Bacterial vaginosis - Management

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What are the characteristic features of bacterial vaginosis?

- Approximately 50% of women with bacterial vaginosis (BV) are asymptomatic.
- When symptoms are present, BV is characterized by a fishy-smelling vaginal discharge.

• Examination may reveal a thin, white, homogeneous discharge coating the walls of the vagina and vestibule.

 The characteristic appearance of the discharge is not specific for BV but supports the diagnosis.

 If the appearance of the discharge is not characteristic, consider other diagnoses, such as trichomoniasis or candidiasis.

Bacterial vaginosis is not usually associated with soreness, itching, or irritation.

 If these symptoms are present, consider other diagnoses, such as trichomoniasis or candidiasis. (There are CKS topics on <u>Vaginal discharge</u>, <u>Trichomoniasis</u>, and <u>Candida - female genital</u>.)

• The <u>pH of the vaginal fluid</u> is greater than 4.5.

Basis for recommendation

These recommendations are based on guidelines from the British Association for Sexual Health and HIV on the management of bacterial vaginosis [BASHH, 2006] and guidance from the UK Health Protection Agency on the management of abnormal vaginal discharge in women [HPA, 2008].

When and how should I test a non-pregnant woman for bacterial vaginosis?

Examination and further tests may be omitted and empirical treatment for bacterial vaginosis
(BV) started in women with characteristic <u>symptoms</u> of BV if all the following apply:

• The woman is not at high risk of a sexually transmitted infection (STI).

• Women are at increased risk of an STI if they are younger than 25 years of age, or have had a new sexual partner in the last 12 months, or more than one sexual partner in the last 12 months.

 The woman does not have symptoms of other conditions causing vaginal discharge (for example itch, abdominal pain, abnormal bleeding, dyspareunia, or fever).

• The woman is not post-natal, post-miscarriage, or post-termination.

• Symptoms have not developed after a gynaecological procedure.

 Symptoms have not recurred soon after treatment for BV or persisted following treatment for BV.

• The woman is not pregnant (see When and how to test pregnant women).

• If empirical treatment is not considered appropriate, or if the diagnosis is uncertain:

• Perform a speculum examination.

∘ If pH paper is available, test the <u>pH of the vaginal fluid</u>.

 Take a high vaginal swab (or use a self-taken low vaginal swab) for Gram staining and to exclude other causes of vaginal discharge.

Samples should be placed in transport media (such as Amie's or Stuart's medium). A Gram stain for mixed flora suggestive of BV and a trichomoniasis culture should be requested from the laboratory.

 $_{\circ}$ If there is a delay in transportation, the swab should be refrigerated at 4°C for no longer than 48 hours.

 If the woman is at high risk of an STI, specimens for chlamydia and gonorrhoea should also be sent, according to local laboratory procedures.

• For further information, see the CKS topic on <u>Vaginal discharge</u>.

Basis for recommendation

Empirical management of bacterial vaginosis

 The recommendation to treat certain women without further examination and tests is based on expert opinion and is consistent with UK guidelines for the management of abnormal vaginal discharge outside of genito-urinary medicine settings [FFPRHC and BASHH, 2006; RCGP and BASHH, 2006].

Examination and investigation

• Recommendations for examination and investigation are consistent with UK guidelines for the management of abnormal vaginal discharge outside of genito-urinary medicine settings [FFPRHC and BASHH, 2006; RCGP and BASHH, 2006].

 Recommendations for transport and storage of swabs are consistent with UK guidelines on testing for sexually transmitted infections in primary care [BASHH, 2004; FFPRHC and BASHH, 2006; RCGP and BASHH, 2006].

When and how should I test a pregnant woman for bacterial vaginosis?

• Examination and further tests are recommended in all pregnant women with characteristic <u>symptoms</u> of bacterial vaginosis.

Perform a speculum examination (unless the woman has a low-lying placenta).

o If pH paper is available, test the pH of the vaginal fluid.

 Take a high vaginal swab for Gram staining and to exclude other causes of vaginal discharge.

Samples should be placed in transport media (such as Amie's or Stuart's medium). A Gram stain for mixed flora suggestive of BV and a trichomoniasis culture should be requested from the laboratory.

 $_{\circ}$ If there is a delay in transportation, the swab should be refrigerated at 4°C for no longer than 48 hours.

 If the woman is at high risk of a sexually transmitted infection, specimens for chlamydia and gonorrhoea should also be sent, according to local laboratory procedures. • For further information, see the CKS topic on <u>Vaginal discharge</u>.

Basis for recommendation

Examination and testing in pregnant women

• CKS found no guidelines specifically regarding examination and investigation in pregnant women, but making an accurate diagnosis and excluding other causes seem prudent, given the potential adverse outcomes of bacterial vaginosis (BV) in pregnancy and that the recommended treatment is with antibiotics.

o CKS expert reviewers agree that examination and testing should always be done in pregnant women with BV, because the symptoms and clinical signs of BV are less reliable in pregnancy and because of the altered risk-tobenefit ratio.

• Recommendations for examination and investigations are consistent with UK guidelines for the management of abnormal vaginal discharge outside of genito-urinary medicine settings [FFPRHC and BASHH, 2006; RCGP and BASHH, 2006].

Transport and storage of swabs

 Recommendations for transport and storage of swabs are consistent with UK guidelines on testing for sexually transmitted infections in the primary care setting [BASHH, 2004; FFPRHC and BASHH, 2006; RCGP and BASHH, 2006].

How do I measure and interpret the pH of vaginal fluid?

• Obtain a sample of vaginal fluid on a cotton-tipped swab (via a speculum) from as high up the vagina as possible.

 Swab the lateral wall and not the posterior fornix, as the latter may collect secretions from the cervix, which has a naturally higher pH.

• Roll the swab over the pH paper.

• Measure the pH by comparing the colour of the moist test section of pH paper against the graded standard.

• A pH greater than 4.5 is consistent with a diagnosis of bacterial vaginosis.

 Although a pH greater than 4.5 is supportive of the diagnosis, it is not specific for bacterial vaginosis; increased vaginal pH can also indicate other conditions, such as trichomoniasis.

Basis for recommendation

These recommendations are based on Scottish regional guidelines on the primary care management of vaginal discharge [<u>NHS Lothian, 2008</u>].

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Should I treat asymptomatic women with a diagnosis of bacterial vaginosis?

• Women with asymptomatic bacterial vaginosis do not usually require treatment, unless they are undergoing termination of pregnancy.

• Women with asymptomatic bacterial vaginosis who are currently progressing with a pregnancy may require treatment; see <u>Scenario: Women who are pregnant</u> for more information.

Basis for recommendation

Asymptomatic women not undergoing gynaecological procedures

• CKS found no evidence on treating non-pregnant asymptomatic women (who are not undergoing a gynaecological procedure) for bacterial vaginosis (BV).

• Recurrence of BV is frequent; therefore, treating asymptomatic BV will have no impact on the population prevalence in women who are not pregnant [Wawer et al, 1999].

 Treatment of asymptomatic non-pregnant women with an incidental finding of BV is not recommended in current UK guidelines for BV [<u>BASHH, 2006</u>].

Termination of pregnancy

 Bacterial vaginosis is common in some populations of women undergoing elective termination of pregnancy and has been associated with post-termination endometritis and pelvic inflammatory disease (PID).

• <u>Evidence</u> from three RCTs suggests that treating BV with either metronidazole or clindamycin cream before termination may reduce the incidence of subsequent genital tract infection.

Other gynaecological procedures

• There is a lack of evidence to support or refute the treatment of asymptomatic BV before other gynaecological procedures.

 CKS found no studies investigating the possible role of BV, or the management of asymptomatic BV, in the development of PID directly after insertion of an intrauterine contraceptive device (IUD).

• The Faculty of Sexual and Reproductive Healthcare guidance on intrauterine contraception recommends that in asymptomatic women attending for insertion of an IUD, there is no indication to test for, or treat, lower genital tract organisms (such as BV) or to delay insertion until results of such tests are available. Women who are at higher risk of a sexually transmitted infection or who request swabs should be tested for chlamydia and gonorrhoea before IUD insertion [FSRH, 2007].

 Bacterial vaginosis has been associated with an increased incidence of vaginal cuff cellulitis and abscess formation after abdominal hysterectomy, but it is unclear whether this is a problem in UK practice, where many units administer perioperative antibiotics.

 CKS found no studies investigating the management of asymptomatic BV in preventing infection after upper genital tract procedures.

 Expert opinion is divided over treatment of BV in asymptomatic women before other invasive procedures, such as IUD insertion or endometrial biopsy. Some CKS expert reviewers would consider treatment of BV in asymptomatic women in this situation; however, current evidence does not support this approach.

 The British Association for Sexual Health and HIV recommends that treatment is indicated for women undergoing some surgical procedures, but the procedures are not specified [BASHH, 2006].

How should I treat a woman with bacterial vaginosis?

• Oral <u>metronidazole</u> is the treatment of choice.

• A dose of 400 mg twice a day for 7 days is recommended.

 If adherence to treatment is an issue, a single oral dose of 2 g may be used, although this is associated with a higher relapse rate.

o If the woman is breastfeeding, see Metronidazole and breastfeeding.

 Intravaginal <u>metronidazole</u> gel or intravaginal <u>clindamycin</u> cream are alternative choices if the woman prefers topical treatment or cannot tolerate oral metronidazole:

o Intravaginal metronidazole gel 0.75% once a day for 5 days, or

o Intravaginal clindamycin cream 2% once a day for 7 days.

• Oral <u>clindamycin</u> and oral tinidazole are alternatives but are less preferred.

 Oral clindamycin (300 mg twice a day for 7 days) is not widely recommended in primary care because of an increased risk of pseudomembranous colitis.

 Tinidazole (2 g as a single oral dose) has been less well studied than metronidazole in the treatment of bacterial vaginosis.

o If the woman is breastfeeding, see Clindamycin and breastfeeding.

A test of cure is not required if symptoms resolve.

Basis for recommendation

The recommendations for drug treatment in symptomatic women with bacterial vaginosis (BV) are consistent with recommendations from the British Association for Sexual Health and HIV [BASHH, 2006].

Antibiotics

• Oral metronidazole is a well-established treatment. It is usually well tolerated and is inexpensive.

• <u>Evidence</u> from a systematic review suggests that:

 Both intravaginal clindamycin and intravaginal metronidazole are more effective than placebo at curing BV.

 There are similar rates of cure with oral metronidazole (7-day regimen), intravaginal clindamycin, and intravaginal metronidazole.

o A single oral dose of metronidazole is associated with a significantly higher relapse rate than the 7-day regimen. However, some experts argue that in clinical practice the effectiveness of the single-dose regimen may be similar to that of the 7-day regimen because a higher adherence rate is expected for the single-dose regimen. CKS found no data to support this argument.

• <u>Evidence</u> from one randomized controlled trial suggests that there is no difference in efficacy between a 7-day regimen of metronidazole and a 7-day regimen of oral clindamycin; further evidence regarding the efficacy and safety of clindamycin is needed.

 The use of oral clindamycin is limited in primary care because of the rare but potentially serious risk of pseudomembranous colitis.

• CKS found no studies directly comparing tinidazole with other treatments for BV.

 Tinidazole has similar activity to metronidazole, but it is more expensive and it generally exhibits cross-resistance with metronidazole.

Vaginal acidification

• Several products containing intravaginal lactic acid are available over-the-counter; however, there is insufficient evidence to make a recommendation on the use of vaginal acidification for the treatment of BV.

• Evidence on the efficacy of vaginal acidification with lactic acid or acetic acid is conflicting and studies are generally small and of poor quality.

Test of cure if symptoms resolve

• The British Association for Sexual Health and HIV does not routinely recommend a test of cure in women who are not pregnant [BASHH, 2006].

How should I manage a woman with persistent symptoms?

 Persistent symptoms are most likely to be due to misdiagnosis or to poor adherence to treatment.

If symptoms persist after initial treatment:

• Reconsider the diagnosis.

 Perform a speculum examination and take swabs if this has not been previously done.

• Check for adherence to treatment.

• Ensure that the current episode is adequately managed.

 If a single 2 g dose of metronidazole has previously been used, a 7-day course of 400 mg metronidazole twice daily can be tried.

 If intravaginal preparations have previously been used, a course of oral metronidazole can be tried.

In the unlikely event that a woman with confirmed bacterial vaginosis (BV) has not responded to a 7-day course of oral metronidazole (and you are confident that she has adhered to the treatment regimen), discussion with a gynaecologist or genito-urinary medicine specialist regarding further treatment is advised.

• For persistent BV in women with an intrauterine contraceptive device, consider removing the device and advising the use of an alternative form of contraception.

Routine screening and treatment of male partners is not indicated.

Basis for recommendation

Persistent symptoms

• CKS found no evidence regarding treatment options if initial treatment is unsuccessful. A pragmatic approach may be needed to ensure that the current episode is adequately managed.

Removal of intrauterine device (IUD)

 Bacterial vaginosis (BV) is more common in women with an IUD; the recommendation to consider IUD removal in a woman with persistent BV is pragmatic, supported by the opinion of CKS expert reviewers.

Not screening and treating male partners

• No reduction in relapse rate was reported from studies in which male partners of women with BV were treated with metronidazole, tinidazole, or clindamycin [BASHH, 2006].

How should I manage a woman with recurrent symptoms?

• Recurrence of symptoms is common.

Reconsider the <u>diagnosis</u> of bacterial vaginosis (BV).

 Perform a speculum examination and take swabs if this has not been previously done.

 Further examination and investigations may not be necessary if a previous episode of recognizably similar symptoms was previously diagnosed to be BV and:

o Characteristic symptoms and signs of BV were present.

 Symptoms, signs, and microbiological evidence from swabs of other conditions causing vaginal discharge were absent.

• Symptoms and signs cleared after antibiotic treatment.

• Treat the current episode with a 7-day course of oral metronidazole.

• Advise the woman that it may be beneficial to avoid vaginal douching, use of shower gel, and the use of antiseptics, bubble baths, or shampoos in the bath.

• If the diagnosis is confirmed and symptoms recur frequently (at least four times a year) despite adequate management in primary care, and symptoms are adversely affecting the woman, consider discussing management with a gynaecologist or genito-urinary medicine specialist.

Basis for recommendation

Recurrence of symptoms

• Up to 30% of women with an initial response to treatment have a recurrence of symptoms within 3 months [Sobel, 1997]. The reasons for this are unclear.

• There are few published studies evaluating the optimal approach in women with frequent recurrences of bacterial vaginosis (BV).

Avoidance of vaginal douching and possible irritants

• Vaginal douching has been identified as a risk factor for BV [Alfonsi et al, 2004].

 A cross-sectional study of 1200 women found that recent douching significantly increased the risk of BV approximately two-fold.

• In the absence of evidence to refute or support women with recurrent episodes of BV avoiding vaginal douching, this recommendation is based on expert opinion [BASHH, 2006].

Possible management options

• <u>Evidence</u> on the management of recurrent BV is insufficient to make recommendations for primary care. Options that have been studied include:

- o Oral metronidazole before and/or after menstruation.
- o Intermittent use of metronidazole vaginal gel.
- o Use of lactobacillus (orally or intravaginally).
- o Vaginal acidification with intravaginal acetic acid or lactic acid gel.

• Given that BV can often be asymptomatic, it may be difficult to distinguish recurrent BV from persistent BV or treatment failure, and adequate treatment of the current episode is therefore essential.

Prescriptions

For information on contraindications, cautions, drug interactions, and adverse effects, see the electronic Medicines Compendium (eMC) (<u>http://emc.medicines.org.uk</u>), or the British National Formulary (BNF) (<u>www.bnf.org</u>).

Oral metronidazole

Age from 12 years onwards Metronidazole tablets: 400mg twice a day for 7 days

Metronidazole 400mg tablets Take one tablet twice a day for 7 days. Supply 14 tablets.

> Age: from 12 years onwards NHS cost: £0.83 Licensed use: yes

Metronidazole tablets: 2g single dose (less preferred)

Metronidazole 400mg tablets Take five tablets together as one dose. Supply 5 tablets.

> Age: from 12 years onwards NHS cost: £0.30 Licensed use: yes

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Intravaginal antibiotics

Age from 12 years onwards

Metronidazole 0.75% vaginal gel: use at night for 5 nights

Zidoval 0.75% gel Insert one 5g applicatorful into the vagina each night for 5 nights. Supply 40 grams.

> Age: from 12 years onwards NHS cost: £4.31 Licensed use: yes

Patient information: Do not use this vaginal gel during your period.

Clindamycin 2% vaginal cream: use at night for 7 nights

Clindamycin 2% vaginal cream Insert one 5g applicatorful into the vagina each night for 7 nights. Supply 40 grams.

> Age: from 12 years onwards NHS cost: £10.86 Licensed use: yes

Patient information: This vaginal cream can cause weakening of condoms. Therefore, during treatment and for 5 days after treatment with clindamycin vaginal cream, do not rely on condoms to protect against pregnancy or sexually transmitted infections.

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Who should I treat?

• Offer treatment to all pregnant women with symptomatic bacterial vaginosis (BV).

• Women who are pregnant should not be offered routine screening for BV. However, if a pregnant woman is incidentally found to have BV and has no symptoms, discuss with the woman's obstetrician whether treatment is appropriate.

Basis for recommendation

Treating all symptomatic pregnant women

• The recommendation to treat pregnant women with bacterial vaginosis (BV) who are symptomatic is consistent with UK and international guidelines [BASHH, 2006; Public Health Agency of Canada, 2008].

Screening for BV in asymptomatic pregnant women

• The National Institute for Health and Clinical Excellence (NICE) does not recommend routine screening for BV because the evidence suggests that identification and treatment of asymptomatic BV does not lower the risk for pre-term birth and other adverse reproductive outcomes [NICE, 2008].

• The British HIV Association recommends screening for BV in pregnant women who are infected with HIV because there is an increased risk of mother-to-child transmission of HIV-1 in the presence of BV [de Ruiter et al, 2008].

Seeking advice regarding whether to treat an asymptomatic pregnant woman

 Because the <u>evidence</u> regarding the treatment of BV to prevent adverse outcomes in pregnancy is conflicting, CKS recommends that the management of asymptomatic pregnant women be considered on an individual basis, after discussion with the woman's obstetrician.

How should I treat a pregnant woman with bacterial vaginosis?

• Oral metronidazole is the treatment of choice.

• A dose of 400 mg twice a day for 7 days is recommended.

 High-dose regimens (single oral dose of 2 g) are not recommended during pregnancy.

 Intravaginal <u>metronidazole</u> gel or intravaginal <u>clindamycin</u> cream are alternative choices for achieving cure if the woman prefers a topical treatment or is unable to tolerate oral metronidazole:

o Intravaginal metronidazole gel 0.75% once a day for 5 days, or

o Intravaginal clindamycin cream 2% once a day for 7 days.

• Oral <u>clindamycin</u> may also be considered, but is less preferred.

 Oral clindamycin (300 mg twice a day for 7 days) is not widely recommended in primary care because of an increased risk of pseudomembranous colitis.

Testing should be repeated after 1 month to ensure that cure was achieved.

Basis for recommendation

Antibiotic choice for eradication of bacterial vaginosis

• Evidence from a Cochrane systematic review (10 randomized controlled trials) indicated that both oral and intravaginal antibiotics are effective at eradicating bacterial vaginosis in pregnant women. Although there was no direct comparison, oral antibiotics appeared to have similar efficacy to intravaginal antibiotics, and clindamycin (oral or intravaginal) appeared to have similar efficacy to other antibiotic treatments.

 High-dose regimens of metronidazole (2 g single dose) are not recommended in pregnancy [ABPI Medicines Compendium, 2008; BNF 56, 2008].

• Metronidazole is preferred over tinidazole in women who are pregnant because there is more experience with metronidazole.

Test of cure

• The recommendation to test all pregnant women 1 month after completion of treatment is based on expert opinion and is consistent with UK guidelines [<u>RCGP and BASHH, 2006</u>].

How should I manage a woman with persistent or recurrent symptoms during pregnancy?

If symptoms persist or recur after initial treatment:

• Reconsider the diagnosis of bacterial vaginosis.

o Check adherence with treatment.

• Ensure that the current episode is adequately managed.

 $_{\circ}$ Oral metronidazole 400–500 mg twice a day for 7 days is generally considered to be the most effective treatment.

 Consider discussing further treatment options with the woman's obstetrician or a genito-urinary physician.

Basis for recommendation

CKS found no evidence regarding treatment options if initial treatment is unsuccessful in a woman who is pregnant. Discussion with the woman's obstetrician or a genito-urinary physician is recommended, to avoid exposing the woman to repeated courses of antibiotics.

Prescriptions

For information on contraindications, cautions, drug interactions, and adverse effects, see the electronic Medicines Compendium (eMC) (<u>http://emc.medicines.org.uk</u>), or the British National Formulary (BNF) (<u>www.bnf.org</u>).

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