Updated program for combating sexually transmissible and blood-borne infections Nunavik

CLINICAL INTERVENTION SECTION

INSTITUT NATIONAL
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DU QUÉBEC

Québec

Updated program for combating sexually transmissible and blood-borne infections Nunavik

CLINICAL INTERVENTION SECTION

Direction des risques biologiques
et de la santé au travail

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GLOSSARY

For purposes of this document, the expressions used herein have the following meanings:

Index case: a person diagnosed with an STBBI.

Screening: a procedure for detecting an infection in an asymptomatic person.

Diagnosis: a procedure for detecting an infection in a person who is symptomatic, or who presents clinical signs and symptoms.

1 CONTEXT AND IMPLEMENTATION STEPS

In Nunavik, the battle against bacterial sexually transmissible and blood-borne infections (STBBIs) has become increasingly urgent. In the wake of mass interventions in the 1990s, and despite more recent efforts, the region has been unable to lower its incidence curves, particularly for gonococcal infection, which has reached epidemic proportions since fall 2007. In this context, and spurred by the renewed interest of medical teams on the ground, the Direction de santé publique (department of public health: DSP) of the Régie régionale de la santé et des services sociaux du Nunavik / Nunavik Regional Board of Health and Social Services (NRBHSS) has asked the Institut national de santé publique (Québec's national public health institute: INSPQ) to support a group of experts in an attempt to optimize the regional program for clinical prevention of STBBIs. Accordingly, a meeting was held on October 2010. In attendance were representatives of the two CSSS organizations (physicians, a consulting microbiologist, the director of professional services, the head of the laboratory, heads of community health services, and clinical nurses), two experts from INSPQ, and professionals from the DSP. Various aspects of the regional program to combat STBBIs were discussed in light of epidemiological trends, region-specific organizational obstacles such as delays in obtaining results and high turnover of clinical teams, and the characteristics of at-risk populations. This meeting was preceded by a training session for physicians who are working in the Hudson's Bay Region (interactive workshop on blood-borne and sexually transmitted infections).

This action was followed up with a number of teleconference meetings and email exchanges, mainly between the consulting microbiologist and the professionals at INSPQ and the DSP.

The main outcomes are as follows:

- Reflections on potential action avenues for improving STBBI prevention and control.
- A set of questions and answers for use in screening and detecting chlamydia and gonorrhea.
- Syndromic management algorithms for presenting and facilitating case management according to sex.
- Descriptions of the appropriate materials required for detecting *Chlamydia trachomatis* and *Neisseria gonorrhoeae* infections for the Ungava Bay and Hudson Bay regions, and the associated preanalytical information.

2 SCREENING AND DETECTION OF GONORRHEA AND CHLAMYDIA: QUESTIONS AND ANSWERS

What does NAAT mean?

NAAT is an acronym that stands for the nucleic acid amplification test. The polymerase chain reaction (PCR) test is just one of several types of NAAT. For example, the BD ProbeTec™ NAAT, used in Ungava, is based on strand displacement amplification (SDA), and not PCR.

Why use the NAAT?

This test has excellent sensitivity and specificity. In addition, it has the advantage of being less fragile during transport than a gonorrhea culture. It also allows testing for gonorrhea and chlamydia at the same time. For all practical purposes, genital chlamydia is analyzed exclusively by the NAAT in Québec.

The sole disadvantage of the NAAT is that it does not determine the antibiogram (the antibiotic sensitivity spectrum), which is vital information in gonorrhea.

Should we continue to culture for gonorrhea in addition to the NAAT?

Yes, in certain situations. However, gonorrhea cultures are not done routinely, or across all communities.

Gonorrhea detection by culture (swab) is indicated in two situations:

1) If the person is **symptomatic** (e.g., a man with a purulent urethral discharge) and consults in a **village with a laboratory** (**Puvirnituq and Kuujjuaq**), which avoids the problem of specimen fragility during transport. A gonorrhea sample should be taken in addition to a NAAT sample, which is required for chlamydia, and the specimen is sent to the laboratory as soon as possible.
2) The DSP could also request that cultures be done in other communities on an episodic basis for surveillance of antibiotic-resistant gonorrhea strains. For example, a blitz campaign of gonorrhea culturing could be held in the first two weeks of August.

Gonorrhea culturing has the advantage of determining the antibiogram (the gonorrhea strain's sensitivity to antibiotics), but it is less sensitive than the NAAT. It allows determining only the local circulation of resistant strains. There is no similar technique for chlamydia, which requires the NAAT for detection.

Could the NAAT test be positive for gonorrhea but with a negative culture result (or vice versa)?

Yes. As soon as one test shows a positive result, the patient is considered to be infected.

What do we do when the test is positive for gonorrhea but negative for chlamydia?

Treat both the gonorrhea and the chlamydia, even if the chlamydia test is negative, but not for the inverse result. That is, if the test is positive for chlamydia but negative for gonorrhea, treat the chlamydia only.

What is the proper intervention for contacts (sexual partners) of the index case?

A preventive intervention in sexual partners includes all partners who have been exposed, and not just the regular partner. Ideally, the aim is to identify, contact, examine, test, and provide preventive counselling to all contacts as soon as possible.

For a chlamydia and/or gonorrhea infection, the partners to contact include the following:

- All partners who have had sexual contact with the infected person in the **60 days** prior to symptom onset or diagnosis.
- If there were no sexual partners in the 60 days prior to symptom onset or diagnosis, the most recent sexual partner of the infected person.
- All partners who have had sexual contact with the infected person before the infected person completed his/her treatment, or within 7 days after a single dose treatment.
- All partners who have had sexual contact with the infected person and who present symptoms (symptomatic).

What should we do if a person who has had contact with an infected person refuses the screening tests?

A contact of an index case is considered to be infected as well. Therefore, the contact must be treated, while ensuring that he/she is not allergic to any prescribed antibiotics.

Early treatment of index cases and their contacts is a key factor in the battle against STBBIs. Given the epidemic scale of gonorrhea and chlamydia in Nunavik, rapid action is required. The sooner that people are treated, the more we can break the infection chain.

The other key factor is to screen as many people as possible.

Is urinary NAAT screening in asymptomatic patients reliable?

Yes, in men.

However, in women, the urine test is not the first choice. It provides an acceptable alternative if the woman refuses genital culturing.

In Québec, the urine test is particularly recommended in outreach work when conditions are unfavorable for taking cultures or if a woman refuses genital culturing.

Is NAAT screening (for gonorrhea and chlamydia) using vaginal secretion swabs reliable?

Yes, with the technology used at Hudson (cobas 4800). No, with the technology used at Ungava (BD ProbeTec™).

Hudson and Ungava use two different NAAT technologies. Since 2013, Hudson has used a new technology that is used at the McGill University Health Centre (CUSM). It is very reliable for testing vaginal secretions. Therefore, if a patient is **asymptomatic** and a pelvic exam is not required (e.g., the patient is not due for a cervical cytology), **vaginal secretion swabs** are recommended over cervical swabs using a speculum. This makes the test more acceptable to patients and enables screening more cases. In addition, all **symptomatic** patients should continue to have a **pelvic exam** with a speculum and cervical swabs. When symptoms are present, a pelvic exam can help determine the diagnosis.

The sampling technique is illustrated on the packaging of the NAAT swabs used at Hudson.

At Ungava, the currently used BD ProbeTec™ system is **not** approved for sampling vaginal secretions. It is significantly less sensitive than the endocervical test, with a risk for a false negative result.

Are there circumstances where gonorrhea is detected in the pharynx?

Gonorrhea can infect the pharynx (throat) without necessarily presenting symptoms. In Nunavik, the prevalence of pharyngeal gonorrhea is unknown. Initially, we would like to document the extent of this type of infection in the communities of Piuvi and Kuujjuaq, and depending on the results, we would then extend the screening scope.

Consequently, from now on, in **Piuvi and Kuujjuaq**, the pharynx should be screened in the following groups:

- Persons who consult with **genital symptoms** and a history of “providing” oral sex. Both genital and pharyngeal samples should be taken. The symptomatic genital infection should be treated immediately. The pharyngeal infection is treated later (via intramuscular injection) if the pharyngeal result comes back positive.
- Persons who are called back for treatment with antibiotics due to a **positive genital gonorrhea test**. They should be asked if there is a history of oral sexual relations, and if affirmative, a pharyngeal sample is taken. The genital infection is treated immediately, and the pharyngeal infection is treated later (via intramuscular injection) if the test comes back positive.

In Piuvi and Kuujjuaq, the pharynx is **cultured** and the sample is sent to the laboratory as soon as possible. The technique involves swabbing the posterior part of the pharynx as well as the tonsillar crypts. The laboratory requisition must be clearly identified, including indication that the test is for pharyngeal gonorrhea.

Can chlamydia infect the pharynx?

Yes, but chlamydia infects the pharynx only temporarily. Therefore, testing the pharynx for chlamydia is **not** indicated.

Does the treatment for pharyngeal gonorrhea differ from that for uncomplicated genital gonorrhea, such as urethritis, cervicitis, and proctitis?

YES.

Intramuscular injection of ceftriaxone 250 mg is used for pharyngeal infection, versus oral dose treatment for genital or anal infection.

Pharyngeal treatment: ceftriaxone 250 mg **IM** + azithromycin 1g **PO**.

Frist-line genital treatment: cefixime 800 (Suprax$^{TM)}$ **PO** + azithromycin 1g **PO**.

Refer to the INESS guide for treatment details: Guides for the Pharmacological Treatment of STBBIs: http://www.inesss.qc.ca/en/publications/publications/publication/guides-sur-le-traitement-pharmacologique-des-itss.html

In an asymptomatic patient, are there circumstances where anorectal gonorrhea should be screened?

With respect to screening, studies show that asymptomatic anal infection is highly frequent in men who have sex with men (MSM).

In women, isolated asymptomatic anal infection is rare. Therefore, there is little benefit in screening the anal site in addition to the genital site.

Anal screening is therefore recommended in MSM only.

Method:

Samples may be collected blind or using an anoscope.

For blind sampling, insert the swab into the anal canal to a depth of about 2 to 3 centimeters while gently hugging the walls to avoid fecal material.

In case of visible fecal contamination, throw out the swab and take another sample.

Fecal contamination can be avoided by using an anoscope lubricated with tap water only, and samples can be taken under direct visual inspection.

What is the test window period?

This is the period of time between the acquisition of the infection and the time at which the test can reliably detect the infection in the majority of infected persons. This period is also called the test incubation period.

For gonorrhea and chlamydia infections, the minimum test window period is 48 hours, and the optimum period is 14 days.

When should treatment effectiveness be determined by a test of cure?

In general, a test of cure should be performed in the following cases:

- Pregnancy.
- Persistent signs or symptoms.
- Treatment compliance problems are anticipated.
- There is demonstrated resistance to the antibiotic used.
- For the partner of a patient with demonstrated resistance to the antibiotics used.
- Previous treatment failure.
- Treatment regimen other than those recommended is being used.
- Pharyngeal gonoccocal infection.

Types of test of cure to use and how long after treatment:

The type (NAAT or culture) of test of cure depends on the infection being treated and the proximity or not of a laboratory. In sum, for the test of cure for:

- **Chlamydia:** the NAAT is used throughout Nunavik.
- **Gonorrhea:** in Kuujjuaq and Piuvi, the preferred test of cure is a culture (swab) test (to be done 2 weeks after treatment completion); elsewhere, the preferred test of cure is the NAAT (3 weeks after treatment completion).

When an infected person has been treated for chlamydia and/or gonorrhea, should the test be redone later?

Yes. Studies have shown that reinfection is frequent. Patients should be retested 6 months after the initial episode.

When a woman comes for her cervical cytology screening and you would like to do an STBBI screening as well, what is the order of tests?

The cytology is done first, followed by sampling (swab) for gonorrhea and chlamydia.

2.1 STBBIS AND INTRAUTERINE DEVICES (IUDS)

When treating a bacterial STBBI (gonorrhea, chlamydia), should the intrauterine device (IUD) be left in place?

Yes. The presence of an infection, even a pelvic inflammatory infection (PID), is **not** a contraindication for using an IUD.

Clearly, the manufacturers' monographs (e.g., Mirena^{TM}) do not recommend inserting an IUD into patients with a pelvic inflammatory infection or an active infection of the lower genitals.

Nevertheless, task forces under the World Health Organization (2009) and the US Centers for Disease Control and Prevention (2010) concluded that a woman can generally keep her IUD if she has contracted an STI (i.e., an STBBI), even when it is complicated by PID, on

condition that she responds to treatment. The data demonstrated that IUD users who were treated for a pelvic infection showed the same clinical course as women who did not use one. **Therefore, the STBBI may be treated without removing the IUD.**

When a PID or gonorrhea or chlamydia infection is found in a woman using an IUD, it is recommended to begin standard treatment and to re-evaluate the patient 48 hours later. If the symptoms have not diminished by 50% or if they have worsened, it is preferable to hospitalize the patient and remove the IUD. It is essential for the nursing staff to consult with the physician in such cases.

In sum, inserting an IUD is contraindicated in the presence of a PID. However, the presence of a PID is not normally a contraindication for continued use of an IUD.

Can a copper or hormonal IUD be inserted into a woman who has had a prior episode of PID?

Yes.

In current practice, it is recommended to wait 3 months after completing the PID treatment before inserting an IUD.

It is essential for the nursing staff to discuss with the physician whether or not to use an IUD as a contraceptive method.

If an infection (STBBI or other) should develop, what is the riskiest time for it to appear?

The risk for developing a PID is significantly higher in the 3 weeks following IUD insertion, and this risk is associated uniquely with the insertion procedure. In general, after the first few months of use, the risk of infection does not differ significantly from the risk for women without an IUD.

Contraceptive users should be reminded that they must continue using condoms to protect themselves from STBBIs.

In a woman at risk, is there any benefit in giving a prophylactic antibiotic treatment before inserting an IUD?

No. All the data on prophylactic antibiotics prior to IUD insertion show that it is completely useless.

2.2 BACTERIAL STBBIS AND PREGNANCY

What test should be used for routine screening during pregnancy?

Classically, the endocervical NAAT has been the test of choice for gonorrhea and chlamydia screening. A swab is gently rotated in the endocervical canal. Midwives are trained to do this, and they work in all the maternity hospitals.

If the woman refuses a gynecological exam or sampling, the urine test is universally acceptable (Hudson and Ungava).

At what times during pregnancy should women be screened for gonorrhea and chlamydia infections?

Given the epidemic scale of these infections in Nunavik, it is recommended to screen at least 2 times during pregnancy: at the beginning and near the end of pregnancy (first and third trimester).

If a pregnant woman has a positive result for chlamydia and/or gonorrhea, should a test of cure be conducted?

Yes. Infection during pregnancy is an indication for a test of cure in order to confirm treatment effectiveness (see the response to the question on tests of cure).

3 SYNDROMIC APPROACH

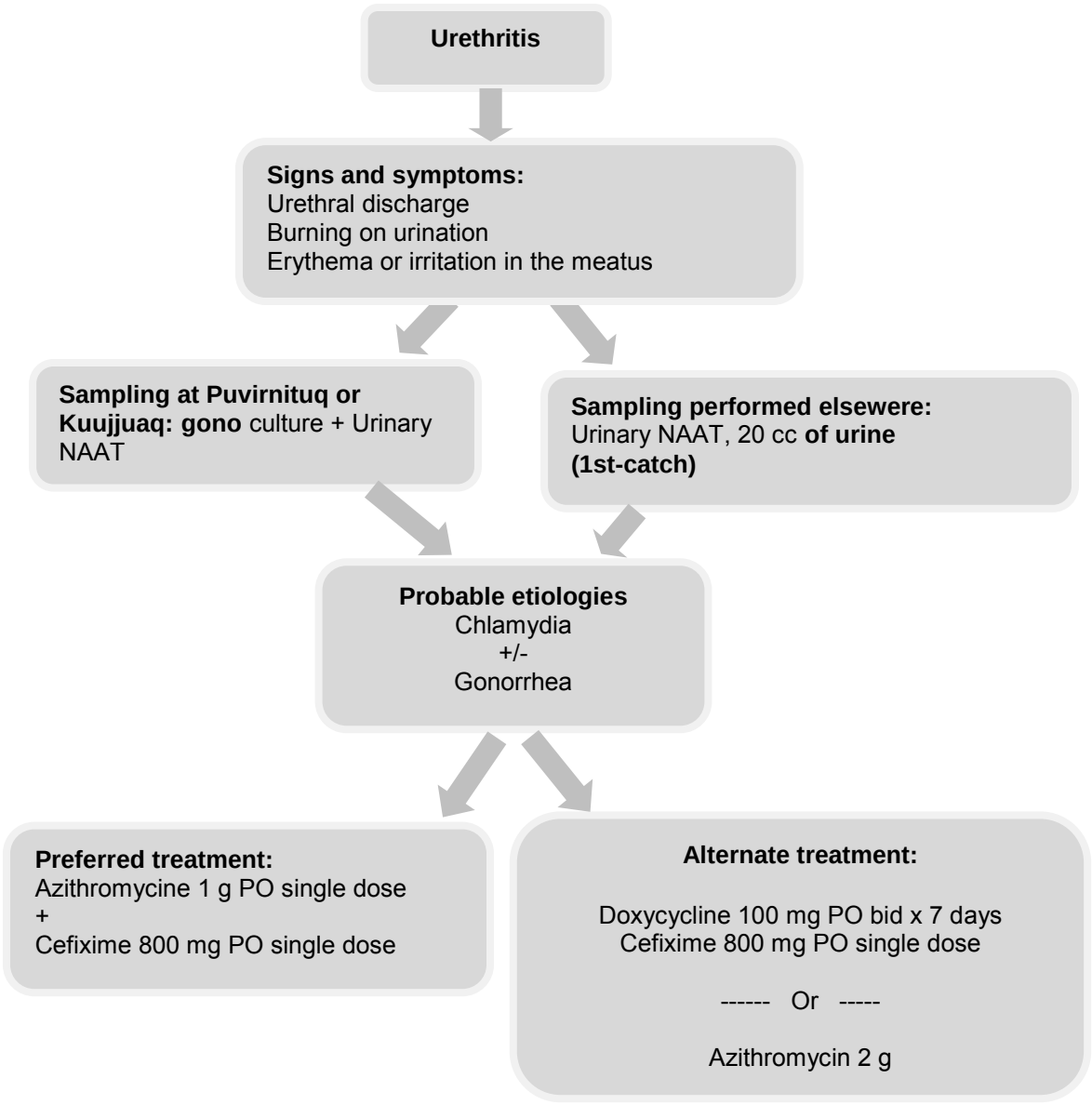

Figure 1 Syndromic approach for MEN with urethritis (symptomatic)

1) IMMEDIATELY treat both the chlamydia and gonor rhea in all symptomatic patients.
2) Contact all sexual partners in the previous 60 days.
3) Treat ALL partners IMMEDIATELY for chlamydia and gonor rhea. They are considered to be infected, so do not wait for test results, either for partners who agree to be tested or for the index case.
4) The ideal sample for gonorrhea and chlamydia is first-catch urine (20 cc), not mid-catch urine.

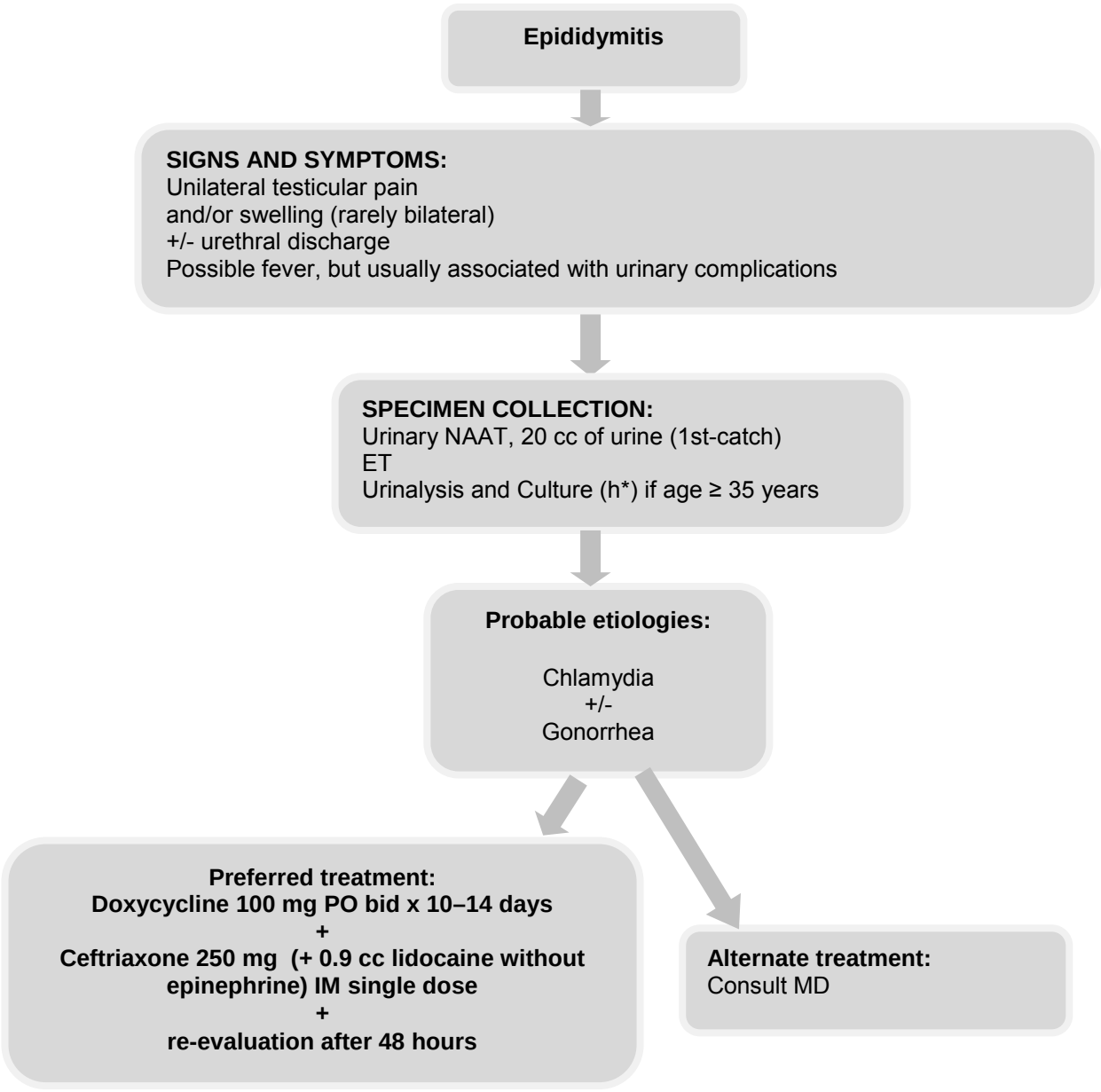

Figure 2 Syndromic approach for MEN with epididymitis (symptomatic)

1) IMMEDIATELY treat chlamydia and gonorrhea in all symptomatic patients.
2) Contact all sexual partners in the previous 60 days.
3) IMMEDIATELY treat ALL partners for chlamydia and gonorrhea. They are considered to be infected, so do not wait for test results, either for partners who agree to be tested or for the index case.
4) The ideal sample for gonorrhea and chlamydia is first-catch urine (20 cc), and not mid-catch urine.
5) **Follow-up on the patient within a maximum of 48 hours** and consult the physician as soon as possible if the clinical response is unsatisfactory (a non-STBBI etiology is possible, requiring a different treatment).

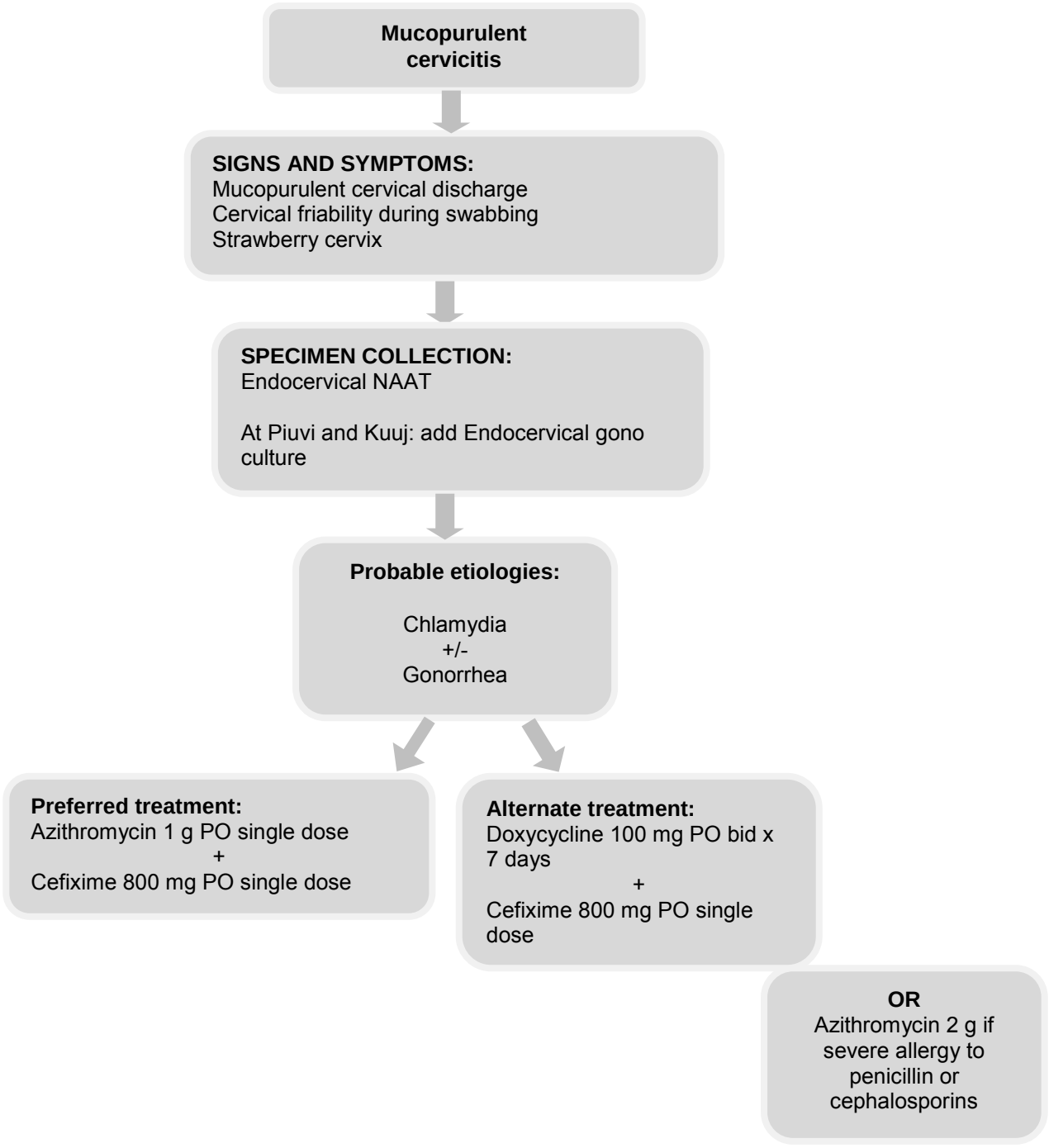

Figure 3 Syndromic approach for WOMEN with mucopurulent cervicitis (symptomatic)

1) IMMEDIATELY treat both chlamydia and gonorrhea in all patients with symptomatic cervicitis.
2) Contact all sexual partners in the previous 60 days.
3) IMMEDIATELY treat ALL contacts for chlamydia and gonorrhea. They are considered to be infected, so do not wait for test results, either for partners who agreed to be tested or for the index case.
4) If the patient refuses endocervical culturing or is menstruating, perform a urinary NAAT. At Hudson, a vaginal NAAT may be used (without speculum).

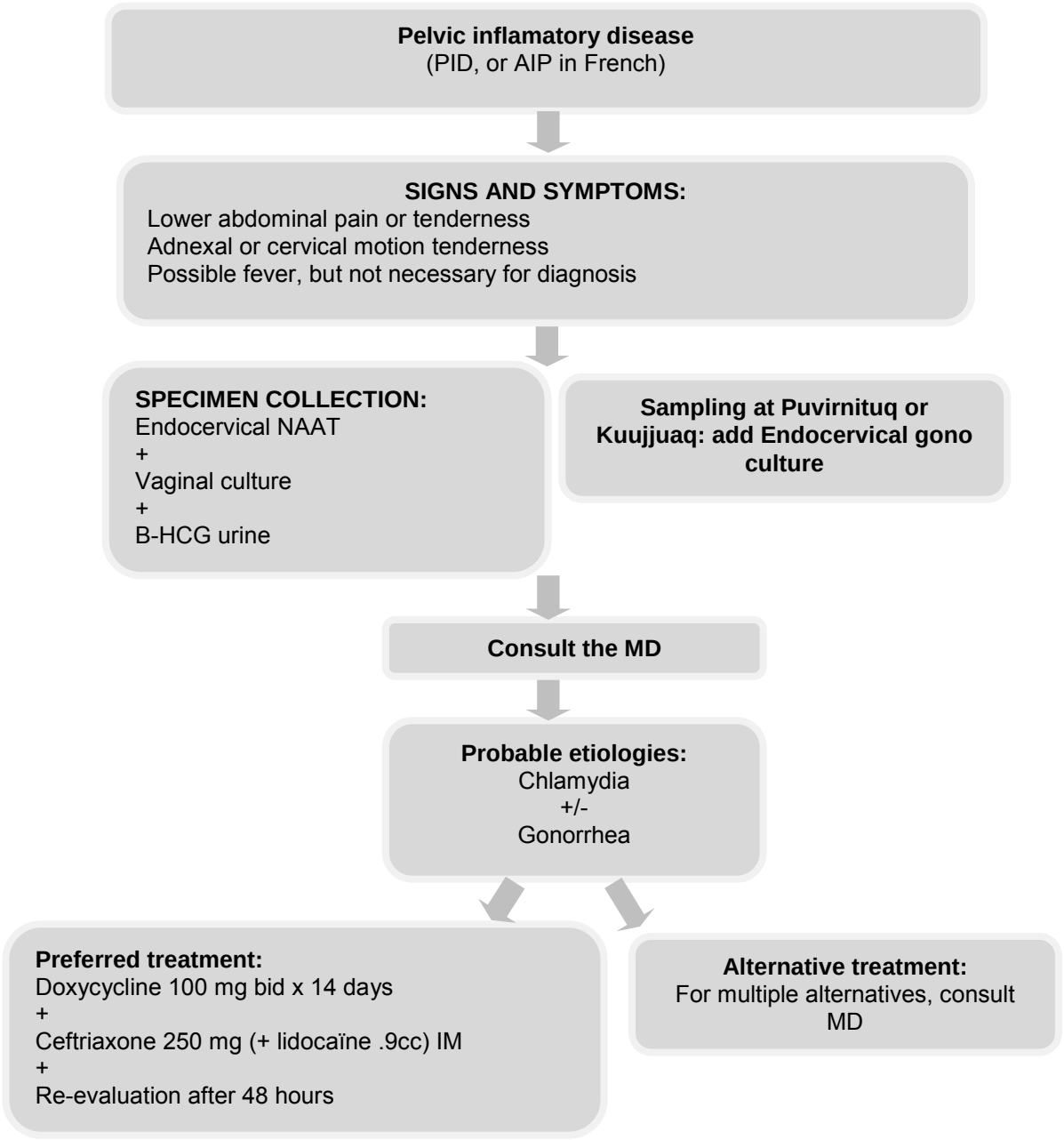

Figure 4 Syndromic approach for WOMEN with pelvic inflammatory disease (symptomatic)

1) IMMEDIATELY treat chlamydia and gonorrhea in ALL patients with symptomatic cervicitis or PID.
2) Contact all sexual partners in the previous 60 days.
3) IMMEDIATELY treat ALL contacts for chlamydia and gonorrhea. They are considered to be infected, so do not wait for test results, either for partners who agree to be tested or for the index case.
4) If the patient refuses endocervical culturing or is menstruating, perform a urinary NAAT. At Hudson, a vaginal NAAT may be used (without speculum).
5) Metronidazole (500 mg PO bid x 14 days) is reserved for patients with the most severe cases of PID (fever, toxicity, high temperature). If metronidazole is given immediately, there is a risk of non-compliance due to side effects and alcohol interaction.
6) For cases of PID, contact the MD and hospitalize in the presence of high fever, other suspected pathology (abcess, appendicitis, upper urinary tract infection), poor overall health, or pregnancy.

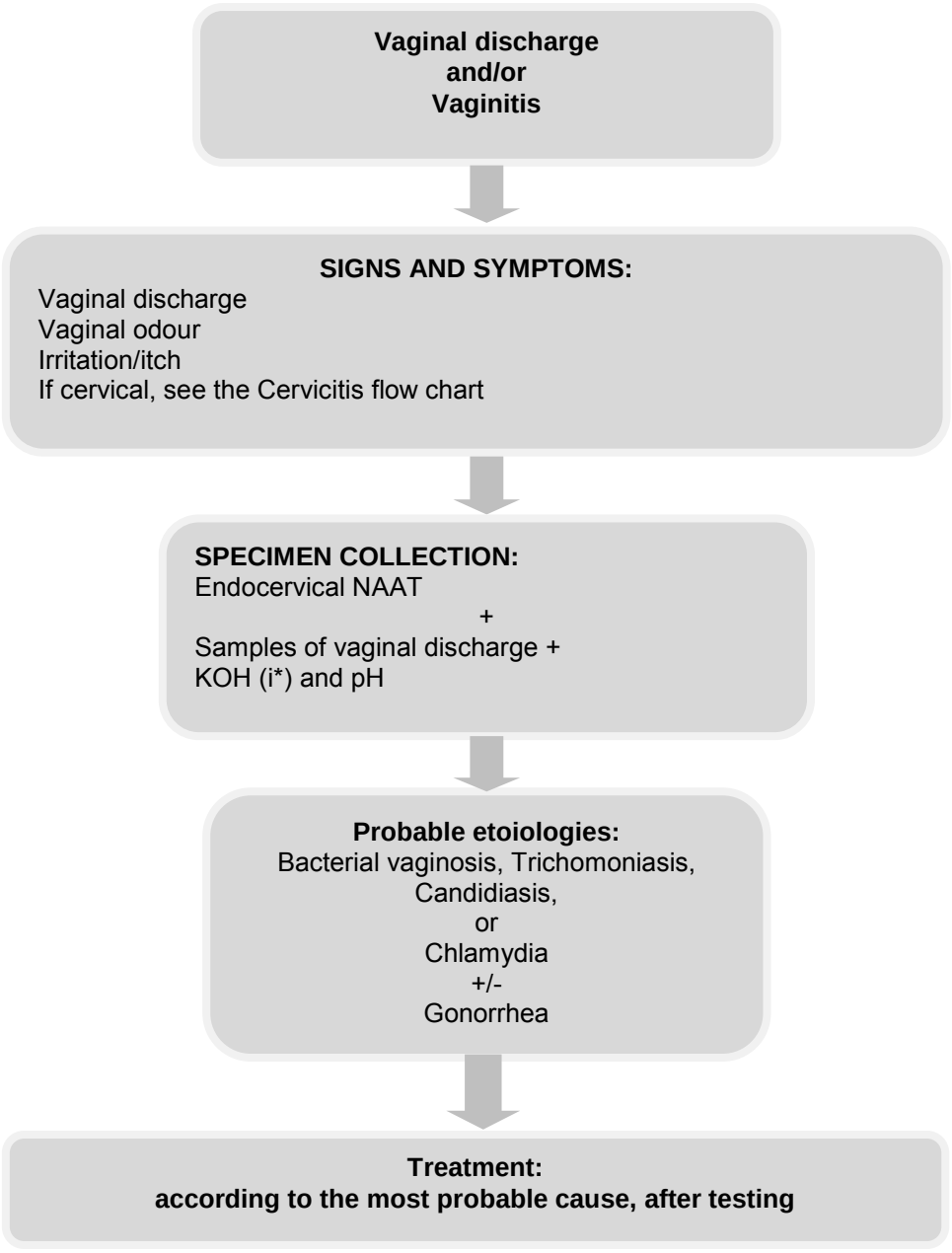

Figure 5 Syndromic approach for WOMENwith vaginal discharge and/or vaginitis (symptomatic)

1) Vaginal discharge is not always cased by STBBIs. Evaluate and treat other causes as appropriate (bacterial vaginosis, trichomoniasis, and candidiasis).
2) Partners of women with trichomoniasis must be treated, as the test is not done in men.

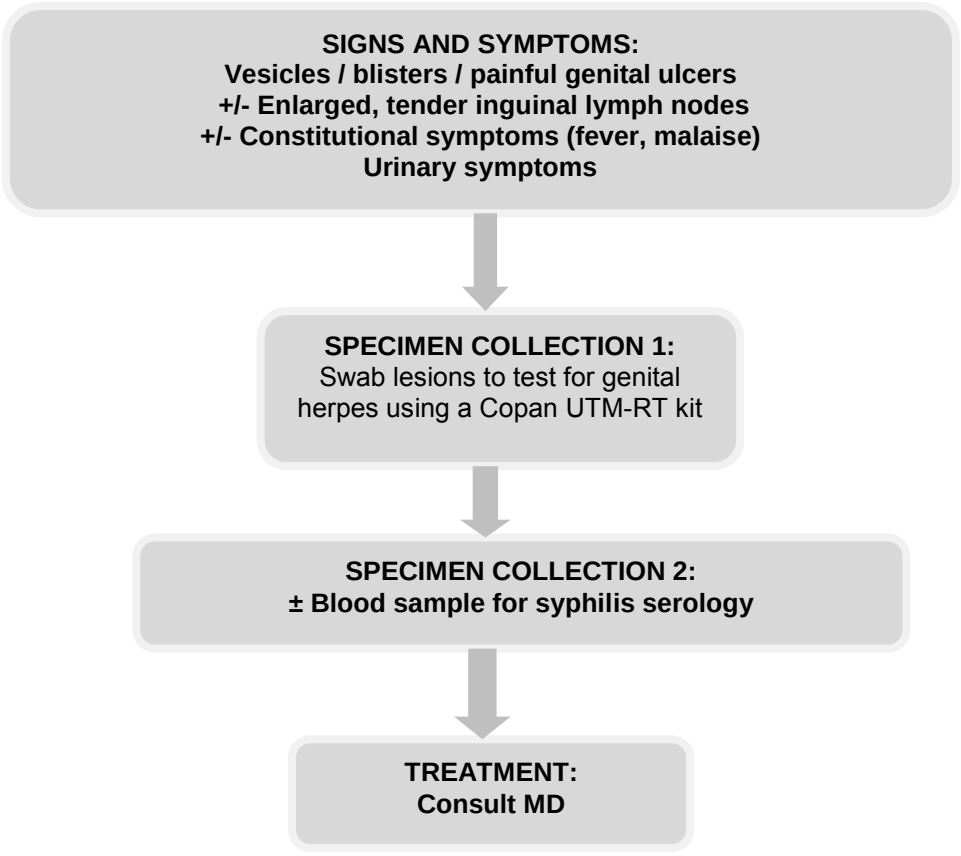

Figure 6 Syndromic approach for MEN AND WOMEN with genital ulcers (symptomatic)

N.B.: As soon as the samples are taken, refrigerate the Copan UTM tube until transport to the laboratory server system.

Table 1 Screening approach (Asymptomatic patients with + test)

+ Test	Treatment	Alternative treatment	Notes
+ Chlamydia	Azithromycin 1 g PO (single dose)	Doxycycline 100 mg PO bid X 7 days	In case of + gono result, it is recommended to treat both (frequent coinfection), even with – chlamydia result at time of intervention.
+ Gonorrhea	Genital or anal: Cefixime 800 mg PO (single dose) Throat: Ceftriaxone 250 mg IM	Azithromycin 2 g PO (single dose)	

1) Contact and treat all sexual partners in the previous 60 days. Ideally, partners should also be tested.
2) Treat partners immediately, according to the results on the index case, without waiting for results on the partners.
3) **Patients who are infected with gonorrhea are also at risk for syphilis and HIV infections. Offer them a screening test for syphilis and HIV and obtain informed consent.**

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