp.br



Registrado no Ministério da Saúde em 30 de
abril de 1997

Botucatu, 04 de setembro de 2006

OF.426/2006-CEP

*Ilustríssima Senhora
Prof.^a Dr.^a Marilza Vieira Cunha Rudge
Departamento de Ginecologia e Obstetrícia
Faculdade de Medicina de Botucatu*


Prezada Dr.^a Marilza,

De ordem da Senhora Coordenadora deste CEP informo que o Projeto de Pesquisa "Importância da rotina diagnóstica das vulvovaginites no acompanhamento pré-natal no Programa de Saúde da Família do Município de Botucatu" a ser conduzido por Fausto Gondo, orientado por Vossa Senhoria, recebeu do relator parecer favorável, aprovado em reunião de 04/09/2006.

Situação do Projeto: APROVADO.

- Ao término deste projeto, apresentar ao CEP Relatório Final de Atividades.*

Atenciosamente,


*Alberto Santos Capellupi
Secretário do CEP.*

unesp



DIVISÃO TÉCNICA ACADÊMICA

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CÂMPUS DE BOTUCATU
FACULDADE DE MEDICINA

Seção de Pós-Graduação

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JUSTIFICATIVA DE ALTERAÇÃO NO TÍTULO DO PROJETO DE PESQUISA

Declaramos que o Projeto de Pesquisa "Importância da rotina diagnóstica das vulvovaginites no acompanhamento pré-natal no Programa de Saúde da Família do Município de Botucatu", aprovado pelo CEP em 04/09/2007, teve seu título alterado para "Prevalência das infecções do trato genital inferior em gestantes de baixo risco na Estratégia Saúde da Família da Atenção Primária em Saúde", sem nenhuma alteração no seu conteúdo metodológico da época de apresentação para análise do CEP.

A presente alteração foi efetuada somente para adequação do título da Dissertação de Mestrado.

Botucatu, 09 / Agosto / 2007

Nome/Assinatura do(a) aluno(a) Fausto Gondo

Nome/Assinatura do(a) orientador (a) Profa. Titular Marilza Vieira Cunha Rudge

Programa de Pós Graduação em Ginecologia, Obstetrícia e Mastologia