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Connections' customer satisfaction survey

By Veronica Restelli, Editor

On August 2011, CMPT performed a Customer Satisfaction Survey on Connections. In this survey, CMPT participants were asked to answer a few questions on the format and content of the newsletter.

We received 65 responses which represents approximately 46% of our participants. Although 58% of the respondents found Connections valuable as a source of continuing education, we would have preferred a higher percentage.

The objective of CMPT newsletter, Connections, is to be informative on a variety of microbiology related topics using a longer and more relaxed format structure than CMPT Critiques. When we asked the laboratories if the newsletter was meeting this objective, 66% of them thought we were.

In order to target laboratories' needs more efficiently, we asked for feedback on what topics they would like to see covered. We received a lot of suggestions which we consider very valuable. From that feedback we know that:

1. Laboratories would like to see more microbiology content with a stronger educational approach.
2. Connections is generally not relevant to Water microbiology participants and is occasionally relevant to Mycology and Parasitology participants.
3. Small laboratories would like to read about topics more related to their needs.

We got a few suggestions on topics that laboratories would like us to cover:

a) New technologies in microbiology (although not routinely used in most laboratories, people want to keep up to day with the new technologies used in the microbiology laboratory)

b) Issues related to antimicrobial resistance such as reporting AmpC producers were suggested.

c) Water microbiology, environmental microbiology.

d) Other: workup flowcharts for wounds, stools, etc

We have learned from the survey and will be adding more educational material including a new series of articles on water and environmental microbiology.

One of the suggestions we received was to get input from the laboratories on the topics they would like to have covered. We thought that this was a good idea so with the help of our web manager, Suhanya, we created a 'Submissions form' on the website. The laboratories can now submit their questions, suggestions, case studies or articles at: www.cmpt.ca/newsletter_bulletin/news_submissions.htm. I will try, to the best of my abilities, to cover and answer your questions and requests.

In this issue, we feature an article by Dr. Deirdre Church and Ms. Beverly Miller on bacterial vaginosis which includes interpretation for postmenopausal women, as suggested by one of the surveys. Also included in this issue is the very relevant and current topic of patient confidentiality.

In the following issues I will try to cover the topics you showed interest in and to publish articles relevant to all CMPT programs.

Thank you for your feedback, I hope we continue this interaction and collaboration.

Alberta Guideline for Laboratory Processing and Interpretation of Vaginal Specimens for Bacterial Vaginosis

Deirdre Church and Beverley Miller
Calgary Laboratory Services, Calgary Zone, Alberta Health Services

Background

Vaginitis is one of the most common infections seen in primary care. Effective treatment of vulvovaginal infections requires accurate diagnosis based on a clinical history and physical exam, and the laboratory testing of a vaginal sample (1-4). Bacterial vaginosis (BV) (~25-30% prevalence) and *Candida* (~20-25% prevalence) overgrowth are by far the most common infections diagnosed in adolescent girls and women (i.e., >13 yrs. to elderly), while *Trichomonas vaginalis* infection occurs much less often (i.e., ~1% prevalence).

Women with BV have an increased susceptibility to sexually transmitted infections (STIs) including human immunodeficiency virus (HIV) and some also have adverse pregnancy outcomes (i.e., pelvic inflammatory disease, premature labor) (2, 4-7). BV is diagnosed by a shift in the normal vaginal flora due to a decline in the levels of 'beneficial' lactic acid and hydrogen peroxide producing lactobacilli towards an overgrowth of a wide variety of fastidious and anaerobic bacteria, most notably *Gardnerella vaginalis*, *Mycoplasma hominis* as well as *Mobiluncus, Prevotella, Peptostreptococcus,* and *Porphyromonas* spp. (1, 3, 8-11). Recent molecular studies of vaginal flora in women with BV have also found a new bacterium, *Atopobium vaginae*, present in the majority of patients but rarely in healthy women (12). A mixture of these organisms is usually present in concentrations 100-1000 times greater in women with BV than in the healthy vagina (1, 3, 9, 10). Although the pathogenesis of BV and the triggers that cause this alteration in the vaginal ecosystem are not understood, several factors have been identified that may predispose women to the development of BV including sexual intercourse, broad-spectrum antibiotic use and more recently, vitamin D deficiency in pregnant women(13). In addition, in many cases, antibiotic treatment of BV results in only a temporary shift in the microbial flora in many cases and greater than 30% of BV patients will have a recurrence by three months.

Reports indicate BV prevalence in post-menopausal women is around 6%, which is consistent with the epidemiology in our region (14). Therefore, physician's orders for BV testing in this population **should not be refused.** However, there are various opinions on the reliability of the Nugent score for BV in post-menopausal women. Although some investigators recommend only applying the Nugent score when women are taking hormone replacement therapy (HRT) (15), other studies have documented how the Nugent score may change in peri-menopausal and post- menopausal women in the presence and absence of HRT (2, 14). Peri- and post-menopausal women who are not on HRT have a marked decrease in the concentration of vaginal lactobacilli but no increase in BV associated flora. Unfortunately, physicians rarely indicate whether a woman is pre-, peri- or post-menopausal or on HRT on the laboratory requisition. Therefore, the microbiology laboratory is most often unable to alter the interpretation of their microscopic examination based on these clinical data. A comment should therefore be placed on all laboratory reports of BV tests in women ≥55 years of age as outlined below (see notes on table 1).

BV is clearly a heterogeneous disorder based on distinct immunological profiles, and currently two populations of women can be distinguished based on these profiles. Vaginal levels of IL-8 and IgA anti-hemolysis are inversely correlated with local concentrations of sialidase and prolidase. Clinical evidence is accruing that only the sub-group of women with elevated levels of these enzymes suffer the sequel of BV such as adverse pregnancy outcomes (14, 16). Measurement of sialidase or prolidase activity may therefore be better markers than a clinical or Gram-stained vaginal smear assessment for women with an increased risk of adverse BV-related pathology. However, most clinical microbiology laboratories continue to rely on microscopic examination of a vaginal smear in order to make a diagnosis of BV. Table 1 outlines the recommended microscopic criteria for assessing both cellular and bacterial components in a vaginal smear and outlines recommended comments for reporting individual results.

The standard scoring system termed the "Nugent Score" (N-score) is used to grade for the presence of normal vaginal flora in a Gram stained smear of vaginal discharge collected onto a swab. The Nugent score is calculated by quantifying the presence of *Lactobacillus* spp., *Gardnerella/Prevotella*, and *Mobiluncus* or their combination (Table 2) (3). A N-score of ≥7 is consistent with BV. Values of ≤3 are consistent with the presence of normal vaginal flora and are clearly BV negative. However, a N-score between 4 and 6 is consistent with some disturbance of the normal vaginal flora, but is equivocal for BV. Although clue cells are not part of the N-score, they are pathognomonic of BV and should be reported if present in all patients with microscopic evidence of vaginal flora disruption (i.e., N-score >4). Confusion also exists about the routine reporting of polymorphonuclear cells (PMNs). Although most women with BV will have scant or few PMNs normally in their vaginal secretions, the presence of moderate to heavy PMNs may represent the presence of another type of infection (i.e., *Trichomonas vaginalis, Neisseria gonorrhoeae,* or *Chlamydia trachomatis*) or other inflammatory conditions such as inflammatory desquamative inflammatory vaginitis and so, the presence of moderate to heavy PMNs should be reported.

Prior Provincial Practice

A review of current procedures for the diagnosis of BV using microscopic exam and N-scoring submitted by clinical microbiology laboratories in Alberta revealed that, although all laboratories are using the N-score, there is inconsistency with regards to the age groups being tested. There is also inconsistency in the reporting of other cellular elements, including polymorphonuclear, clue and epithelial cells, and their interpretation.

Recommended Protocol – Bacterial Vaginosis

1) **Pediatric patients** (≤13 yrs.) – Vaginal smears should have a Gram stain and culture done. All potential urogenital pathogens should be reported.

2) **Adult patients** (>13 yrs including ≥55 yrs): Although the Nugent score has not been validated for post-menopausal women, Gram stained vaginal smears should be scored in these cases and a comment placed on all reports as outlined below.

Table 1. Guideline for Microscopic Cellular and Bacterial Analysis of Vaginal Smears for BV

Microscopic Cellular Components	Adult Women (>13 - ≤ 55 yrs)	Post-Menopausal Women (> 55 yrs)[a]
Nugent Score (N-Score)[a]	Yes	Yes
Clue Cells[a,b,c]	Report presence of Clue cells	Report presence of Clue cells
Polymorphonuclear Cells (PMNs)[d]	Report moderate (3+) or heavy (4+ amounts)	Report moderate (3+) or heavy (4+ amounts)
Epithelial Cells	No	No
Non-sufficient quantity of Vaginal Sample	Report insufficient sample to assess for vaginitis. Immediate recollection required.	Report insufficient sample to assess for vaginitis. Immediate recollection required.

a. See Table 2 for Nugent Scoring Criteria (N-Score).
- N-Score ≤3 = Report "Smear negative for Bacterial Vaginosis"
- N-Score 4-6 and no clue cells seen = Report "Gram stain shows altered vaginal flora. Results are indeterminate for Bacterial Vaginosis"
- N-Score 4-6 and clue cells seen, report: "Presence of Clue cells suggest transition of vaginal flora towards Bacterial Vaginosis; repeat testing of another vaginal smear is recommended."
- N-Score ≥7, report: "Smear consistent with Bacterial Vaginosis."
- Post-Menopausal Women (>55 yrs) should have an additional comment added to all vaginal smear reports: **"Results may not be reliable in post-menopausal women. Correlate with the clinical picture."**

b. Look for and report the presence of Clue cells if the N-Score ≥4. If the N-Score is indeterminate (i.e., 4-6) then additional fields should be examined for Clue cells before reporting.

c. If the N-Score is indicative of BV (i.e., 7-10) then report Clue cells only if found as part of the routine microscopic exam.

d. Report the presence of 3+ to 4+ PMNs. Add an additional comment "Presence of purulence suggests the presence of another infection and/or inflammatory condition. Correlate with clinical picture. Testing for *N. gonorrhoeae, C. trachomatis* and *T. vaginalis* may be indicated."

Table 2. Nugent Scoring Criteria for the Microscopic Diagnosis of Bacterial Vaginitis

Number of *Lactobacillus*	Score	Number of *Gardnerella/Bacteroides*	Score	Number of CGNB	Score	N-Score
≥ 30	0	0	0	0	0	0
5-20	1	<1	1	<1	1	3
1-4	2	1-4	2	1-4	1	5
<1	3	5-20	3	5-20	2	8
0	4	≥ 30	4	≥ 30	2	10

N-Score = The sum of the scores for the presence/absence of *Lactobacillus, Gardnerella/Bacteroides* and curved Gram-negative bacilli (CGNB)

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PATIENT CONFIDENTIALITY

In a recent CMPT paper challenge, laboratories were asked to respond to a scenario where a woman known to the laboratory personnel asks for test results belonging to her husband. The participants unanimously chose the correct answer "You do not give her the test results and suggest she contact his physician." It is reassuring to see that when confronted with the situation, participants had the capacity to understand that the request constituted a violation of privacy.

Less evident is the violation of privacy that occurs when a result test is sent to the wrong physician or to the wrong patient. This is, unfortunately, a quite common error where the wrong identifier (doctor's name, patient's name, wrong address, or fax number) is attached to a result letter. In a recent CMPT challenge 6 laboratories (5%) reported results with the wrong identifier. In the real world, these 6 reports would have been sent to the wrong person and would have constituted a breach of patient confidentiality.

I asked Dr. Michael Noble to expand on this topic that affects laboratories in new and challenging ways.

Confidentiality issues that surround the release of laboratory information.

by Dr. M. A. Noble, MD FRCPC, CMPT chair and managing director.

Healthcare's currency of confidence surrounds the patient. All healthcare professionals have a legal and ethical duty to keep medical information private [1]. Confidentiality restricts the release of "non-public" information within fiduciary, professional, and contractual relationships [3].

In the medical laboratory, breeches to confidentiality occur commonly and throughout the whole of the laboratory testing cycle. Samples may be left available in areas where patients can see and read names on labels, discussions about patients and their samples frequently occur in public places, and results often end up being sent to the wrong person in a way that discloses patient information to inappropriate readers.

Confidentiality is one place where practice is either right or it is wrong; there is rarely any middle ground. Phillip Crosby's dictum of Do it Right the First Time (DIRFT) clearly and absolutely can and must be followed when it comes to identifying patients and their specimens.

In Canada, confidentiality of identity and related fact impression, events and data, is an ethical and professional binding legal duty [1] and it is achieved through silence, discretion, and security of information [1].

In an on-line survey directed to the general public, [2] 88% of respondents thought that confidentiality of medical records was either "very important" or "somewhat important".

There is a natural tension that draws a line between the convenience that comes through technology and confidentiality. As convenient as telephones, answering machines, faxes, and email are, each has been associated with significant breeches in confidentiality. Inadvertent incorrect sharing of information can occur with the slightest slip of the lip (errant speech on telephones and answering machines) or keyboard errors with telephones and faxes, and in particular with emails.

Confidentiality in conventional terms has a balance that is sometimes referred to as the "community of authorized recipients" [1]. These are the people that have a legal need to be informed. It may be a small group such as the parent of a child, or as large as a certain specific people in an insuring/funding agency. In the conventional doctor-patient relationship, the "doctor has the need to know".

Errant release of medical records or results will inevitably become a greater challenge as a result of Direct-to-Patient (DTP) reporting. DTP reporting is the norm in some countries where patients interact directly with the laboratory ordering their own tests and receiving their own results. While relatively uncommon in North America and in Europe, increasing legislation points out that pathology test results are the property of the patient [6]. Also recent practices of self-ordering private genetic testing where there is no physician involved is becoming increasingly popular.

Currently, there are laboratories that provide broad medical laboratory results through DTP reporting systems in Canada, United States, and Europe. In recent months the US Commission for Medicare and Medicaid Services (CMS) has drafted a proposal that would oblige laboratories in the United States, even in states where local legislation prohibits it, to release results directly to patients, most often by electronic email transfer. [4]

Very recently, medical records were potentially released into the public when a laptop computer containing the records was forgotten in a Canadian airport; [5] another example of the links between errant information and technology.

In many countries, the right to privacy may exist in principle but may not be thoroughly protected under the law. In Canada, in many professions an oath obliges its members to hold confidentiality to the highest level. That oath obligation relationship is in most instances protected even within the legal system.

In Canada we have Privacy Offices at both the federal and provincial levels, but medical confidentiality is addressed mainly as a provincial matter (BC Personal Information Protection Act – 2003). While it has been interpreted that the Canadian Charter of Rights and Freedoms (1982) protects privacy under the clause of "right to …security of the person", neither the Personal Information Protection and Electronic Documents Act – PIPEDA - (2004) nor The Privacy Act (1983) addresses the issue of medical confidentiality. PIPEDA restricts the release of a data collected by federal agencies

PATIENT CONFIDENTIALITY

and the Privacy Act addresses the privacy issues around private sector organization.

Confidentiality does not mean holding information as exclusively private, but allows for "disclosure of non-public information only within fiduciary, professional and contractual relationships" [3]. As mentioned earlier, communication is restricted to the "community of authorized recipients" [1] which means that information can be shared with those who have a right and responsibility to know. In many respects the challenge is to sort out who falls into the categories of those who have the right and responsibility to know. In many regards that group is often in a state of dynamic flux. For example the medical laboratory technologist has the obligation to know the name of the patient and the results of their previous tests related to the sample they are currently working on; the same obligation would not exist for others in the organization.

Within the laboratory community, new programs challenge the limits of confidentiality. Pre-employment and random drug screening can be required by employers or other authorized persons in a variety of fields. In some situations it is defined as a protection to the public time for some decision making.

To a person with the most intense sense of confidentiality, the option of self-testing through on-line laboratories provides the most direct and private testing option. In a recent discussion this was described as "the norm in many countries" and "good business". Clearly these may be debateable opinions today but it is evident that laboratories are entering a period of considerable change.

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New Program!

Trichomonas antigen

A new proficiency testing program "Trichomonas antigen" has been implemented by CMPT. The program's objective is to provide EQA samples to those laboratories performing laboratory diagnosis of trichomoniasis using the OSOM® Genzyme Trichomonas Rapid Test kit.

Check the link for more Info: http://www.cmpt.ca/programs_trich/trich_program.htm

Upcoming events

JANUARY 2012

POLQM - Laboratory Qualtiy Management Certification Course

Starts January 12, 2012 (20 weeks) Online

More information: http://www.polqm.ca/description.htm

International Science Symposium on HIV and Infectious Diseases

January 20 - 22, 2012 Chennai, India

Further information: http://hivscience.yrgcare.org/

MARCH 2012

22nd European Congress of Clinical Microbiology and Infectious Diseases ECCMID

March 31 - April 3, 2012 London, UK

Further information: http://www.congrex.ch/eccmid2012/

ABOUT CONNECTIONS

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Editor: Veronica Restelli

Contact Connections:

By mail:
Room 328A, 2733 Heather Street,
Vancouver, BC
V5Z 1M9
Canada

By phone: 604-875-4685
By fax: 604-875-4100
By e-mail: restelli@mail.ubc.ca

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