Alberta Surveillance Protocol for Antimicrobial Resistance in Gonorrhea

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the Alberta Gonorrhea AMR Surveillance Working Group

Contents

ACRONYMS AND ABBREVIATIONS

AHS: Alberta Health Services

AMR: Antimicrobial resistance

CDRS: Communicable Disease Reporting System

CMOH: Chief Medical Officer of Health

MIC: Minimum Inhibitory Concentration

MSM: Men who have sex with men

NAAT: Nucleic acid amplification test

NG-MAST: *N. gonorrhoeae* multiantigen sequence typing

NML: National Microbiology Laboratory

ProvLab: Provincial Laboratory for Public Health

STI: Sexually transmitted infections

This protocol outlines the province-wide plan for maintaining surveillance for antimicrobial resistance in gonorrhea.

INTRODUCTION

Gonorrhea remains one of the oldest infections known to man. Infections can result in significant morbidity in males and females and increase the risk of HIV transmission and acquisition (1). The incidence of gonorrhea in Canada has been increasing since 1998 and it is the second most common notifiable sexually transmitted infection (STI) in Canada. In 2010, the national gonorrhea rate was 33.4 per 100,000 (2), while in Alberta the rate was 32.0 per 100,000 (3) and has increased to 40.0 per 100,000 in 2011.

Since the 1940s, gonorrhea has developed resistance to multiple classes of antibiotics (1). Previous reviews of Alberta data have informed the revision of treatment guidelines. Data from 2001-2007 demonstrated an initial rise in ciprofloxacin resistance in gonorrhea in men who have sex with men (MSM) with eventual spread to heterosexual persons prompting changes to provincial treatment guidelines. This surveillance data allowed Alberta to switch to oral cephalosporin antibiotics in MSM in November 2005 and for all cases in May 2007 (4).

Following the widespread global use of oral cephalosporins for the treatment of gonorrhea, initial reports of gonococci with reduced susceptibility and cases of treatment failure have been reported in Japan (5, 6). Similar cases have since been reported from other parts of the world (1). In Canada, Martin et al reported a rise in modal minimum inhibitory concentration (MIC) in third generation cephalosporins among gonococcal isolates from 2000 to 2009 (7). In 2010, the first gonococcal isolates with MIC values of 0.25 μg/mL, the break point for cefixime resistance, were reported in Alberta.

Due to rising rates of decreased susceptibility and the possibility of the development of frank antimicrobial resistance (AMR) to cefixime and ceftriaxone among gonococcal isolates in Canada, national treatment guidelines were revised in December 2011 and higher doses of these antibiotics was recommended (8). In February 2012, an Alberta communicable disease advisory was issued for the treatment of gonorrhea recommending cefixime 800 mg for heterosexuals and pregnant women and ceftriaxone 250 mg for men who have sex with men and all pharyngeal infections with concurrent treatment for chlamydia (9).

In light of these observations, surveillance of the epidemiology of AMR in gonococcal isolates collected through Alberta's established surveillance system (4) continues.

GOAL

To provide surveillance support to the provincial Sexually Transmitted Infections (STI) program and its efforts to control *N. gonorrhoeae* and minimize the impact of antimicrobial resistance among recommended treatment agents.

OBJECTIVES

1. To monitor trends in antimicrobial susceptibilities of gonococcal isolates.
2. To monitor demographic and behavioural characteristics among reported gonorrhea cases, particularly those with resistance/reduced susceptibility to antimicrobials.
3. To monitor trends in phenotypic and genotypic variations using sequence type data of gonococcal isolates.
4. To monitor treatment failures to currently used treatment regimes.

PATIENT POPULATION

All confirmed cases of *N. gonorrhoeae* and treatment failures reported to Alberta Health Services (AHS) STI Centralized Services.

METHODOLOGY

Collection of Isolates

Health Care Providers

Under Section 22(3) and 22(4) of the Public Health Act, health care providers and laboratories are responsible for notifying the designate of the provincial chief medical officer of health (AHS STI Centralized Services) of all confirmed *N. gonorrhoeae* cases within 48 hours. They are also responsible for completing and forwarding the Notification of Sexually Transmitted Infection form (Appendix A), which contains clinical, treatment and exposure information, to the designate of the CMOH within two weeks of notification (10).

Calgary and Edmonton STI Clinics

AMR is primarily monitored through two sentinel sites, the Calgary and Edmonton STI Clinics. Culture is the primary method for detection of gonorrhea in these two clinics. Specific indications for cultures include: exams following sexual assaults, non-genital sites, symptomatic clients, contact to an STI and test of cures. Clinic staff inoculate selective media (Thayer Martin) on site, incubate cultures in 5-7% CO_2 at 35^{o}C until the cultures are transported to the Provincial Laboratory for Public Health (ProvLab) site daily.

In response to concerns expressed about the discomfort of the urethral swab among asymptomatic male clients, Edmonton STI Clinic data for gonorrhea diagnosis by visit type was reviewed for 2011 and 2012. 2012 data showed that 0.4% of all asymptomatic, non-contact screening visits were positive for gonorrhea (19/4638) as compared to 5.3% (63/1195) of contact-related visits and 3.6% (128/3525) of symptomatic visits. Findings were similar for 2011. Due to the low yield of positive results, a decision was made to allow asymptomatic, non-contact males to undergo NAAT testing and once positive a culture would be obtained prior to treatment (Appendix B).

Cases outside of Calgary and Edmonton STI clinics
Additional isolates are obtained through healthcare providers following the criteria for performing culture outlined in the provincial treatment guidelines (e.g., non-genital sites, persistent symptoms post-therapy, treated with an alternate regime, contact to a case with resistance, pregnant women, sexual assault/abuse, treatment failure, and sexual contact outside of Alberta) (11). All isolates from regional microbiology laboratories are submitted to the two ProvLab sites for confirmation of speciation and antimicrobial susceptibility testing.

Provincial Laboratory for Public Health
Isolates confirmed as *N. gonorrhoeae* undergo E-tests for susceptibility to multiple antibiotics. The results of susceptibility testing on antibiotics currently recommended for treatment in the Alberta Treatment Guidelines for STI are reported to the testing physician. Isolates demonstrating resistance and isolates with cefixime MIC values of ≥0.06 µg/mL (beginning in 2011) are submitted to the National Microbiology Laboratory (NML) for sequence typing (Figure 1).

Criteria for interpretation of MIC values were based on Clinical Laboratory Standards Institute (CLSI) standards (12) (Table 1). None of the isolates submitted between 2007 and 2011 were considered "nonsusceptible" (>0.25 µg/mL) by Clinical Laboratory Standards Institute (CLSI) interpretive criteria for cefixime; therefore to understand characteristics associated with rising MIC values for provincial analysis, cefixime MIC values were grouped into 3 categories: 0.25 µg/mL, 0.06 – 0.125 µg/mL, and ≤0.016 – 0.03 µg/mL. As CLSI does not provide interpretive criteria for azithromycin; an MIC value of ≥2.0 µg/mL is considered to have decreased susceptibility by the American Gonococcal Isolate Surveillance Project (13). ProvLab will also undertake molecular sequencing for single nucleotide polymorphisms associated with cefixime nonsusceptibility and NG-MAST typing on an as needed basis.

Table 1. Clinical Laboratory Standards Institute Criteria for MIC Interpretations

	MIC (µg/mL)		
	Resistance	**Intermediate**	**Susceptible**
Penicillin	**≥2.0**	**0.125-1.0**	**≤0.06**
Tetracycline	**≥2.0**	**0.5-1.0**	**≤0.25**
Ciprofloxacin	**≥1.0**	**0.125-0.5**	**≤0.06**
Cefixime	**-**	-	**≤0.25**
Ceftriaxone	**-**	-	**≤0.25**

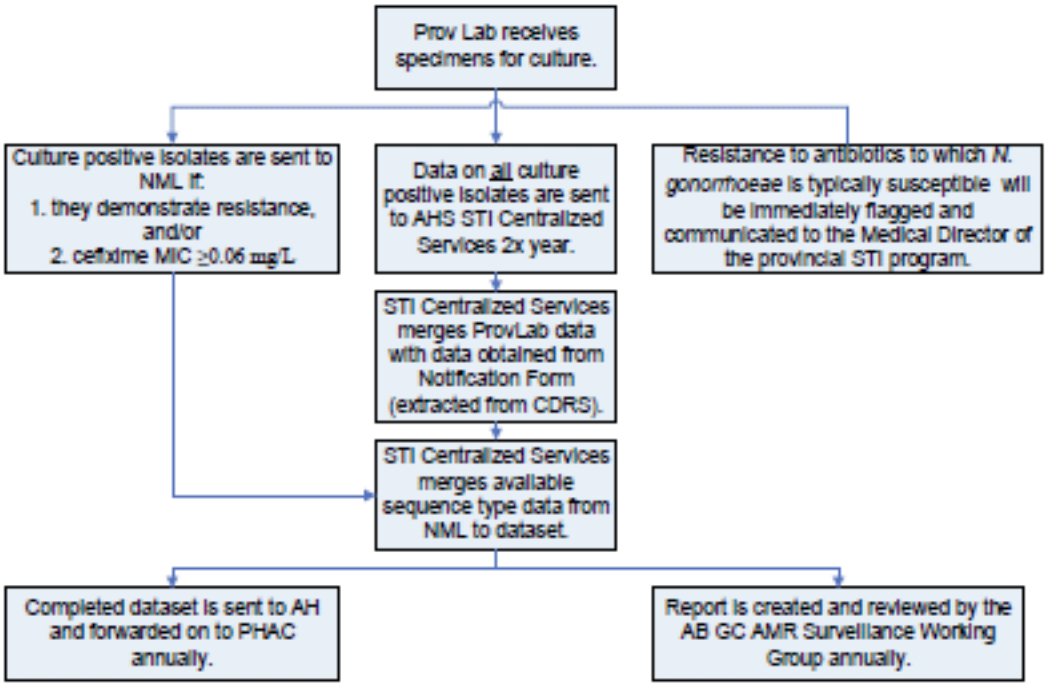
National Microbiology Laboratory
Isolates demonstrating antibiotic resistance (to one or more of the following antibiotics: penicillin, tetracycline, ciprofloxacin, cefixime, ceftriaxone, azithromycin) and isolates with cefixime MIC values of ≥0.06 µg/mL are submitted to the NML for *N. gonorrhoeae* multiantigen sequence typing (NG-MAST). Plans to expand sequence typing for susceptible isolates and to confirm cases with potential treatment failure are underway. A nucleotide sequence-based typing method, NG-MAST is used to compare and contrast *N. gonorrhoeae* isolates and offers a means of making molecular epidemiologic linkages. NG-MAST is based on two genes, *por* and *tbpB*, both highly variable genes with extensive sequence variation to provide substantial levels of discrimination between isolates. These laboratory results are and will continue be returned to the

ProvLab and STI Centralized Services on a mutually agreed upon schedule.

STI Centralized Services

STI Centralized Services receives all positive laboratory results and notifications from health care providers. This information is entered into the STI module of the Communicable Disease Registry System (CDRS) each day. Once the positive laboratory results have been received, an investigation is sent to the partner notification nurse in the corresponding area to ensure treatment is received. A reminder letter to complete the notification form is sent to the physician if the form has not been received within 2 weeks of the positive lab report (this process commenced in late 2012).

Figure 1. Alberta Gonorrhea AMR Data Flow



Treatment Failures

STI Clinic staff also collects information on possible treatment failures identified through the clinics by completing a Gonorrhea Treatment Failure Data Collection Tool (Appendix C) and sending to STI Centralized Services. A notation on the case will be made in CDRS.

Case Definitions

Confirmed case (10)

Genital Infections

Laboratory confirmation of infection in genitourinary specimens:

• Isolation of *Neisseria gonorrhoeae* by culture

OR

• Detection of *N. gonorrhoeae* nucleic acid (e.g., nucleic acid amplification test [NAAT]).

Extra-genital Infections
Laboratory confirmation of infection from pharynx, rectum, joint, conjunctiva, blood or other extragenital sites:
• Isolation of *N. gonorrhoeae* by culture
OR
• Detection of *N. gonorrhoeae* nucleic acid (e.g., nucleic acid amplification test [NAAT]).

Perinatally Acquired Infections
Laboratory confirmation of infection from a neonate in the first four weeks of life leading to the diagnosis of gonococcal conjunctivitis, scalp abscess, vaginitis, bacteremia, arthritis, meningitis or endocarditis:
• Isolation of *N. gonorrhoeae* by culture
OR
• Detection of *N. gonorrhoeae* nucleic acid (e.g., nucleic acid amplification test [NAAT]).

Gonorrhea Treatment Failure Definition
(adapted from the World Health Organization[14])

Inclusion Criteria:
• A person who received a recommended treatment regime[11]
AND
• had persistently positive cultures ≥5 days or NAAT ≥ 3 weeks post-treatment
AND
• denied sexual contact post treatment.
AND
- When available, matching sequence types per and post-treatment

DATA COLLECTION

Provincial Laboratory for Public Health

Biannually, the ProvLab will send AHS STI Centralized Services a data extract of all *N. gonorrhoeae* isolates and their associated MIC values for azithromycin, cefixime, ceftriaxone, ciprofloxacin, penicillin, tetracycline, beta lactamase results, as well as any available results for single nucleotide polymorphism analysis and NG-MAST typing. Other relevant fields will include: specimen type and source as well as received date. The extract will contain sufficient information to allow matching of cases to the data in the CDRS STI module. This will include: specimen number, patient name or unique identifier, gender, age, testing agency.

National Microbiology Laboratory

The NML will provide ProvLab with a data extract which will contain specimen numbers for matching, sequence, *por* and *tbpB* type data.

AHS STI Centralized Services

An extract of *N. gonorrhoeae* cases and their associated behavioural and treatment data elements as completed on the Notification of STI form is created annually. Minimum case information (for

cases without a notification form completed) includes age, gender, and testing healthcare provider. The lab specimen number is used to match with the laboratory derived data. Data elements for treatment failures include specimen numbers, results, MIC values, demographic and behavioural elements, and treatment details.

DATA ANALYSIS

Specimen-based line lists obtained from the laboratories is converted to a case-based line list so that trends are not over-represented for cases with multiple isolates. If more than one culture positive isolate per patient was submitted on the same day, only one isolate is selected for data analysis. MIC data for duplicate/triplicate specimens from the same patient submitted on the same day with the same sequence typing data are reviewed, and the most resistant isolate is selected. If MIC patterns are the same for multiple isolates, the following hierarchy is used to select the isolate: throat/genital/rectum.

Similarly for treatment data, when multiple drugs are prescribed for gonorrhea cases, cases are assigned to a treatment agent based on the following hierarchy: cefixime, ceftriaxone, ofloxacin, ciprofloxacin, azithromycin and other drugs.

Limitations

Previous analysis has identified differences between NAAT positive and culture positive cases, and therefore GC AMR results may not be representative of cases throughout the province. Culture positive cases were more likely to be male, Caucasian, and have reported same sex partnering. Differences are most likely related to the collection of cultures being concentrated in the two STI clinics.

Another limitation to the behavioural data is the proportion of “unknown” values from cases that have not had a notification form completed by a healthcare provider. Caution is recommended in interpreting behavioural data where denominators fall due to missing data.

Due to the widespread availability of GC NAAT testing by front-line laboratories, a significant proportion of specimens from lower risk patients are unavailable for strain typing and antimicrobial susceptibility testing. It is anticipated that newer technologies will make this feasible in the future.

DATA MANAGEMENT

Data collected by Alberta Health Services is for the care of individuals and is maintained in accordance with the Freedom of Information and Protection of Privacy Act and the Health Information Act to maintain confidentiality and privacy of individuals' personal and health information. The Alberta Ministry of Health and the Public Health Agency of Canada have a Memorandum of Understanding which allows de-identified information on STI cases to be transferred between parties.

The surveillance protocol has received approval from the University of Alberta’s Research Ethics Board from 2007-2017 to allow prompt dissemination of findings with external parties.

SURVEILLANCE PERIOD

Provincial surveillance for AMR in gonorrhea will be ongoing. GC AMR surveillance preceded this protocol and will continue until at least April 2017.

Denominator Data

Whenever possible, annual laboratory testing data with test type, specimen source, result, testing agency and address, submitting laboratory and a unique patient identifier will be provided for analysis of provincial screening practices.

REPORTING

Communication and dissemination of surveillance reports is an integral part of surveillance, to inform STI practice within AHS. Responsibility for compiling, reporting, and disseminating data and reports is shared between the AHS STI Program and the Alberta Health Communicable Disease Program. Preliminary results will be shared with the data sources to ensure correct interpretation of results. Formal reports are generated routinely (annually). The reports contain information on the characteristics of *N. gonorrhoeae* cases, trends in MIC values for various antimicrobials, and the diversity of strains through sequence typing data. Reports are presented to the Alberta Gonorrhea AMR Surveillance Working Group (Appendix D) for approval. This working group reports to the Chief Medical Officer of Health (Alberta Health) and Senior Medical Director, Population & Public Health (AHS).

Resistance to currently recommended antibiotics (cefixime, ceftriaxone, azithromycin) for the treatment of *N. gonorrhoeae* is flagged by the ProvLab and promptly communicated to the Provincial Medical Director for Centralized STI Services.

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APPENDIX A: NOTIFICATION OF STI FORM

Government of Alberta

Notification of Sexually Transmitted Infections

The partner notification nurse may contact your patient to obtain additional information.

Section 1 - Patient Information *(Please print)*

Patient name *Last name* / *First name* / *Middle name* | Gender ☐ Male ☐ Female

Current address | City/Town | Province and Country | Postal code

Telephone number | Birthdate Year Month Day | Personal health number | Marital status

Lives on reserve? If yes, name of First Nations community ☐ Yes ☐ No | Occupation and place of work | Ethnicity ☐ Caucasian ☐ Oriental ☐ First Nations ☐ Inuit ☐ Other, specify ☐ Black ☐ Other Asiatic ☐ Metis ☐ Other Unknown

Behaviour attitudes *(X all that apply)*
☐ Sex with females only ☐ Sex with both males and females ☐ Injection Drug User (IDU) ☐ Sex Work
☐ Sex with males only ☐ Sex with IDU ☐ Sex with Sex Trade Worker

Reason for visit: *(X all that apply)*
☐ Symptoms ☐ STI Screening ☐ Annual Checkup ☐ Therapeutic Abortion
☐ Contact ☐ Prenatal ☐ Sexual Assault

Section 2 - Laboratory/Clinical Findings

Clinical findings *(X all that apply)*

				Duration
Asymptomatic	☐ Yes	☐ No	☐ Unknown	
Vaginal discharge	☐ Yes	☐ No	☐ Unknown	
* Cervical discharge	☐ Yes	☐ No	☐ Unknown	
* Friable cervix	☐ Yes	☐ No	☐ Unknown	
◆ Urethral discharge	☐ Yes	☐ No	☐ Unknown	
◆ Dysuria	☐ Yes	☐ No	☐ Unknown	
Rectal symptoms	☐ Yes	☐ No	☐ Unknown	
Other (please describe)	☐ Yes	☐ No	☐ Unknown	

Pregnant ☐ Yes ☐ No ☐ Unknown — If yes, test of cure recommended. *(see reverse)*

Complications *(X all that apply)*
☐ PID ☐ Epididymitis ☐ Other, specify: _____

Specimen Sites *(X all that apply)*
☐ Urethra ☐ Rectum ☐ Eye ☐ Pharynx
☐ Endo-cervix ☐ Urine ☐ Other, specify: _____

Blood Tests *(X all that apply)*
☐ Syphilis: ☐ Positive ☐ Negative ☐ Pending — Date Year Month Day
☐ HIV: ☐ Positive ☐ Negative ☐ Unknown/Indeterminate ☐ Pending — Date Year Month Day

Section 3 - Treatment Details *(X all that apply)*

Notifiable Diseases	Code*	Treated with:		Office Use
☐ Chlamydia Trachomatis	A	☐ Azithromycin	1 gm	☐
☐ Gonorrhea	B	☐ Cefixime	400 mg	☐
☐ Non-Gonococcal Urethritis ◆	C	☐ Doxycycline	100 mg bid x 7 days	☐
☐ Mucopurulent Cervicitis *	D	☐ Doxycycline	100 mg bid x 14 days	☐
☐ Syphilis	E	☐ Ciprofloxacin	500 mg	☐
☐ Chancroid	F	☐ Ceftriaxone	250 mg IM	☐
☐ Lymphogranuloma Venereum	G	☐ Amoxicillin	500 mg tid x 7 days	☐
	H	☐ Erythromycin	500 mg qid x 7 days	☐
	I	☐ Erythromycin	250 mg qid x 14 days	☐
	J	☐ Ofloxacin	400 mg bid x 14 days	☐
	K	☐ Metronidazole	500 mg bid x 14 days	☐
	L	☐ Special Drugs *(see reverse)*		☐
	M	☐ Other *(specify name and dosage)*		☐

Date of treatment Year Month Day

Physician's name (Please print)

Where would you like replacement drugs sent: ***(see reverse for more information).***

USE OFFICE STAMP OR MAILING LABEL ON ALL 3 PAGES.

☞ **The Public Health Act requires that all reportable Sexually Transmitted Communicable Disease cases be reported to Alberta Health and Wellness with names of all sexual partners.**
☞ **Please send a separate notification form if additional contacts are identified.**
☞ **The partner notification nurse may contact your patient to obtain additional contact information.**

Section 4 - Sexual Contact One Information

Contact name *Last* / *First* / *Middle*

Gender ☐ Male ☐ Female | Birthdate (year/month/day) | Age | Marital status

Current address

City/Town | Province and Country | Postal code

Telephone number | Cell number

Occupation and place of work

Distinguishing features | Ethnicity *(see section 1)*:

Date and Location of exposure

Relationship to patient *(X all that apply)*
☐ Regular partner ☐ Working in sex trade
☐ Casual known ☐ Sex for money
☐ Casual unknown ☐ Sex for cigarettes or alcohol
☐ Ex-Partner ☐ Sex for drugs

Contact treated? ☐ Yes ☐ No
Date: Year Month Day
Medication code * *(see Section 3)*: | Office Use ☐

Sexual Contact Two Information

Contact name *Last* / *First* / *Middle*

Gender ☐ Male ☐ Female | Birthdate (year/month/day) | Age | Marital status

Current address

City/Town | Province and Country | Postal code

Telephone number | Cell number

Occupation and place of work

Distinguishing features | Ethnicity *(see section 1)*:

Date and Location of exposure

Relationship to patient *(X all that apply)*
☐ Regular partner ☐ Working in sex trade
☐ Casual known ☐ Sex for money
☐ Casual unknown ☐ Sex for cigarettes or alcohol
☐ Ex-Partner ☐ Sex for drugs

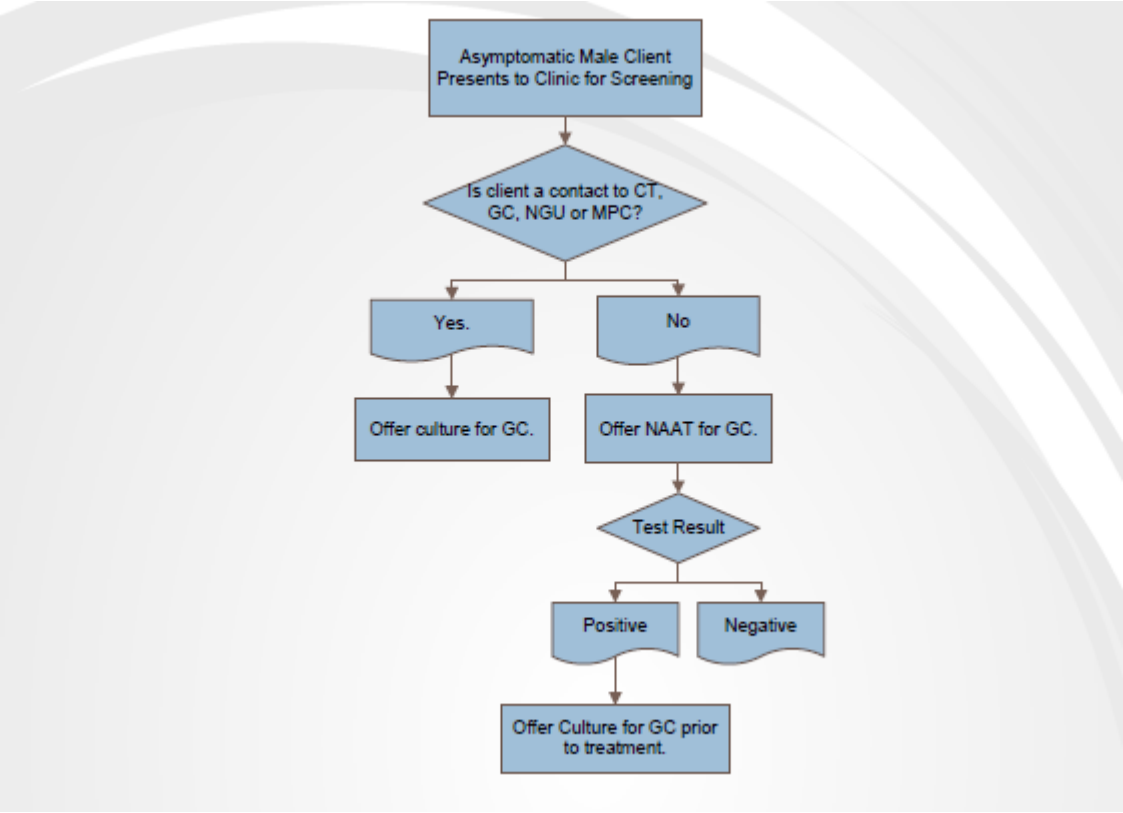
Contact treated? ☐ Yes ☐ No
Date: Year Month Day
Medication code * *(see Section 3)*: | Office Use ☐

☞ **If you require assistance or consultation call 780-735-1466 or toll free 1-888-535-1466 if calling long distance.**
☞ **Mail all copies, sealed in the envelope provided.**

☞ **Indicate if you require any of the following:**
☐ Billing number ☐ Notification forms
☐ Patient literature

AH0332 (2010/09)

APPENDIX B: ALGORITHM FOR ASYMPTOMATIC MALES PRESENTING TO THE STI CLINICS FOR SCREENING



APPENDIX C: DATA COLLECTION TOOL

Gonorrhea Treatment Failure Data Collection Tool for STI Clinics

To be completed when a client is positive on their Test of Cure (TOC) and denies sexual contact between treatment and TOC.

Demographics		
Patient Name (Last, First)		**Chart Number**
Current Address Municipality		Postal Code
Date of Birth: YYYY/MMM/DD		**Gender:** □ Male □ Female □ Other
Personal health number:		**Reporting Physician Name and Address:**
Ethnicity: □ Black □ Caucasian □ First Nations □ Métis □ Inuit □ Oriental □ Other Asiatic □ Unknown □ Other, Specify _____		
Clinical Details		
Isolate #1: First Positive Isolate		
Date of Specimen Collection: YYYY/MMM/DD	**Lab Specimen Number:**	**Test Type:** □ Culture □ NAAT
Site of Specimen Collection: □ Cervix □ Eye □ Pharynx □ Rectum □ Urethra □ Urine □ Unknown □ Other, specify: _____		
Treatment Date: YYYY/MMM/DD	**Drugs:** □ Cefixime 800 mg + Azithromycin 1gm □ Ceftriaxone 250 mg + Azithromycin 1gm □ Other:	
Isolate #2: Test of Cure		
Date of Specimen Collection: YYYY/MMM/DD	**Lab Specimen Number:**	**Test Type:** □ Culture □ NAAT
Site of Specimen Collection: □ Cervix □ Eye □ Pharynx □ Rectum □ Urethra □ Urine □ Unknown □ Other, specify: _____		
Treatment Date: YYYY/MMM/DD	**Drugs:** □ Cefixime 800 mg + Azithromycin 1gm □ Ceftriaxone 250 mg + Azithromycin 1gm □ Other:	
Risk Factor Information		
Sexual Activity: □ Sex with male □ Sex with female □ Sex with both	**Denies Sexual Exposure between Treatment and Test of Cure?** □ Yes □ No □ Unknown Comment: _____	
Did client report sex with anyone that resides outside of Alberta in last 2 months (or if no sexual contact in last 2 months – was most recent contact from outside Alberta?) □ Yes □ No □ Refused □ Unknown If yes, specify location where likely acquired (i.e., name of city, province/territory and/or country).		
Completed by:	**Date:** YYYY/MMM/DD	

APPENDIX D: MEMBERS OF THE AB GONORRHEA AMR SURVEILLANCE WORKING GROUP

The Alberta Gonorrhea AMR Surveillance Working Group	
Members:	
Dr. Ameeta Singh (Chair)	Medical Director, Edmonton STI Clinic, Alberta Health Services
Joshua Bergman	Clinical Instructor, Edmonton STI Clinic, Alberta Health Services
Lindsay Bertholet	Manager, STI Centralized Services, Alberta Health Services
Dr. Steven Drews	Clinical Microbiologist Alberta health Services, Assistant Professor Microbiology, Immunology and Infectious Diseases, University of Calgary, Site Program Lead for STI, Provincial Laboratory for Public Health
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Marguerite Lovgren	Manager, Bacteriology, Provincial Laboratory for Public Health
Dr. Sabrina Plitt	Alberta Field Surveillance Officer, Public Health Agency of Canada
Dr. Ron Read	Medical Director, Calgary STI Clinic, Alberta Health Services
Dr. Barbara Romanowski	Clinical Professor, University of Alberta
Kimberley Simmonds	Epidemiologist, Alberta Health
Dr. Petra Smyczek	Provincial Medical Director (STI), Alberta Health Services
Dr. James Talbot	Chief Medical Officer of Health, Alberta Health and Wellness

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