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Attitudes towards Microbicide Use for Bacterial Vaginosis in Pregnancy

Marina Catalozzi, MD, MSCE [Assistant Professor of Pediatrics and Population & Family Health at Columbia University Medical Center],

Department of Pediatrics, Columbia University College of Physicians & Surgeons-Morgan Stanley Children's Hospital of New York Presbyterian; Heilbrunn Department of Population & Family Health, Mailman School of Public Health, New York, New York, USA

Camille Y. Williams, BA,

Department of Pediatrics, Columbia University College of Physicians & Surgeons-Morgan Stanley Children's Hospital of New York at New York Presbyterian Hospital, New York, New York, USA

Gregory D. Zimet, PhD [Professor of Pediatrics & Clinical Psychology],

Department of Pediatrics, Indiana University School of Medicine, Indianapolis, Indiana, USA

Katharine M. Hargreaves, BA,

Department of Pediatrics, Columbia University College of Physicians & Surgeons, Morgan Stanley Children's Hospital of New York at New York Presbyterian Hospital, New York, New York, USA

Shari E. Gelber, MD, PhD [Assistant Professor of Obstetrics and Gynecology],

Weill Cornell Medical College, New York, New York, USA

Adam J. Ratner, MD, MPH [Associate Professor of Pediatrics],

Department of Pediatrics, Columbia University College of Physicians & Surgeons- Morgan Stanley Children's Hospital of New York Presbyterian, New York, New York, USA

Lawrence R. Stanberry, MD, PhD [Reuben S. Carpentier Professor and Chairman of the Department of Pediatrics at Columbia University Medical Center], and

Pediatrician-in-Chief of the Morgan Stanley Children's Hospital of New York Presbyterian, New York, New York, USA

Susan L. Rosenthal, PhD [Professor of Medical Psychology (in Pediatrics and Psychiatry)]

Columbia University Medical Center- Morgan Stanley Children's Hospital of New York Presbyterian, New York, New York, USA

Abstract

Objectives—Bacterial vaginosis (BV) is the most common reproductive tract infection (RTI) and is a significant risk factor for preterm birth. Microbicides could be an option for prevention

Corresponding Author: Marina Catalozzi, MD, MSCE, Assistant Professor of Pediatrics and Population & Family Health at Columbia University Medical Center, 622 W 168th Street, VC-402C, New York, New York 10032, mc2840@columbia.edu, Tel: 212-305-9256, Fax: 212-305-8819.

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and treatment of BV in pregnancy and understanding use of the product will be crucial to its success. The present study explored attitudes of women in the third trimester of pregnancy regarding topical microbicide use for prevention and treatment of BV.

Methods—Twenty-six women in their third trimester were interviewed regarding their knowledge and beliefs about RTIs during pregnancy and attitudes concerning the use of topical microbicides for prevention and treatment of BV.

Results—Participants had a mean age of 24.9 years, were largely underrepresented minorities and the majority had past pregnancies. Participants had knowledge and experience with RTIs but not BV. They were open to the use of microbicides for either prevention or treatment of BV, but believed that women requiring treatment would be more motivated. Rationales for acceptability were most commonly related to the baby's health. Practical issues that may interfere with use were often, but not always, related to pregnancy. There was a range of attitudes about partner involvement in decision-making and the practicalities of product use.

Conclusion—Pregnant women are knowledgeable about RTIs but not necessarily BV. The women in this study found microbicide use acceptable, particularly for treatment. To improve acceptability and use, education would be needed about BV and possible complications, how to overcome practical problems, and the value of involving partners in the decision.

Keywords

bacterial vaginosis; topical microbicides; acceptability; prevention; treatment

Introduction

During pregnancy women are especially vulnerable to infection with HIV, other sexually transmitted infections (STIs) and reproductive tract infections (RTIs) for both physiological and behavioral reasons. In pregnancy there is relative immunosuppression and women are less likely to use condoms, as there is no need for contraception. Bacterial vaginosis (BV) is an RTI that is particularly problematic. BV has been described as an abnormal overgrowth of anaerobic bacteria and decrease in normal vaginal flora (lactobacilli) resulting in an abnormal vaginal pH. This overall imbalance of the vaginal flora leads to odor and discharge.^{1,2} BV is a common RTI in women of reproductive age.^{1,3} Rates in pregnant women have been reported to be between 20 and 31% throughout pregnancy.⁴⁻⁸ BV has been associated with an increased risk of STI⁹ and HIV¹⁰ acquisition, preterm delivery⁸ and postpartum infections¹¹. Prematurity causes significant morbidity and mortality among infants.^{2,8} To date, there has been minimal success in disrupting the link between BV and pre-term birth², making prevention of BV a priority.

For some women, BV is a persistent or recurrent condition. *Gardnerella vaginalis*, which tends to be the predominant organism in BV, forms groups which stick to each other on a surface known as a biofilm.^{12,13} Biofilm makes antibiotics less effective in preventing BV's recurrence¹⁴, and, as a result, they have not significantly reduced BV-related preterm births.² However, there are new approaches being studied that may be more effective than antibiotics. One such approach is to re-establish the vaginal flora disrupted in BV¹⁵; another is to inhibit formation of or disrupt the biofilm using DNase.¹⁶ DNase is an enzyme that

disrupts DNA; DNase-containing microbicide inhibits both newly forming and established biofilms.¹⁶ This can be applied through a topical microbicide which would be inserted into the vagina.¹⁶

It has been argued that relevant behavioral research should be conducted in parallel with product development¹⁷, an argument that is supported by experiences with recent HIV/STI microbicide clinical trials in which poor adherence may have undermined determination of efficacy¹⁸⁻²⁰. Therefore, given the current interest in, and on-going work to develop biomedical strategies to prevent and/or treat BV during pregnancy, it is important to begin investigating the perceptions and attitudes of pregnant women toward microbicide use. Little is known about their attitudes; in the historical context of HIV/STI prevention microbicide trials, women have been told to discontinue product use if they become pregnant. Understanding the unique attitudes of pregnant women is important because women may alter their health behaviors during this critical time²¹⁻²⁴. Motivation to use a microbicide, and consistent use, could be lower than when not pregnant, because of issues such as fatigue or low risk perception, or could be higher because of the drive to protect themselves and their babies. Thus, the goal of the present study was to understand the context of decision-making about microbicide use during pregnancy. We explored attitudes of women in their third trimester of pregnancy regarding a topical microbicide used for either prevention or treatment of BV.

Materials and Methods

Women were recruited from the waiting room of a university-based obstetrics clinic in New York City to complete in-person semi-structured interviews. The study was approved by the Weill-Cornell Medical College and Columbia University Medical Center Institutional Review Boards and written informed consent was obtained. Participants were reimbursed \$30.00 and a subway card. Eligible women were in their third trimester, at least 16 years old, and fluent in English or Spanish.

A portion of the interview focused on knowledge, perceptions and beliefs about RTIs during pregnancy and attitudes regarding the use of a topical microbicide for prevention or treatment of RTIs during pregnancy. This portion of the interview was structured such that the women responded to statements (see Table 1) regarding RTI knowledge and perceptions with a 5 point Likert response scale ranging from “strongly disagree” (score = 1) to “strongly agree” (score = 5), which was then followed with semi-structured probes. Women were then given information about a gel product that scientists are developing to prevent infection (in pregnant women and their babies) and preterm birth. Women were informed that the gel product was to be used in the last three months of pregnancy without specific discussion regarding application method. Next, women were asked about their likelihood of use (using a likert scale as above) of this product for prevention of BV, followed by their likelihood of use for treatment of BV. Respondents were also asked follow-up questions regarding their reasoning, what type of woman would use it, potential barriers to use including specific questions about leakage and panty liners, and partner involvement in use. Consistent with a semi-structured interview format, interviewers followed up as appropriate for clarity and to pursue important points. Interviews were completed by a trained research

assistant. Pregnant women were approached and data was collected on those who agreed to participate until saturation of themes was achieved and no new ideas were being elicited.

Each interview was audio-recorded and transcribed, including one that was conducted in Spanish and translated into English. Framework analysis was used, which began with familiarization through independent reading of the transcripts and development of a thematic framework^{25,26}. An MS Word file was made for each theme, and an iterative process was used to code and interpret qualitative data. Three researchers created the coding scheme. Two researchers coded independently and then reviewed the codes. There was a high rate of agreement and the few disagreements were resolved through discussion.

Results

Participants

Of 59 women approached in the waiting room, 26 (44%) participated with 24 (40%) having a complete interview (two interviews were interrupted due to clinic flow). Of the 33 women who were approached but did not participate, n=18 (54%) agreed to be contacted but did not successfully schedule a return appointment; 4 (12%) requested the contact information of the interviewer, and did not follow up. The remaining 11 (33%) declined at the time of recruitment citing lack of time, fatigue, lack of interest and transportation issues. The participants had a mean age of 24.9 years, were largely underrepresented minorities and the majority had been pregnant in the past (Table 2).

BV and RTI Knowledge and Experience

In response to an open-ended question, many of the women (n = 18) reported not knowing anything about BV; a few (n=5) had general knowledge about RTIs; only 3 of the 29 women reported BV-specific knowledge. Eighteen women reported a history of an RTI (Table 2), including 2 women with a history of BV.

Despite having little to no specific knowledge about BV, when asked about agreement to statements regarding RTI knowledge, perceptions and beliefs during pregnancy, women's responses reflected an overall understanding of and risk for RTIs (Table 1). The mean score of 4.28 (between moderately and strongly agree) in response to the statement: *Having a vaginal infection at the time of birth may cause long term problems for the baby* suggests that women have some awareness or concern regarding the potential harm to a baby's health.

Likelihood of Topical Microbicide Use for Prevention and Treatment

Most of the participants thought that women would be likely to use a microbicide for prevention and/or treatment during the third trimester. The reasons given related to the health of both the baby and mother and are illustrated by the following comment:

“... if the gel is to be used during the last three months, and is to keep the baby healthy and the woman herself healthy, I think, me being a pregnant woman will definitely be for it.”

Two women reported neither agreeing nor disagreeing that women would use the microbicide for prevention (one for treatment as well); only one woman strongly disagreed with a pregnant woman using the product for either prevention or treatment and her reasons for disagreement varied for each. For this participant, disagreement regarding a pregnant woman using the product for prevention was based on concern for the baby's health. However, disagreement with a woman's use of microbicide for treatment was focused on medication delivery.

Prevention

“...the baby might ingest the gel. Or it might, I don't know, a certain reaction the baby might have - you might have an allergic reaction in the inside of you...that may cause a rash.”

Treatment

“I'd rather take a pill first before I take a gel. You know, I guess it is faster, you don't have to worry about, you know, if your husband...wants to have sex with you.”

The quote regarding prevention reflects the lack of understanding regarding anatomy leading to unfounded concerns for the baby's health and safety.

Women who found topical microbicide use acceptable for both prevention and treatment also demonstrated within-woman differences in rationales. For example, one woman said “strongly agree” to both questions, yet her rationale for prevention was based on weighing the risk of medication versus risk of infection, while her rationale for treatment was based on the health of her baby.

Prevention

“I think if enough research will be done and it's determined that there is no harm or less harm compared to whatever [possible] infection it is that you have it is definitely worth the try...”

Treatment

“...it'll be even better because you know you're treating to prevent something from happening to the child.”

Other women varied in their ratings, and when they did, the use for treatment was always favored over the use for prevention. For example, one woman said “moderately agree” for the use for prevention and when asked about her reasons said:

“I think some women would choose to do it if they really had to for the benefit of the baby. But others might not be too comfortable with it so...maybe because they're just, um, scared of the risk to the baby.”

In contrast, when asked about treatment, this same woman said “strongly agree” and stated that... “*if I had an infection, I would want it to be treated before I had the baby.*”

When responding to *what type of woman* would use the microbicide for prevention and treatment, participants focused on specific characteristics (age, history of infections, level of sexual activity, current risk for infection), attitudes (woman's interest in benefitting her baby's health), and gel characteristics (effectiveness and impact on sexual activity). Consistent with a stronger interest in use for treatment, some women indicated that a universal interest in use for treatment would be likely. For example, one woman said with regards to use of the gel for prevention:

“...Like older women, older married women probably would use it more than teenage, pregnant women or younger women that's not ready to stop having sex to use a medicine.”

For treatment, she indicated that: “*I truly think it's for everybody. I think if you have an infection, and this is the cure, I think you'll be willing to do it.*” It is worth noting that the participants were not told anything about increasing or decreasing frequency of sex with microbicide use so the assumption was made that sexual activity would decrease.

Practical Issues with Use for Prevention and Treatment

The interviewer specifically asked about issues associated with leakage, messiness and the need for panty liners with product use. Other issues were raised spontaneously by the participants. In order of frequency these were: leakage, messiness, difficulty remembering daily use or incorporation into the daily routine and difficulty of applying the gel due to their physical size in the third trimester. A few women spontaneously noted that they would prefer an oral medication to a gel. Although the issues were similar across prevention and treatment, some women viewed barriers to use of the gel product as more relevant for prevention versus treatment. The following is an example regarding daily use and incorporation into a pregnant woman's routine. It also highlights the impact of fatigue in the third trimester.

Prevention

“Or sometimes you know - you know being a pregnant woman, you just get tired, so - and frustrated. So you might just want to like say not today.”

Treatment

“...you could put the - set the alarm or the daily planner everyday to your phone, just as a reminder. But if you don't have that then yeah, you're going to slip up a few times...Because there's going to be some women who will feel like, if they take it to prevent infection, if they don't have it, then it has no use for it. But if they needed to treat an infection, then they'll probably take it every day.”

Some thought that these practical problems may matter less to women when pregnant, others that they would matter more.

For example, leakage and messiness (a traditionally mentioned barrier to topical microbicides use)²⁷⁻³¹ was perceived as less of an issue during the pregnancy. For example, in response to the question, *What if it leaked a little and you had to wear a panty liner every day, how would that affect your decision to use the gel or not?* one woman said “*Not at all*

'cause I already use a panty liner everyday.' Similarly, another woman said *"Like when you're pregnant sometimes, you have discharge anyway, so probably it wouldn't make a difference."*

As described by the following woman, fatigue and physical size during the third trimester of pregnancy were perceived as barriers to incorporating daily gel use:

"...I mean, it would be hard for them because as - your belly is getting big and big, and sometimes you can't even..., I guess, you might - probably they might can't reach it or it might be hard for them, so they - that's why they might not use it like every day."

Partners' Involvement in Use for Prevention and Treatment

The women were asked about the potential involvement of partners in decision-making about microbicide use and in helping in use of the gel. The women described a range of involvement of their partners in gel use for both prevention and treatment.

Involvement of Partner

"...I think he shouldn't have no part in it because, number one, she's a grown woman, she can make her own decisions. And to be honest with you, there's - a man shouldn't be telling you what to do."

Partner Help with Reminders

"Reminding them, letting them know like you know, use it. It is going to help you. Like, you know, it's going to help whatever you have to go away. Basically reminding them like, use it. Did you remember, like you know, to use it today or whatever like did you use it, did you do what you have to do, you know."

Partner Help with Insertion

"Yeah, if the person feels comfortable. But as a woman, I think you will want to push that up yourself than rather somebody else, well, the father doing it, because to them, it's like it will be a weird feeling to them."

Partner Involved in Decision-Making

"I think he would probably take active, like he would want to say - he would want to have a say because it's his child too."

For the majority of participants, their view of partner involvement was the same across prevention and treatment. There were, however, some participants who differentiated between the two, largely around partner involvement in decision-making. For example, one woman just said no without elaboration for prevention, and then said in response to treatment, *"[they] should also think about their baby. It's not about them anymore. So, they should try to keep up also with the mother to make sure she is doing what's supposed to be done."*

Discussion

The results suggest that if a safe and effective topical microbicide becomes available for use during the third trimester of pregnancy, many women would be willing to use it. However, similar to the experience of the use of topical microbicides for the prevention of STIs/HIV³², there would be many challenges to fostering both initial uptake and sustained use. Prior microbicide acceptability research shows that women are interested in effective microbicides and have opinions about how and when to use them. These opinions range from whether or not the microbicide should be coitally-dependent to specific gel characteristics.³³⁻³⁶ Despite this interest in and support of topical microbicides for prevention of infections, studies with microbicides have shown difficulty with sustained adherence with rates varying from 42 to 55% depending on when the microbicide was initiated.^{18,19} While these studies look at coitally-dependent rather than daily application, the issue of sustained adherence is one that must be considered carefully. As other authors have suggested, behavioral and social factors must also be considered.¹⁷

Additionally, it may be difficult for women to adopt a new health behavior in pregnancy. Even in high stakes situations like HIV infection where there is concern about perinatal transmission, medication adherence issues exist³⁷. While oral antiretroviral treatment is different than application of a microbicide, the motivation is still to benefit the baby. These adherence issues are important to consider when implementing any medication regimen during pregnancy. Studies of topical vaginal treatment for candidal infections in pregnancy have not identified difficulty with adherence but these are short term treatments (up to 7 days).^{38,39} While studies of treatment of vaginal candidiasis support that women may be comfortable with topical treatments during pregnancy, they do not address the challenge of daily sustained application during the third trimester.^{38,39}

While increased knowledge is not sufficient for individuals to adopt health behaviors, lack of knowledge can be a significant barrier. Although the women demonstrated a general awareness of the risk of infections to the baby, they lacked specific knowledge about BV. We did not ask about their understanding of the risk associated with preterm birth, however, research is increasingly showing its negative impact on babies⁴⁰⁻⁴². Fostering greater knowledge about BV, its link to pre-term birth and the potential adverse outcomes of preterm birth could lead to increased concerns about risks and thus increased motivation for adherence. Studies where knowledge of the impact of folate on neural tube defects increases vitamin adherence demonstrates the link between greater knowledge and adherence in pregnancy²¹. The current study's results indicate that both pregnant women and their partners fear harm to the pregnancy by application of microbicides. General knowledge regarding anatomy related to pregnancy and safety of the baby would help to guide their decision making.

However, understanding risks typically increases adherence when individuals feel able to implement the behavior change. The possibility of leakage and attendant need for panty liners has been a problem for non-pregnant women in microbicide studies⁴³. Most of the women in this study regarded it as a surmountable barrier given that panty liner use is common during pregnancy; educating women to expect the leakage will still be important.

Other commonly cited barriers by these women included incorporating use into daily schedules and perceived awkwardness of insertion given increased abdominal girth during pregnancy. For some, partners could help by reminding them and helping with insertion for a woman who cannot do it on her own. As such, this will need to be done on an individual basis, as women had widely ranging views of the appropriateness of partner involvement. Past studies looking at candida treatment have not remarked on difficulty with application of vaginal treatments due to size,^{38,39} but women in this study had these concerns. Perhaps the idea of gel application throughout the third trimester when pregnant women are at their largest, felt overwhelming. This is another opportunity for education around the delivery vehicle, whether by pessary or applicator, for use during the third trimester of pregnancy. Clear education around application of the topical gel would also allow for directions to ensure that application did not endanger the pregnancy.

The distinction that women made between perceived reasons for use or non- use of microbicides for prevention and treatment is an important one to consider when fostering uptake and adherence. In general, women viewed use for treatment as more acceptable, and even when their views about acceptability of microbicide use for prevention and treatment were similar, their reasoning differed. For women who are at low risk of infection barriers will seem more problematic when using the product for primary prevention. Women who have experienced recurrent BV infection or a premature delivery (whether or not it was associated with BV) will be important populations to assess with regard to topical microbicide use for BV prevention.

Women raised the issue of how the microbicide might impact sexual contact particularly regarding their partner's response to the microbicide. Past studies have highlighted the importance of considering the impact of microbicides on sexual contact and have noted that there may be some benefit to the lubricating properties of a microbicide from the perspective of both women and of men.⁴⁴⁻⁴⁶ Again, education around the possible impact of a microbicide on sexual contact and how to discuss this with a partner would be beneficial to women using microbicides in pregnancy.

As mentioned, given the experience of poor adherence to vaginal microbicides in STI/HIV trials¹⁸⁻²⁰, the additional barriers that pregnant women may face with regards to difficulties with insertion will need to be addressed. The use of illustrated guides and videos may be helpful in instructing women how to overcome some of the physical challenges. When counseling around use of microbicides in the absence of an infections, educational efforts could be used to capitalize on the concept of prevention that is already stressed for pregnant women. In contrast, women with an active infection will still need to know that use is safe and be guided to overcome the barriers. It is possible that motivation can be enhanced by the knowledge that an active infection needs to be treated, and this may provide sufficient reason to overcome barriers.

This was a qualitative study of minority women in their third trimester designed to identify pregnant women's perceptions of potential microbicide use. Most of these women did not have experience with BV, and their answers may differ from those who have experienced recurrent BV infections. Although they did not have specific knowledge, their knowledge

seemed sufficient to answer these questions. As a qualitative study, it does not allow for the evaluation of which women will find topical microbicide use most acceptable or to predict which women would involve their partners in decision-making and use. Questions about prevention of BV were always presented first and thus may be the reason for the differential in rationales and responses. However the consistency of participants' increased acceptability of microbicides for treatment over prevention makes this less likely.

Despite these limitations, this study establishes that it is important to understand pregnant women's perspectives on topical microbicide use for BV. The findings suggests that pregnant women would consider the use of topical microbicides to prevent and treat specific RTIs that would put their baby at risk for preterm birth. They would be more likely to be motivated to use the microbicide if they had an existing infection compared to using it to prevent an infection from occurring. Future research could explore methods for overcoming the barriers to adherence, whether in the context of prevention or treatment. Research could also explore attitudes toward topical microbicide acceptability and adherence in a greater range of women to determine if there are demographic or situational predictors associated with barriers to use, and potential solutions including partner involvement.

Conclusion

This study found that pregnant women in university-based obstetrics clinics are knowledgeable about RTIs but not necessarily BV. Education about BV and its potential sequelae, including preterm birth, may generate more concern about the risk of BV and could foster the use of a preventive method. This study found that pregnant women would consider using topical microbicides for RTIs during the third trimester of pregnancy, particularly for treatment of an RTI related to prematurity. Education around overcoming barriers that are specific to pregnant women in their third trimester may help with product adherence. Providers can encourage the involvement of partners in decision-making as well as in assistance with practical issues of microbicide use if women are interested in their partner's help.

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Table 1
Likert Scale Responses to RTI Knowledge, Perception & Belief Questions (N = 25)

Knowledge, Perception and Belief Questions	Mean and Range
<i>During pregnancy, a woman can get a new vaginal infection even if she and her partner only have sex with each other.</i>	mean score = 4.4 ± 0.7, range 2-5 21 strongly/moderately agree 3 neither agree/disagree 1 moderately disagree
<i>Having a vaginal infection at the time of birth, may cause long term problems for the baby.</i>	mean score = 4.28 ± 1.24, range 2-5 18 strongly/moderately agree 3 neither agree/disagree 4 moderately disagree
<i>Some treatments for vaginal infections can be used safely during pregnancy.</i>	mean score = 4.36 ± 0.55, range 3-5 21 strongly/moderately agree 8 moderately agree 4 neither agree/disagree
<i>Some women seem to get bacterial vaginosis (BV) more often than other women.</i>	mean score = 3.84 ± 0.69, range 2-5 16 strongly/moderately agree 8 neither agree/disagree 1 moderately disagree
Likelihood of Use	
<i>A pregnant woman would be very likely to use the product once a day to prevent an infection for the last three months of her pregnancy.</i>	mean score of 4.24 ± 0.82, range: 1-5 22 strongly/moderately agree 2 neither agree/disagree 1 strongly disagree
<i>A pregnant woman would be very likely to use the product once a day to treat an infection for the last three months of her pregnancy.</i>	mean score of 4.63 ± 0.79, range 1-5 22 strongly/moderately agree 1 neither agree/disagree 1 strongly disagree 1 did not answer

Table 2
Participant Demographic Information (N=26)

Age	mean: 24.9 yrs, range: 21 to 34 years
Race/Ethnicity	Hispanic, n = 13 (50%) African-American, n = 10 (38.5%) Caucasian/other, n = 3 (11.5%)
Previous pregnancy and child-rearing	7 primigravidas (27%) 7 with only history of induced termination or spontaneous abortion (no live births) (27%) 11 with previous pregnancies and currently raising their children (42%) 1 with previous deliveries and children are under care of NYS Office of Child and Family Services (4%)
Education	3 completed some high school (11.5%) 5 graduated from high school or received GED (19.2%) 10 completed some college (38.5 %) 8 graduated from college (30.8%)
Cohabitation with partner	15 partners not in household (57.7%), 11 partners in household (42.3%)
STI and other RTI history	3 reported experience with STIs (2 chlamydia, 1 herpes) 15 report experience with other RTIs (some with overlap: 2 BV, 14 yeast, and 2 "mild infection")