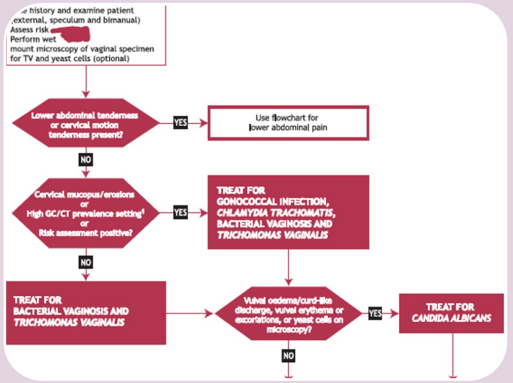
Guidelines for the management of symptomatic STIs

GUIDELINES FOR THE MANAGEMENT OF SYMPTOMATIC STIs

https://www.who.int/publications/i/item/9789240024168

Teodora Elvira Wi, MD
Medical Officer, STI
Department of Global HIV, Hepatitis & STI Programmes

STI CASE MANAGEMENT APPROACHES



Syndromic

- Signs and symptoms
- Treat base on most common aetiologies of the syndrome (urethral discharge– NG/ CT)

Clinical

- Clinical acumen
- Treat base on clinical findings (Mucopurulent urethral discharge – NG, watery urethral discharge - CT)

Etiologic

- Laboratory test (precise)
- Treat base on laboratory results (NAAT NG, CT, TV – treat if positive)

RE-THINKING SYNDROMIC CASE MANAGEMENT

- Challenges
  - Low diagnostic performance of vaginal discharge to manage cervical infection
  - Low diagnostic performance of ano-rectal infection (entry point is anal sex)
- Emerging antimicrobial resistance
- Changing aetiologies of syndromes (e.g. HSV)
- Symptomatic and not for screening
- Availability of point-of-care test

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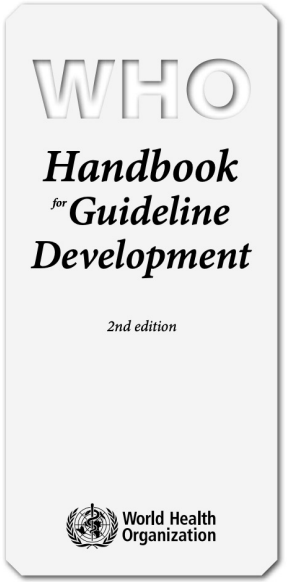
OBJECTIVES OF THE GUIDELINES

- to provide updated, evidence-informed clinical and practical recommendations on case management of people with symptoms of STIs; and
- to support countries in updating their national guidelines for the case management of people with symptoms of STIs.

TARGET AUDIENCE

- programme managers for STI prevention and control
- health-care providers at the frontline in primary, secondary and tertiary health-care facilities
- Policy makers and stakeholders

WHICH MANAGEMENT APPROACHES SHOULD BE USED FOR PEOPLE WITH SYMPTOMS RELATED TO SEXUALLY TRANSMITTED INFECTIONS?



Establish group of experts → Identify important questions to answer → Review the evidence → Make recommendations

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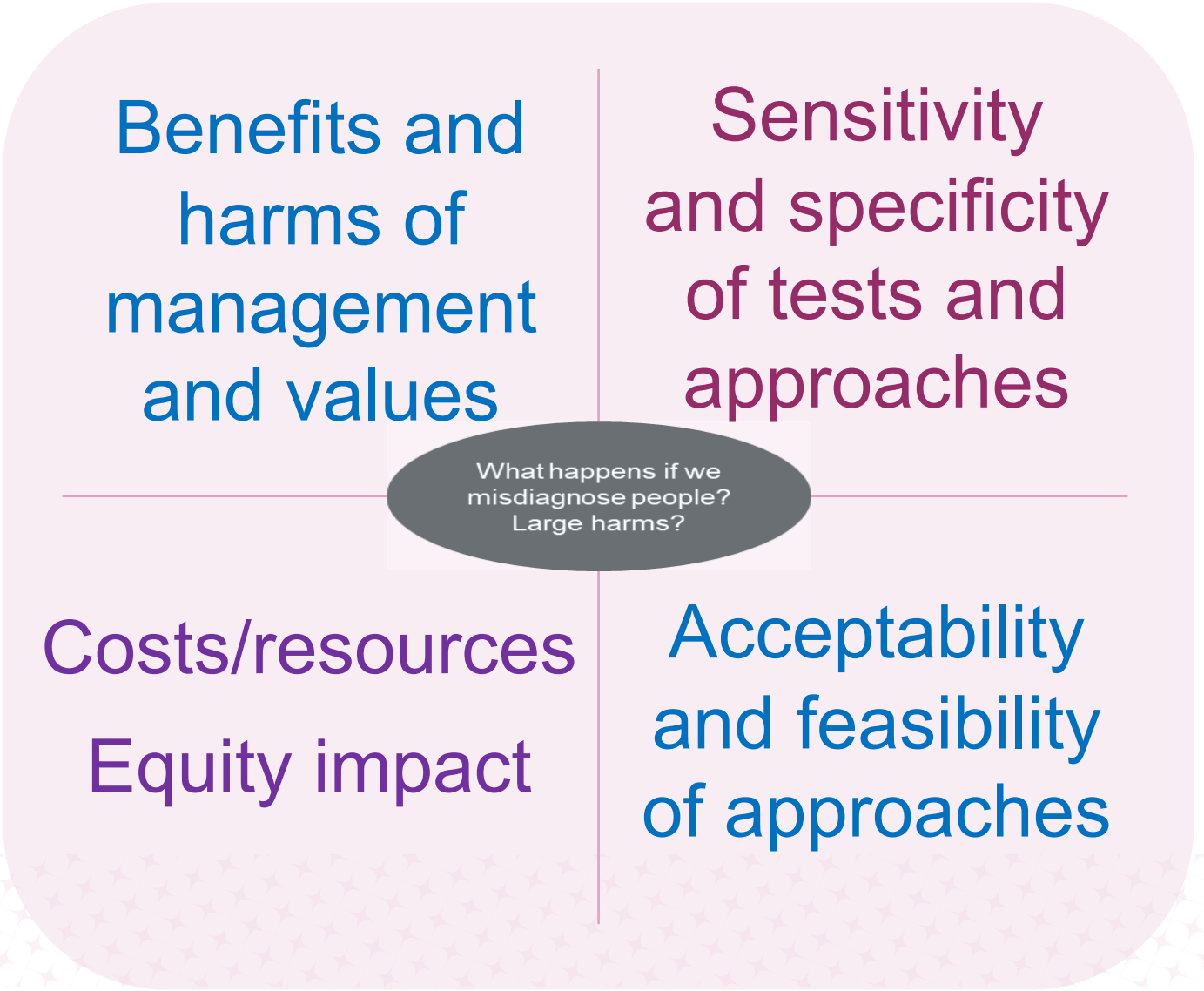
REVIEWS OF THE EVIDENCE

- **Follow-up studies**
- Evaluation studies
- Accuracy of risk assessment, clinical exam, and different tests

- Modelling to pull together the evidence to calculate what happens to people over time and how much it costs



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BALANCE OF CRITERIA LEADS TO RECOMMENDATION

Good practice statements

scale tips all to one side

strong recommendation

WHO recommends…

scale tips *slightly* to one side

conditional recommendation

WHO suggests…

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STI CASE MANAGEMENT

For people with symptoms of vaginal discharge, good practice includes:

- taking a medical and sexual history and assessing the risk of STIs;
- performing a physical examination, including abdominal and pelvic examination,
- bimanual digital examination of the vagina (
- offering HIV and syphilis testing and other preventive services as recommended in other guidelines.

Medical and sexual history

Physical and genital examination

Diagnosis (syndromic/ etiologic)

- Same-day treatment

Appropriate treatment/ compliance to treatment

Health education and Counselling

- HIV and syphilis testing
- Condoms
- PrEP
- Vaccination (Hep)
- Circumcision (men)

Partner management

Promote and provide prevention services

IMPORTANT CONSIDERATION IN STI CASE MANAGEMENT

- Evidence-based STI case management guidelines
  - ✓Etiologies of syndrome studies
  - ✓Patterns of antimicrobial resistance
- Overcome programmatic challenges:
  - ✓Service delivery models for integration – integrated laboratory platform - molecular assay and POCT for HIV/syphilis, and training
- Logistic support – drugs, diagnostics
- Referral centers and sentinel site laboratories
- STI reporting and surveillance

RESEARCH NEEDS IN STI CASE MANAGEMENT

- The role of overtreatment in developing or accelerating antimicrobial resistance, especially for *N. gonorrhoeae* and *M. genitalium*.
- *M. genitalium*: how important is this organism in pathogenicity and the need for control?
- *H. ducreyi*: this pathogen seems to have been controlled, but it is occasionally detected in some settings through infrequent etiological studies.
- *C. trachomatis* genovar L1–L3: there seems to be a resurgence of lymphogranuloma venereum, especially among men who have sex with men, causing rectal infections.
- Validation studies and cost–effectiveness studies of the various recommended flow charts, considering important outcomes, such as pelvic inflammatory disease and the development of antimicrobial resistance.
- Studies on the prevalence and effective treatment of people with anorectal and pharyngeal infections and the role of pooled sampling.
- Real rapid low-cost point-of-care tests for diagnosing *N. gonorrhoeae* and *C. trachomatis* need to be developed.

WHO STEERING COMMITTEE

- Teodora Elvira Wi , Meg Doherty, Rachel Baggaley, Theresa Babovic, Meg Doherty, Nathan Ford, Cadi Irvine, Yamuna Mundade, Annette Vester, Marco Vitorio, Lara Vojnov and Mayada Youssef-Fox;
- Ian Askew, Nathalie Broutet, Venkatraman Chandra-Mouli, Sami Gottlieb, James Kiarie, Melanie Taylor, Igor Toskin, Francis McConville, Carmen Pessoa.
- Jasmin Leuterio, Laurent Poulain and Danilo Salvador , Adriana De Putter,Jerome Peron , Yann Seigenthaler
- Hugues Lago , Massimo Ghidinelli , Joumana Hermez , Nicole Seguy ,Bharat Rewari , Naoko Ishikawa

STI GDG MEMBERS

Ilya Abellanosa-Tacan (Cebu City, Philippines), **Laith Abu-Raddad** (Weill Cornell Medical College, Qatar), **Yaw Adu-Sarkodie** (Kwame Nkrumah University of Science and Technology, Ghana), **Chris Akolo** (FHI 360, Washington, DC, USA), **Andrew Amato** (European Centre for Disease Prevention and Control, Sweden), **Mircea Betiu** (Nicolae Testemițanu State University of Medicine and Pharmacy, Republic of Moldova), **John Changalucha** (National Institute for Medical Research, United Republic of Tanzania), **Rizwana Chaudhri** (Islamabad Specialists Clinic, Islamabad, Pakistan), **Xiang-Sheng Chen** (National Center for STD Control of Chinese CDC and Chinese Academy of Medical Sciences Institute of Dermatology, Nanjing, China), **Amina El Kettani** (Ministry of Health, Morocco), **Patricia Garcia** (Ministry of Health, Lima, Peru), **William M. Geisler** (University of Alabama at Birmingham, USA), **Edward W. Hook III** (University of Alabama at Birmingham, USA), **Rossaphorn Kittyaowamarn** (Ministry of Public Health, Thailand), **Jeffrey D. Klausner** (UCLA David Geffen School of Medicine and Fielding School of Public Health, Los Angeles, USA), **Ranmini Kularatne** (National Institute for Communicable Diseases, Johannesburg, South Africa), **David Lewis** (University of Sydney, Australia), **Nicola Low** (Institute of Social and Preventive Medicine, Berne, Switzerland), **Philippe Mayaud** (London School of Hygiene and Tropical Medicine, United Kingdom), **Daniel McCartney** (International Planned Parenthood Federation, United Kingdom), **Nelly Mugo** (Kenya Medical Research Institute, Kenya), **Saiqa Mullick** (Wits Reproductive Health and HIV Institute, South Africa), **Francis Ndowa** (Harare, Zimbabwe), **Kees Rietmeijer** (Denver Public Health Department, USA), **Pachara Sirivongrangson** (Ministry of Public Health, Thailand), **Katayoun Tayeri** (Ministry of Health, Tehran, Islamic Republic of Iran), **Ann Natalia Umar** (Ministry of Health, Jakarta, Indonesia), **Magnus Unemo** (Örebro University Hospital, Sweden), **Noor Mohamed Usman** (Chennai, India), **Bea Vuylsteke** (Institute of Tropical Medicine, Antwerp, Belgium) and **Judith Wasserheit** (University of Washington, USA).

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EXTERNAL REVIEW GROUP

Anupong Chitwarakorn (Silom Clinic, Thailand), **H.J.C. de Vries** (Amsterdam, Netherlands), **Hans Benjamin Hampel** (University of Zurich, Switzerland), **Kausar Jabeen** (Aga Khan Foundation, Pakistan), **Monica Lahra** (New South Wales, Australia), **Ahmed Latif** (Public Health Consultant, National Territory, Australia), **Ioannis Mameletzis** (consultant, Ukraine), **Angelica Espinosa Miranda** (Ministry of Health, Brazil), **Koleka Mlisana** (University of KwaZulu Natal, South Africa), **Lori Newman** (National Institutes of Health, Washington, DC, USA), **Catherine Ngugui** (Ministry of Health, Kenya), **Lilani Rajapaksa** (National STD AIDS Control Programme, Sri Lanka), **Reshmie Ramautarsing** (Bangkok, Thailand), **Danvic Rosadiño** (Love Your Self Clinic, Mandaluyong City, Philippines) and **Janet Wilson** (International Union of STI, Leeds, United Kingdom).

OBSERVERS

Laura Bachmann (United States Centers for Disease Control and Prevention, USA), **Cecilia Ferreyra** (FIND, Switzerland)**, Fernando Pascual Martinez** (GARDP, Switzerland) and **Tim Sladden** (UNFPA, New York, USA)**.**

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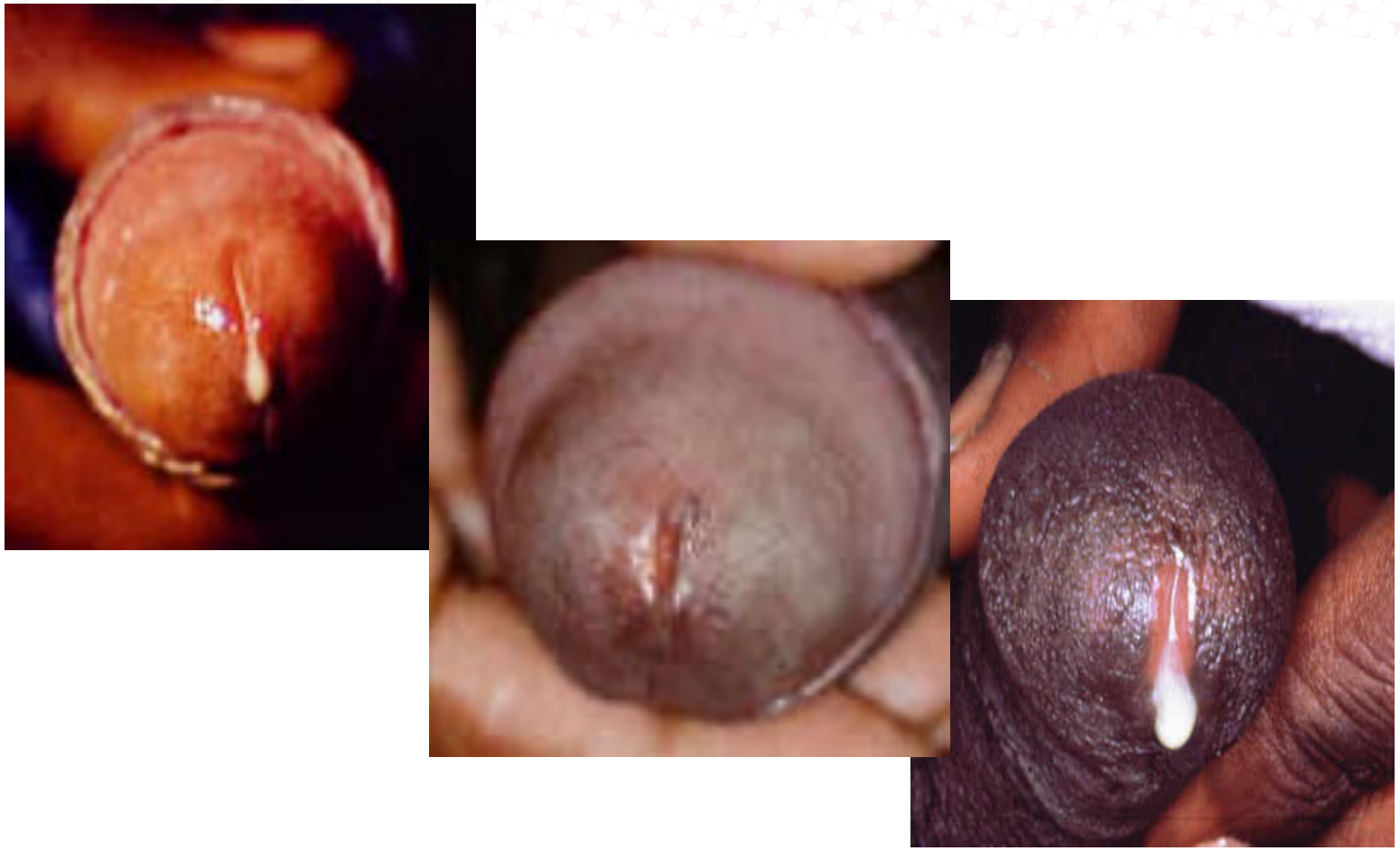
WHO Guidelines for the management of symptomatic STIs

URETHRAL DISCHARGE – EVIDENCE AND RECOMMENDATIONS

URETHRAL DISCHARGE FROM THE PENIS



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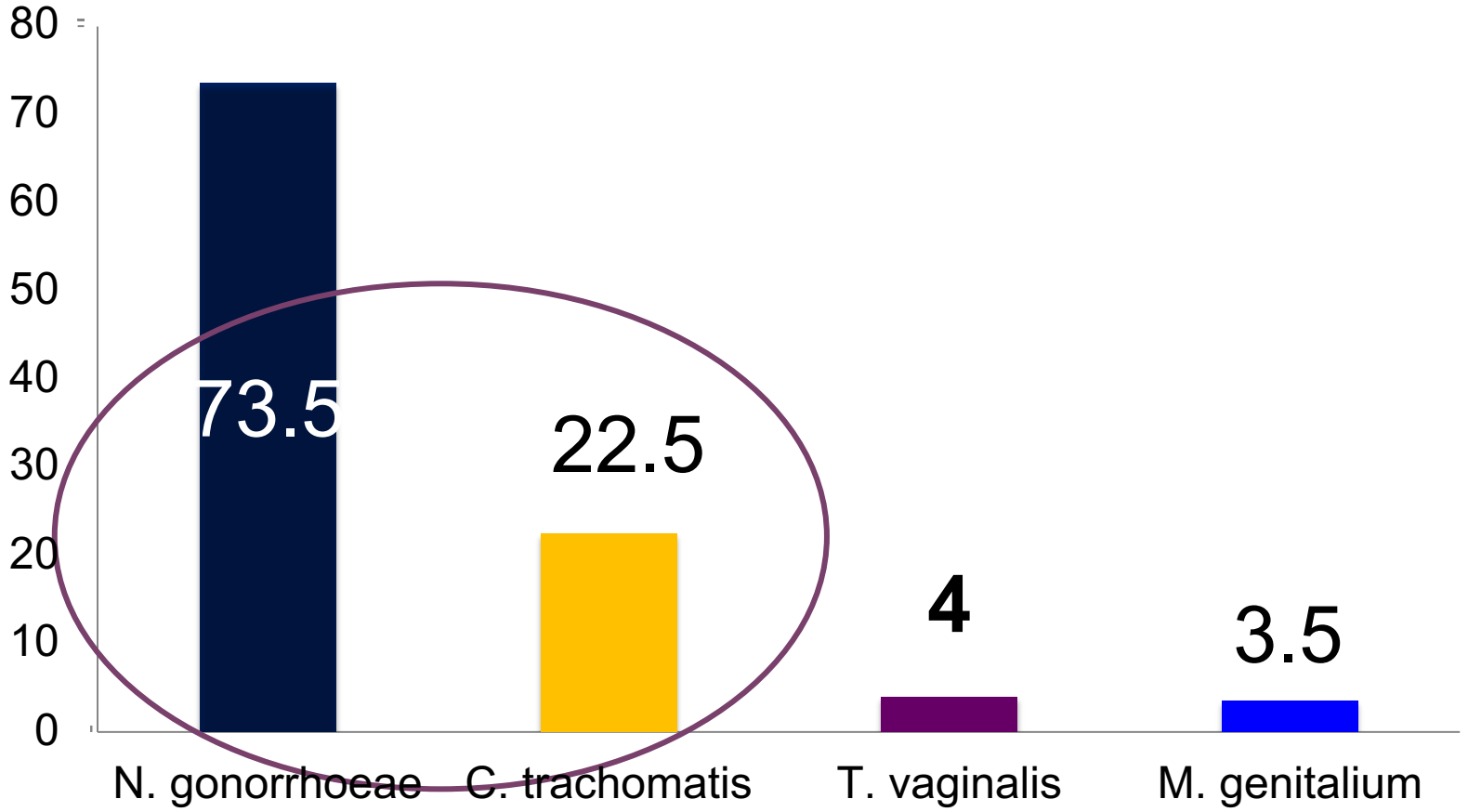
AETIOLOGY OF MALE URETHRAL DISCHARGE SYNDROME BY MULTIPLEX PCR (N=200) IN ZIMBABWE



Source: CA Rietmeijer et al. The etiology of male Urethral Discharge in Zimbabwe: Results from the Zimbabwe STI Etiology Study. *Sex Transm Dis 2018;45:56-60.*

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RESEARCH EVIDENCE

- A systematic review of risk factors for ***N. gonorrhoeae*** **and/or** ***C. trachomatis*** in men with urethral discharge found **62 studies** that showed that **the odds of** ***N. gonorrhoeae*** **or** ***C. trachomatis*** **infection among men with urethral discharge is 10 times the odds among men with no urethral discharge**.
- Another systematic review analysed the association of ***M. genitalium*** among men with persistent or recurrent urethral discharge and showed that the **odds of** ***M. genitalium*** **infection among men with persistent of recurrent urethritis is 20 times the odds among men without persistent or recurrent urethral discharge**

RESEARCH EVIDENCE

Table A3.3. In the Guidelines) Absolute effects by true and false positives and negatives based on the sensitivity and specificity of syndromic approaches

	Prevalence of *Neisseria gonorrhoeae* or *Chlamydia trachomatis*		
	10%	40%	60%
History and risk			
True positive	10	38	57
False negative – missed treatment	0	2	3
True negative	37	25	16
False positive – unnecessary treatment	53	35	24
History, risk and examination			
True positive	9	34	51
False negative – missed treatment	1	6	9
True negative	60	40	27
False positive – unnecessary treatment	30	20	13

	Prevalence of *Neisseria gonorrhoeae* or *Chlamydia trachomatis*		
	10%	40%	60%
History, risk, examination and microscopy			
True positive	9	37	55
False negative – missed treatment	1	3	5
True negative	4	3	2
False positive – unnecessary treatment	86	57	38
Point-of-care testing (80% or 90%)			
True positive	8	32	48
False negative – missed treatment	2	8	12
True negative	81	54	36
False positive – unnecessary treatment	9	6	4
GeneXpert® (95%, 98%)			
True positive	10	38	57
False negative – missed treatment	0	2	3
True negative	88	59	39
False positive – unnecessary treatment	2	1	1

VALUE JUDGEMENT: WEIGHING THE RESEARCH EVIDENCE FOR RECOMMENDATIONS

- The Guideline Development Group placed greater value on **avoiding missed cases** despite possible unnecessary treatment for some cases.
- The undesirable effects of a syndromic approach (such as missed cases) were greater than treating all or treating according to molecular testing; and the desirable effects (such as correct treatment) of a syndromic approach were none to trivial compared with treating all or molecular testing.
- Therefore, the balance of benefits and harm favoured using molecular testing or treating all.

VALUE JUDGEMENT: WEIGHING THE RESEARCH EVIDENCE FOR RECOMMENDATIONS

- Therapy for all positives (N. gonorrhoeae or C. trachomatis) was 1 gram azithromycin + ceftriaxone 250 mg intramuscularly = US$ 1.66
- Costs of flowchart 1,2 = US$0
- Costs of flowchart 3 = US$1
- Costs of point-of-care test = US$3
- GeneXpert costs: US$16
- Estimated costs of treatment for *N. gonorrhoeae* or C. trachomatis with antimicrobial resistance: US$25

RECOMMENDATIONS MANAGEMENT OF URETHRAL DISCHARGE

Recommendations for the management of urethral discharge

(Strong recommendation; moderate-certainty evidence)

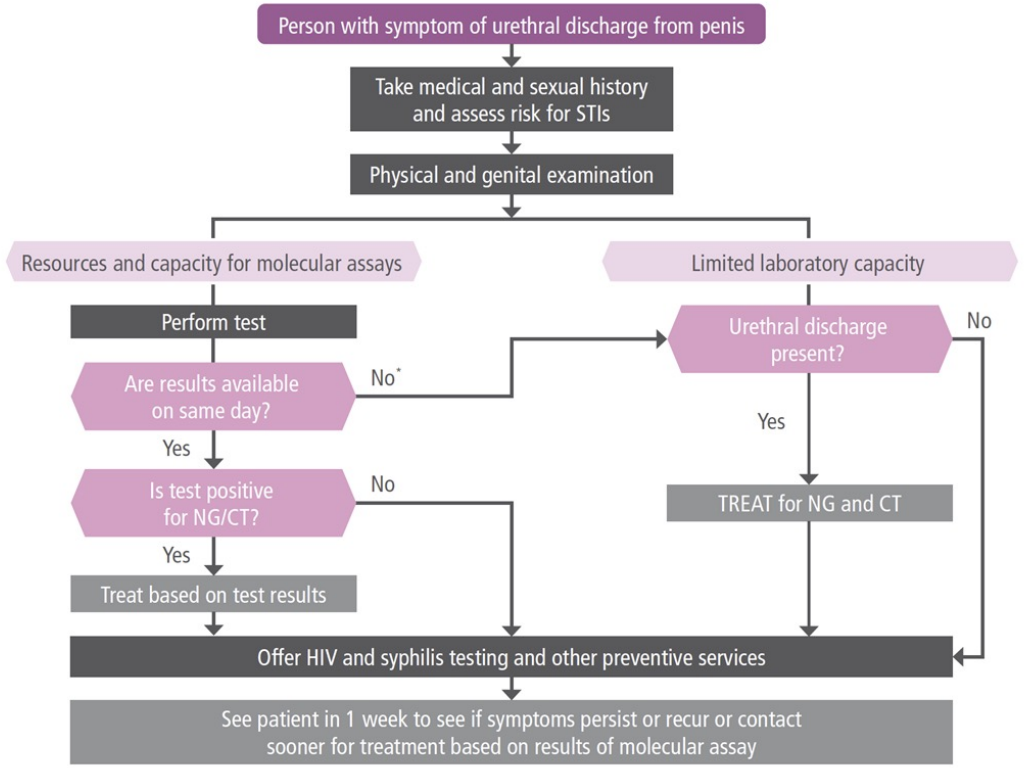
- For people with symptom of urethral discharge from the penis, management is recommended to be based on the results of quality-assured molecular assays.
- However, in settings with limited or no molecular tests or laboratory capacity, WHO recommends syndromic treatment to ensure treatment on the same day of visit.
- Good practice includes:
  - taking a medical and sexual history and assessing the risk of STIs;
  - performing a physical examination of the genital and anal areas; and
  - offering HIV and syphilis testing and other preventive services as recommended in other guidelines.

RECOMMENDATIONS MANAGEMENT OF URETHRAL DISCHARGE

Settings with quality-assured molecular testing in a laboratory with a fully operational quality management system and results available on the same day of the visit.

WHO recommends the following: *(Strong recommendation; moderate-certainty evidence)*

- Perform molecular assays such as nucleic-acid amplification testing (NAAT) to confirm or exclude Neisseria gonorrhoeae and Chlamydia trachomatis.
- Treat according to the test results on the same day. If urethral discharge is present but tests are negative, treat for non-gonococcal and non-chlamydial urethritis (such as *Mycoplasma genitalium* or *Trichomonas vaginalis*).
- When treatment based on molecular assays is not feasible on the same day of the visit, WHO recommends syndromic treatment of infection with *N. gonorrhoeae* and *C. trachomatis* and using the test results to support managing the partner when tests are available.
- Treat people with recurrent or persistent urethral discharge based on a repeat molecular assay (such as NAAT) after 21 days, testing for *N. gonorrhoeae*, *C. trachomatis* as well as *M. genitalium* and *T. vaginalis* and testing for antimicrobial-resistant *N. gonorrhoeae*.



NG, *N.gonorrhoeae*; CT, *C. trachomatis*.

* If molecular assay was performed and results were not available on same day, revise the syndromic treatment initially provided according to the test results when available

If test is negative but urethral discharge is present, treat for non-gonococcal/non-chlamydial urethritis (such as *M. genitalium*, *T. vaginalis* or herpes simplex virus)

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RECOMMENDATIONS FOR THE MANAGEMENT OF URETHRAL DISCHARGE

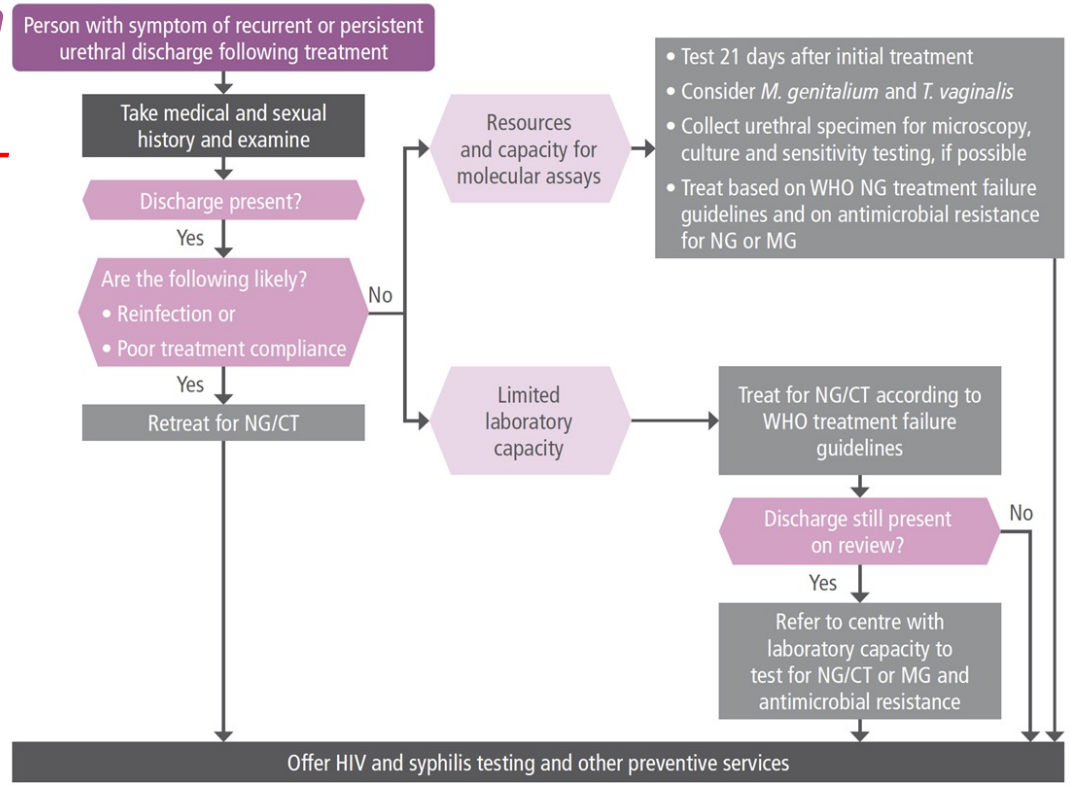
Settings in which same-day treatment is not feasible with molecular testing or with limited or no molecular testing

WHO suggests the following: *(Conditional recommendation; low-certainty evidence)*

- Treat people who have urethral discharge confirmed on examination for *N. gonorrhoeae* and *C. trachomatis* to ensure same-day treatment.
- Treat people with recurrent or persistent urethral discharge for treatment failure based on WHO guidelines and review.

Good practice includes:

- if symptoms persist at review, checking partner notification and treatment history; and
- for people with recurrent or persistent urethral discharge, referring people to a centre with laboratory capacity to diagnose *N. gonorrhoeae*, *C. trachomatis*, *M. genitalium* and *T. vaginalis* and to test for antimicrobial-resistant *N. gonorrhoeae* and *M. genitalium*



NG, *N.gonorrhoeae*; CT, *C. trachomatis*; MG, *M. genitalium*.

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RECOMMENDED TREATMENT OPTIONS FOR URETHRAL DISCHARGE SYNDROME

Infections covered	First-line options	Effective substitutes
In settings in which local antimicrobial resistance data are not available, the WHO STI guideline suggests dual therapy for gonorrhoea.		
N. gonorrhoeae[a]	**Ceftriaxone 250 mg**, intramuscularly, single dose *Plus* **Azithromycin 1 gram**, orally, single dose	**Cefixime 400 mg**, orally, single dose *Plus* **Azithromycin 1 gram**, orally, single dose
C. trachomatis	**Doxycycline 100 mg**, orally, twice daily for seven days (to be given only if gonorrhoea therapy did not include azithromycin)	**Azithromycin 1 gram**, orally, single dose *or* **Erythromycin 500 mg**, orally, 4 times a day for 7 days *or* **Ofloxacin 200–400 mg**, orally, twice a day for 7 days. (to be given only if gonorrhoea therapy did not include azithromycin)

Infections covered	First-line options	Effective substitutes
In settings in which local antimicrobial resistance data reliably confirm the susceptibility of *N. gonorrhoeae* to the antimicrobial agent, singe therapy may be given.		
N. gonorrhoeae	**Ceftriaxone 250 mg**, intramuscularly, single dose	**Cefixime 400 mg**, orally, single dose *or* **Spectinomycin 2 grams**, intramuscularly, single dose (availability makes this antibiotic impractical)
Additional therapeutic options for recurrent or persistent infections		
T. vaginalis	**Metronidazole 2 grams**, orally, single doses	**Metronidazole 400 or 500 mg**, twice daily for 7 days
M. genitalium	**Azithromycin 500 mg**, orally on day 1, 250 mg daily on days 2–5	

[a]Because of increasing antimicrobial resistance to azithromycin in *N. gonorrhoeae* and *M. genitalium* and reduced susceptibility of *N. gonorrhoeae* to cephalosporins, WHO is in the process of revising current treatment recommendations and dosages.

Guidelines for the mgt. of symptomatic STIs

VAGINAL DISCHARGE: EVIDENCE AND RECOMMENDATIONS

05/01/2022

VAGINAL DISCHARGE SYNDROME WORKS FOR VAGINAL INFECTIONS (*T.vaginalis* and Bacterial vaginosis)

POOLED DIAGNOSTIC VALIDITY OF VD FLOWCHART TO DIAGNOSE TV/BV (VAGINAL INFECTION)

Flowchart	N. Studies	Sensitivity	Specificity	Certainty of evidence
1 Risk assessment	9	56.2 (54.5 - 57.9)	71.0 (69.4 - 72.6)	Moderate
2 + speculum exam	8	74.8 (74.0 - 75.6)	53.2 (52.5 - 54.0)	Moderate
3 Lab (WM, GS)	2	91.7 (89.2- 94.2)	100 (99.9– 100)	Moderate
4 (Local adaptation)	5	53.1 (50.5 - 55.6)	85.8 (84.7 - 86.9)	Moderate

Microscopy was accurate but the cost of setting up microscopy outweighs the cost of treating everyone with confirmed vaginal discharge

pH testing – negligible difference

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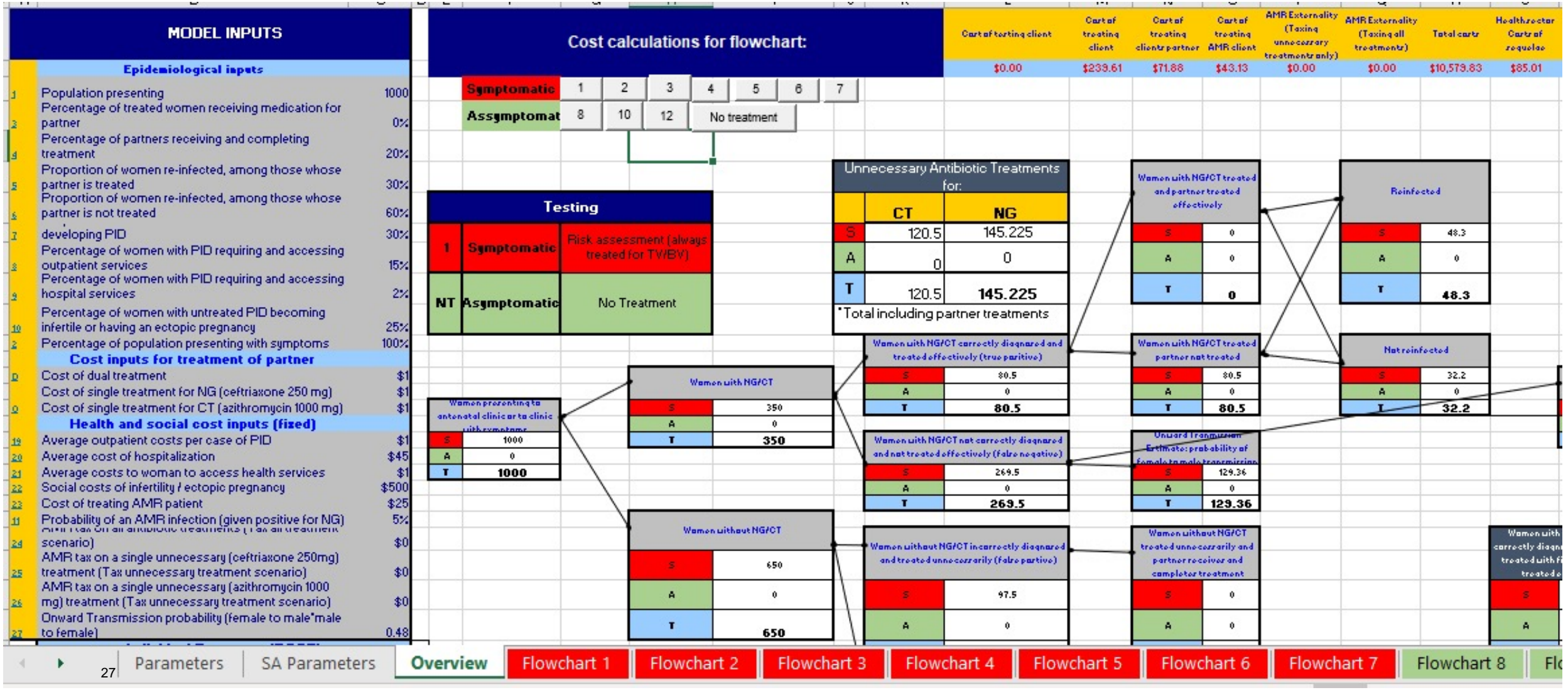
MODELLING TOOL : DIFFERENT MANAGEMENT STRATEGIES FOR WOMEN WITH GONOCOCCAL AND CHLAMYDIAL INFECTION



SENSITIVITY AND SPECIFICITY OF TEST FOR CERVICAL INFECTIONS

To identify N. gonorrhoeae and/or C. trachomatis

	Sensitivity (%)	Specificity (%)
Treat all	100	0
Risk assessment	63	60
Risk assessment or genital exam	92	12
Genital exam	78	20
Speculum	73	56
Gram stain and microscopy	52	73
Speculum or microscopy	87	41
WHO algorithm by risk (low prevalence)	90	34
WHO algorithm by risk (high prevalence)	100	0
WHO algorithm by speculum (low prevalence)	49	68
WHO algorithm by speculum (high prevalence)	78	20
Low-cost point of care test	80	90
Molecular assay point of care test	95	100

ASSUMPTIONS – OUTCOME OF TREATMENT

Treatment effects	%
Proportion completing treatment when indicated	100
Pelvic inflammatory disease	
Proportion of women with untreated gonorrhoea or chlamydia developing (pelvic inflammatory disease)	0.3
Proportion of women with pelvic inflammatory disease requiring and accessing outpatient services	0.15
Proportion of women with pelvic inflammatory disease requiring and accessing hospital services	0.02
Proportion of women with untreated pelvic inflammatory disease becoming infertile or having an ectopic pregnancy	0.25
Partner management and reinfection	
Proportion of treated women receiving partner treatment	0.8
Number of partners receiving treatment per woman	0.2
Proportion of women re-infected among those whose partner is treated	0.3
Proportion of women re-infected among those whose partner is not treated	0.6

COST USED IN THE COST EFFECTIVENESS MODEL

Costs of flow charts	Cost in US dollars
Risk assessment	0.00
Speculum exam	1.00
Speculum and Gram stain	1.50
Point-of-care test: lower sensitivity of 80% and specificity of 90%	3.00
Flow chart 4, 5, 6: point-of-care test (best sensitivity of 95% and specificity of 98%)	16.00
Treatment and outcome costs	
Dual treatment (chlamydia and gonorrhoea)	1.66
Treatment for T. vaginalis and bacterial vaginitis	0.10
Partner treatment	0.12
Average outpatient costs per case of pelvic inflammatory disease	4.00
Average cost of hospitalization	45.00
Average costs to woman to access health services	1.00
Social costs of infertility and ectopic pregnancy	500.00
Cost of antimicrobial resistance	
Tax	5.00

VAGINAL DISCHARGE TO DIAGNOSE GONORRHOEA AND CHLAMYDIAL INFECTION : FINE BALANCE OF OVERTREATMENT , MISSED TREATMENT AND COST

	Treat all who complain	1a *RA then treat*	2a *spec then treat*	11a *POCT low cost ($3)*	12 *RA and/or GE to POCT high cost ($16)*	13a *RA to POCT high cost ($16)*	14a *POCT high cost ($16)*	15 WHO risk *Low: spec and/or RA treat High: all treat*	16 WHO spec *Low: GE to RA then treat High: GE then treat*
Sens/Spec	100/0	63/60	73/56	80/90	92/12 95/98	63/60 95/98	95/98	L:90/34 H:100/0	L:49/68 H:78/20
5% prevalence									
Infected and treated correctly	50	32	37	38	43	30	46	45	25
Uninfected and treated unnecessarily	950	380	418	180	33	15	38	627	304
Infected and not treated	0	19	14	12	7	20	3	5	26
Uninfected and not treated	0	570	532	770	917	935	912	323	646
Cases of PID	0	6	4	4	2	6	1	2	8
Cost/person AMR tax 5	**$8.09**	**$4.11**	**$5.26**	**$5.25**	**$15.08**	**$7.83**	**$16.89**	**$6.67**	**$3.72**
20% prevalence									
Infected and treated correctly	200	126	146	151	172	118	187	200	156
Uninfected and treated unnecessarily	800	320	352	152	28	13	32	800	640
Infected and not treated	0	74	54	49	28	82	13	0	44
Uninfected and not treated	0	480	448	648	772	787	768	0	160
Cases of PID	0	22	16	15	8	25	4	0	13
Cost/person AMR tax 5	**$8.09**	**$6.50**	**$7.15**	**$7.31**	**$16.90**	**$11.38**	**$18.27**	**$9.09**	**$8.14**

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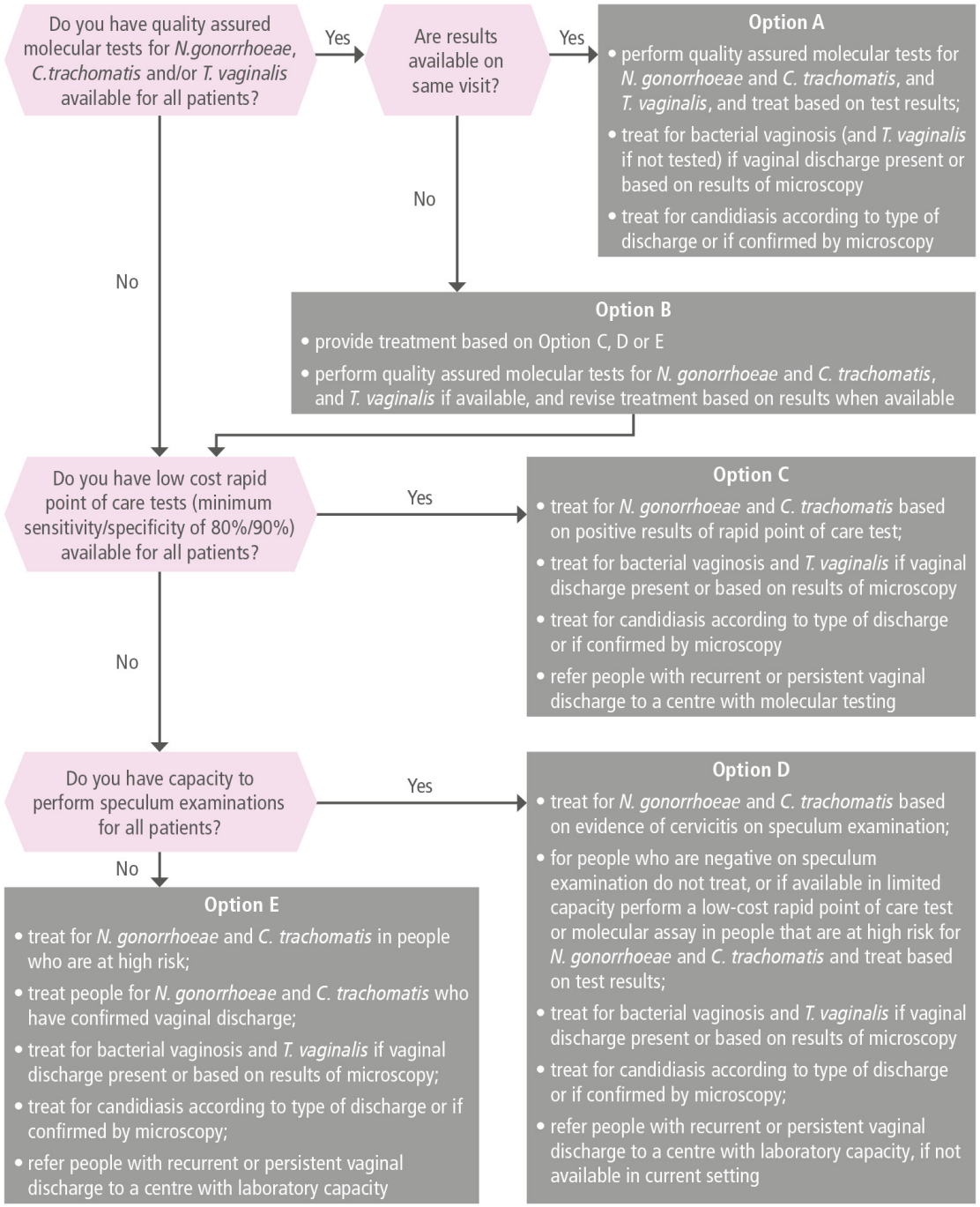
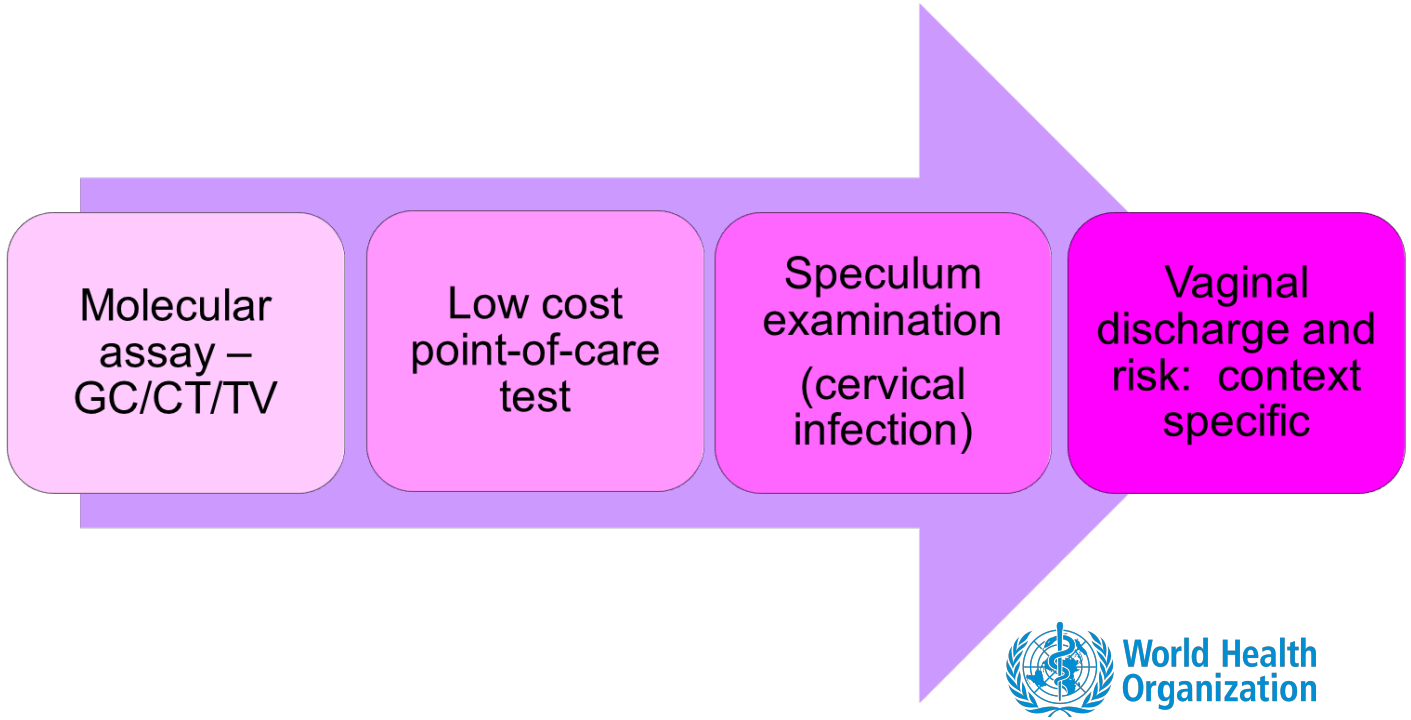
FLOWCHART FOR PROGRAMME MANAGERS TO DETERMINE WHICH MANAGEMENT OPTIONS TO IMPLEMENT FOR VAGINAL DISCHARGE





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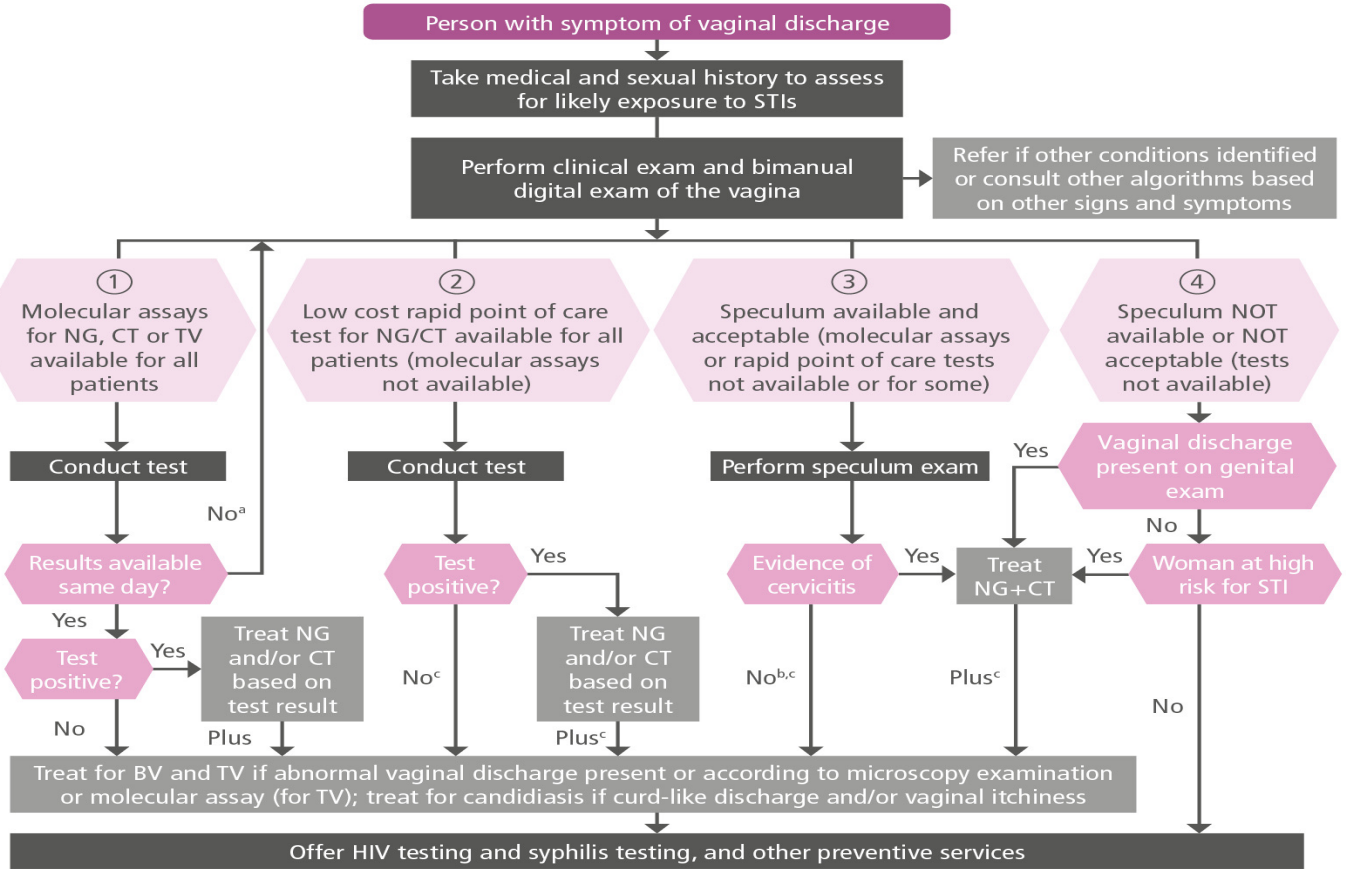
FLOWCHART FOR HCP TO MANAGE VAGINAL DISCHARGE ACCORDING TO LOCAL AVAILABILITY OF RESOURCES AND PREFERENCES



For people with symptom of vaginal discharge, WHO recommends treatment for *N. gonorrhoeae* and/or *C. trachomatis* and/or *T. vaginalis* on the same visit. *(Strong recommendation; moderate-certainty evidence)*

WHO suggests treatment based on the results of quality-assured molecular assays for *N. gonorrhoeae* and/or *C. trachomatis* and/or *T. vaginalis.* In settings in which treatment based on the results of molecular assay in the same visit is not feasible or that have limited or no molecular testing, WHO suggests treatment based on testing with quality-assured rapid point-of-care tests or on syndromic treatment.

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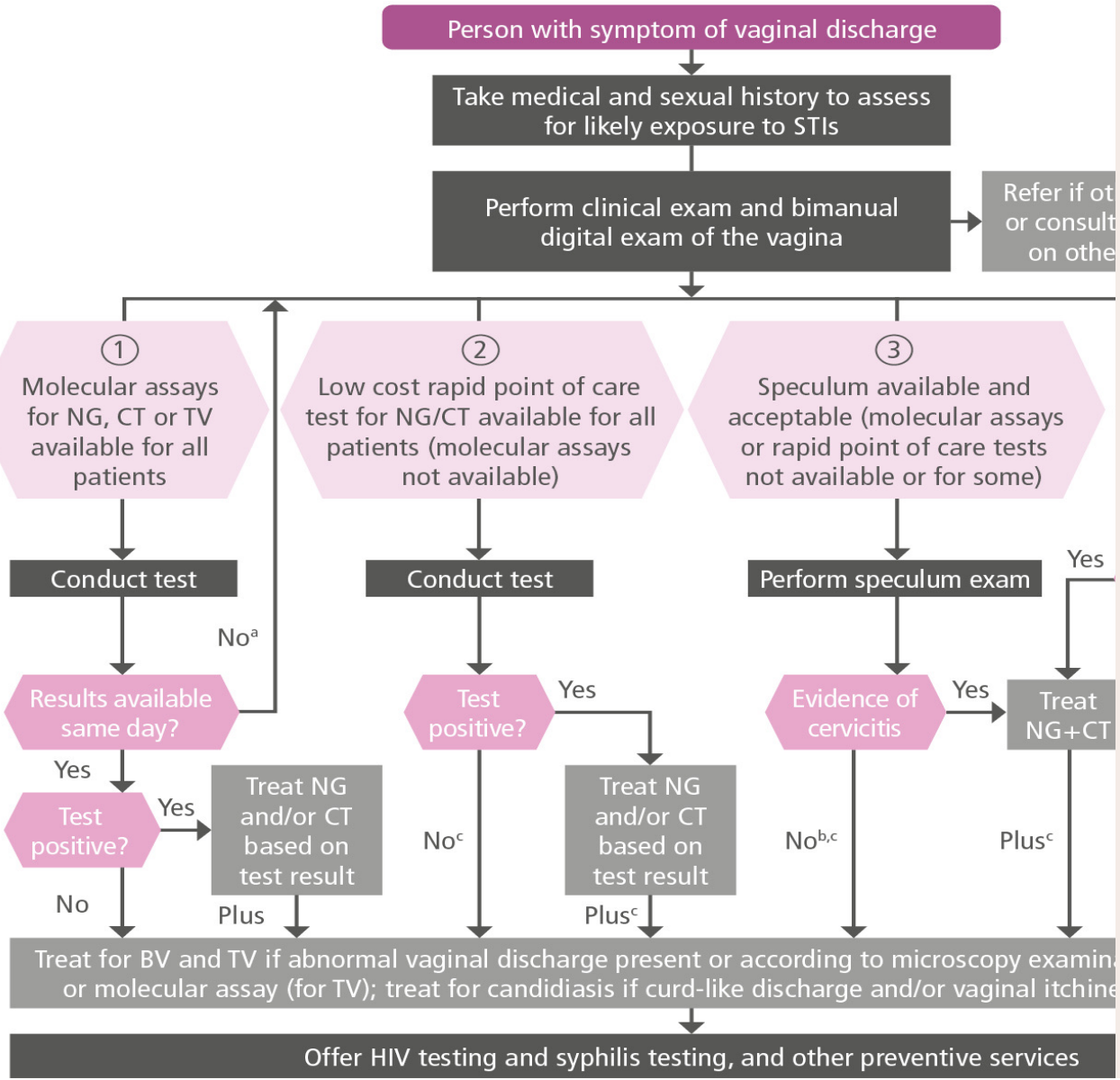
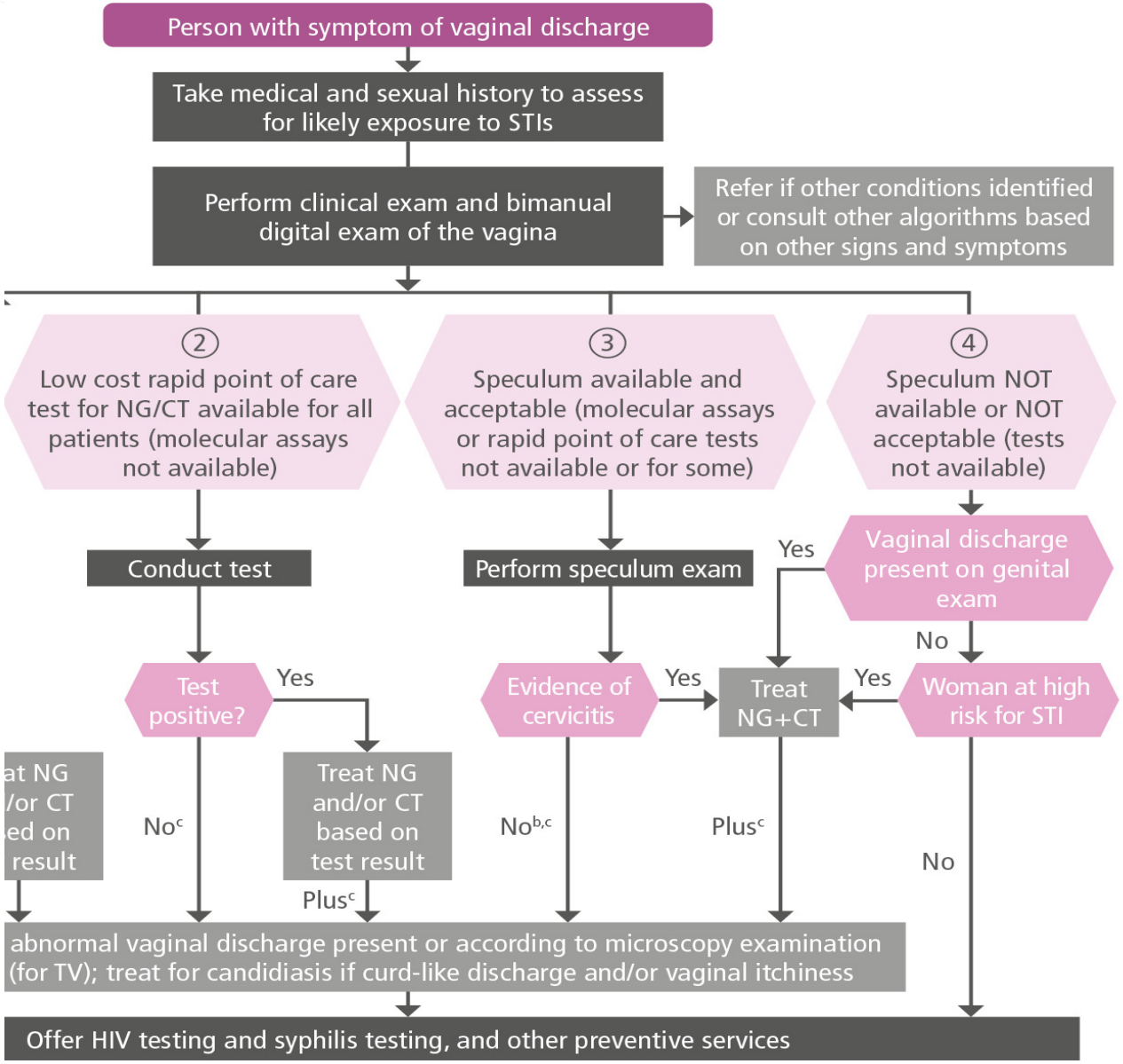
FLOWCHART FOR HCP TO MANAGE VAGINAL DISCHARGE ACCORDING TO LOCAL AVAILABILITY OF RESOURCES AND PREFERENCES



Settings in which treatment is based on quality-assured molecular assays in a laboratory with a fully operational quality management system and results available on the same day of the visit

(Strong recommendation; moderate -certainty evidence)

- WHO recommends treating *N. gonorrhoeae* and/or *C. trachomatis* and/or *T. vaginalis* based on the results of quality-assured molecular assays on a self-collected, or clinician-collected, vaginal swab or on a urine specimen (Algorithm ①).
- WHO suggests treating for bacterial vaginosis if vaginal discharge is present (for example, tenacious or thin) or based on the results of microscopy, if available.
- WHO suggests treating for candidiasis, where indicated by type of discharge (such as curd-like with vaginal itching) or by the results of microscopy, if available.

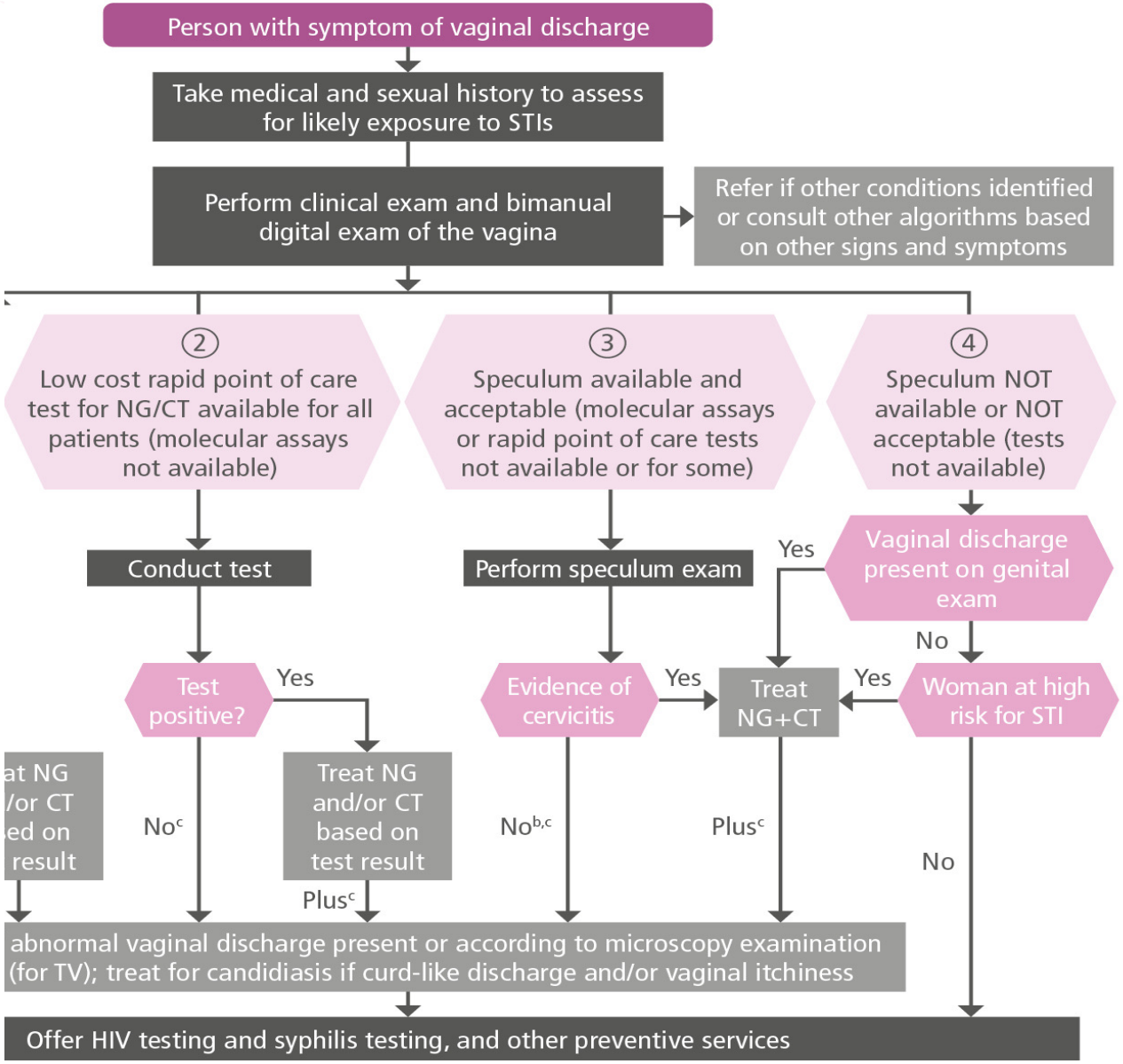


Settings in which same-day treatment is not feasible with molecular testing or with limited or no molecular testing

(condition recommendation, low-certainty evidence)

- WHO suggests treating based on a quality-assured rapid test with a minimum sensitivity of 80% and specificity of 90%, if available, to confirm or exclude infection with N. gonorrhoeae and C. trachomatis (Algorithm ②).
- If the availability of a low-cost rapid test or molecular assay is limited, WHO suggests performing a speculum examination and treating for N. gonorrhoeae and C. trachomatis if there is evidence of cervicitis and performing a low-cost rapid test or molecular assay for people with a negative speculum examination who are at high risk of infection with N. gonorrhoeae and C. trachomatis and treating based on the test results (Algorithm ③[a]).

FLOWCHART FOR HCP TO MANAGE VAGINAL DISCHARGE ACCORDING TO LOCAL AVAILABILITY OF RESOURCES AND PREFERENCES



Settings in which same-day treatment is not feasible with molecular testing or with limited or no molecular testing

(condition recommendation, low-certainty evidence)

- If a rapid test is not available, WHO suggests treating people who have signs of cervicitis on speculum examination for infection with N. gonorrhoeae and C. trachomatis (Algorithm ③).
- If a rapid test is not available and a speculum examination is not feasible or acceptable, WHO suggests treating people for N. gonorrhoeae and C. trachomatis, all people at high risk of STIs and all people who have vaginal discharge on genital examination (Algorithm ④).
- WHO suggests treating people for bacterial vaginosis and T. vaginalis if vaginal discharge is present or based on the results of microscopy, if available.
- WHO suggests treating people for candidiasis, where indicated by type of discharge (such as curd-like with vaginal itching) or by the results of microscopy, if available.
-

GOOD PRACTICE STATEMENT

For people with recurrent or persistent vaginal discharge, good practice includes **referring to a centre with laboratory capacity** to diagnose infection with *N. gonorrhoeae, C. trachomatis, M. genitalium* and *T. vaginalis* and bacterial vaginosis and to test for antimicrobial-resistant *N. gonorrhoeae* and *M. genitalium* (if there is a test) or for a specialist's assessment (STI expert and physician or a gynaecologist), when no such testing is available in primary health care centres.

TREATMENT OPTIONS FOR VAGINAL INFECTIONS

- **Therapy for bacterial vaginosis and trichomoniasis plus**
- **Therapy for yeast infection if curd-like white discharge, vulvovaginal redness and itching are present**

Infections covered	First-line options	Effective substitutes	Options for pregnant women or during breastfeeding
Bacterial vaginosis	Metronidazole 400 mg or 500 mg, orally, twice daily for 7 days	Clindamycin 300 mg, orally, twice daily for 7 days or Metronidazole 2 grams, orally, single dose	Metronidazole 200 mg or 250 mg, orally, 3 times a day for 7 days or Metronidazole gel 0.75%, one full applicator (5 grams) intravaginally, twice a day for 7 days or Clindamycin 300 mg, orally, twice daily for 7 days
T. vaginalis	Metronidazole 2 grams, orally, in a single dose or Metronidazole 400 mg or 500 mg, orally, twice daily for 7 days	Tinidazole 2 grams orally, single dose or Tinidazole 500 mg orally, twice daily for 5 days	Metronidazole 200 mg or 250 mg, orally, 3 times a day for 7 days or Metronidazole gel 0.75%, one full applicator (5 grams) intravaginally, twice a day for 7 days
C. albicans (yeast infection)	Miconazole vaginal pessaries, 200 mg inserted at night for 3 nights or Clotrimazole vaginal tablet, 100 mg, inserted at night for 7 nights	Fluconazole 150 mg (or 200mg), orally, single dose or Nystatin, 200,000-unit vaginal tablet, inserted at night for 7 nights	Miconazole 200 mg vaginal pessaries inserted once daily for 3 days or Clotrimazole vaginal tablet 100 mg inserted at night for 7 days or Nystatin pessaries 200,000 units, inserted at night for 7 nights

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People taking metronidazole should be cautioned to avoid alcohol. Use of metronidazole in the first trimester of pregnancy is not recommended unless the benefits outweigh the potential hazards.

TREATMENT OPTION FOR CERVICAL INFECTION

- **Therapy for uncomplicated N. gonorrhoeae plus**
- **Therapy for C. trachomatis**

Infections covered	First-line options (choose one from each cell below)	Effective substitutes	Options for pregnant women or during breastfeeding
N. gonorrhoeae[a]	Ceftriaxone 250 mg, intramuscularly, single dose plus Azithromycin 1 gram, orally, single dose	Cefixime 400 mg, orally, single dose plus Azithromycin 1 gram, orally, single dose	Ceftriaxone 250 mg, intramuscularly, single dose plus Azithromycin 1 gram, orally, single dose or Cefixime 400 mg, orally, single dose plus Azithromycin 1 gram, orally, single dose
C. trachomatis	Doxycycline 100 mg, orally, twice daily for 7 days (to be given only if gonorrhoea therapy did not include azithromycin)	Azithromycin 1 gram, orally, single dose or Erythromycin 500 mg, orally, 4 times a day for 7 days or Ofloxacin 200–400 mg, orally, twice daily for 7 days (to be given only if gonorrhoea therapy did not include azithromycin)	Erythromycin 500 mg, orally, 4 times a day for 7 days or Azithromycin 1 gram, orally, single dose (to be given only if gonorrhoea therapy did not include azithromycin)
M. genitalium	Azithromycin 500 gram, orally day 1, 250 mg daily, days 2–5 (absence of macrolide resistance)		Azithromycin 500 gram, orally, day 1, 250 mg daily, days 2–5 (absence of macrolide resistance)

[a]Because of increasing antimicrobial resistance to azithromycin in *N. gonorrhoeae* and *M. genitalium* and reduced susceptibility of *N. gonorrhoeae* to cephalosporins, WHO is in the process of revising current treatment recommendations and dosages.

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Guidelines for the management of symptomatic STIs

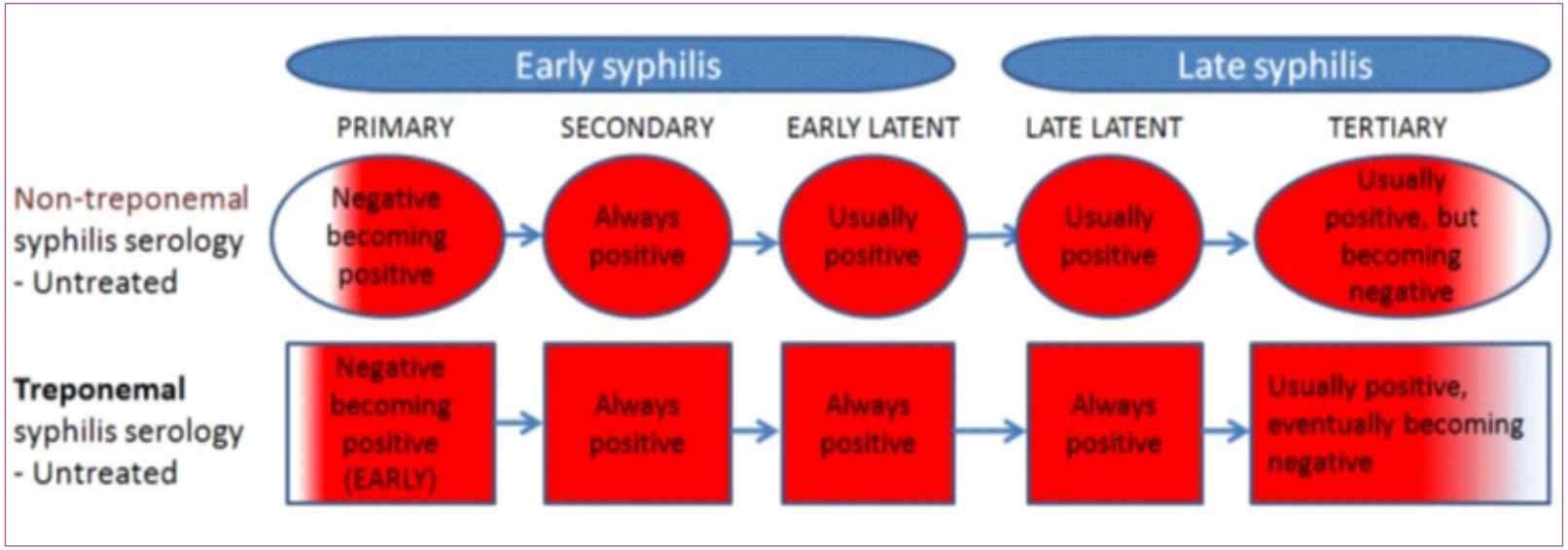
GENITAL ULCER DISEASE
EVIDENCE AND RECOMMENDATIONS

ANO-GENITAL ULCERATION – AETIOLOGY AND DIAGNOSIS

- Ano-genital herpes, syphilis, lymphogranuloma venereum (LGV), chancroid and donovanosis can all cause ano-genital ulceration.
- Clinical diagnoses of ano-genital ulceration has been shown to be inaccurate in over 50% of cases, even by experienced clinicians.
- The management of people with genital ulcer disease must be based either on laboratory-based aetiological testing or a syndromic approach, guided by periodic evaluation of the causative agents at the local setting.
- In settings with limited or no molecular tests/laboratory capacity, WHO recommends syndromic treatment to ensure treatment on the same day of the visit.

DIFFICULTIES WITH INTERPRETING SYPHILIS SEROLOGY

- Syphilitic anogenital ulceration may present despite non-reactive treponemal/non-treponemal tests.
- In settings with a high prevalence of syphilis, a person with an anogenital ulcer may have a reactive serological test for syphilis from a previously treated infection or untreated latent syphilis, YET the current ulcer may be due to another pathogen.



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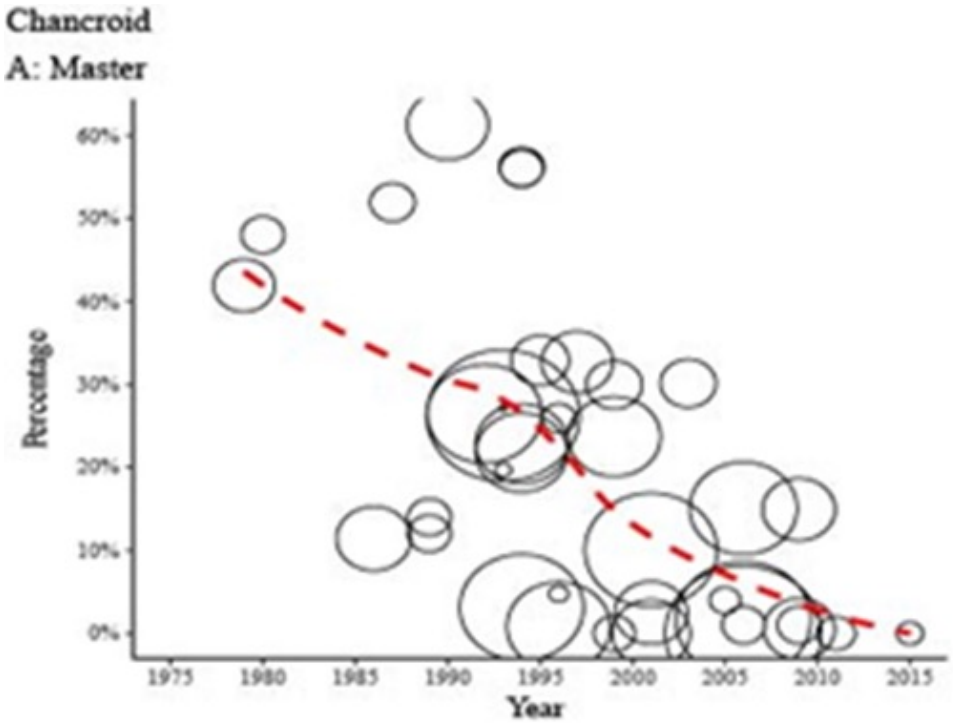
CHANCROID

- *Haemophilus ducreyi* has almost disappeared globally as a cause of genital ulcer disease.
- Clinicians must have a high index of suspicion when they see an unusually painful, suppurative ulcer among men or women.
- If there are also painful inguinal lymph nodes/buboes with the ulcer, especially among men, chancroid must be high in the list of differential diagnoses.
- If clinical presentations consistent with chancroid become apparent, then the national authorities should be alerted so that (where possible) confirmation of chancroid re-emergence can be confirmed through surveillance activities/diagnostic testing and the treatment regimen adapted accordingly.



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EVIDENCE BASE TO SUPPORT SYNDROMIC APPROACH VS. CLINICAL DIAGNOSIS IN ABSENCE OF LABORATORY TESTING

Disease (relative prevalence for GUD)	Sensitivity	Specificity	Missed cases	Over-treated cases	Comment
Syphilis (5-10%)					
Clinical diagnosis	64%	84%	2-4/100	14-15/100	Long-term consequences of missed cases important
Syndromic Rx			0/100	90-95/100	No missed cases; added minimal cost
Herpes (30-70%)					
Clinical diagnosis	40%	88%	18-42/100	4-8/100	Uncertain missing a case would cause serious harm; may increase HIV acquisition and HSV transmission risk
Syndromic Rx			0/100	30-70/100	No missed cases; improved QoL, added minimal cost

Note:

1. NAAT tests will substantially reduce the number of patients over-treated due to their high sensitivity and specificity
2. Chancroid prevalence has decreased globally; using a clinical diagnosis to determine treatment will only result in a trivial number of missed cases/unnecessary treatments, hence no treatment for chancroid is recommended.
3. No evidence for cost-benefit/harm of the clinical diagnosis approach for LGV; treatment should be based on positive test result.

WHO RECOMMENDATIONS FOR THE MANAGEMENT OF GENITAL ULCER DISEASE, INCLUDING ANORECTAL ULCERS

(strong recommendations; moderate-certainty evidence)

WHO recommends treatment based on quality-assured molecular assays of the ulcer.

- However, in settings with limited or no molecular tests or laboratory capacity, WHO recommends syndromic treatment to ensure treatment on the same day of the visit.

Good practice includes:

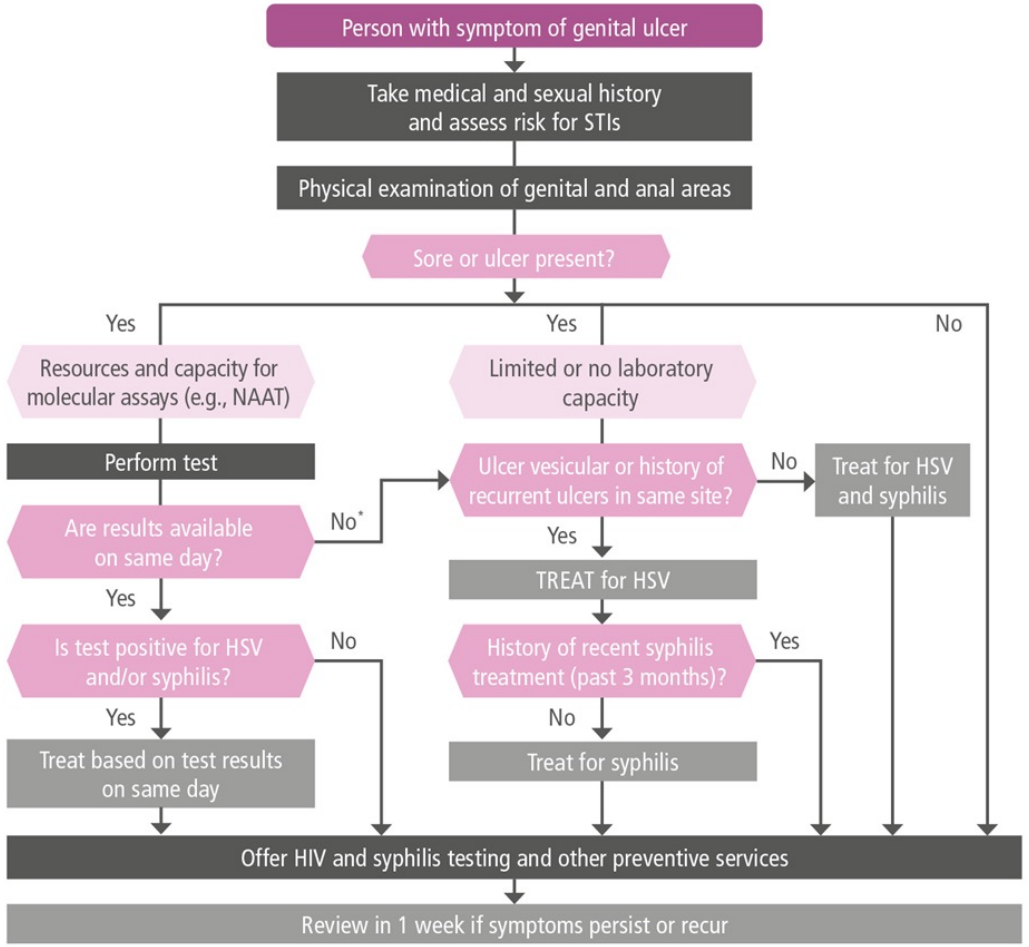
- taking a medical and sexual history and assessing the risk of STIs
- performing a physical examination of the genital AND anal areas
- offering HIV and syphilis antibody-based testing and other preventive services
- providing analgesics where indicated

RECOMMENDATIONS MANAGEMENT OF GENITAL ULCER DISEASE, INCLUDING ANORECTAL ULCERS

Settings with quality-assured molecular testing in a laboratory with a fully operational quality management system

(strong recommendations; moderate-certainty evidence)

- Perform molecular assays (NAAT) from anogenital lesions to confirm or exclude herpes simplex virus and Treponema pallidum (syphilis).
- Perform molecular assays from anogenital lesions to confirm lymphogranuloma venereum in geographical settings and/or populations in which cases are reported or emerging.
- Perform serological tests for syphilis, with appropriate interpretation for management depending on the test or tests used.
- Treat for syphilis and/or herpes simplex virus according to the results available on the same day of the visit or treat syndromically and revise management according to the results when available.
- Treat for lymphogranuloma venereum when the results are positive. (*Chlamydia trachomatis* L1-L3 genovars)
- Treat for chancroid only in geographical settings where cases are reported or emerging.



HSV, herpes simplex virus

* If molecular assay was performed and results were not available on same day, revise the syndromic treatment initially provided according to the test results when available

RECOMMENDATIONS MANAGEMENT OF GENITAL ULCER DISEASE, INCLUDING ANORECTAL ULCERS

Settings in which same-day treatment is not feasible with molecular testing or with limited or no molecular testing

(conditional recommendations; moderate-certainty evidence)

- Treat syndromically for syphilis and herpes simplex virus on the same day.
- Treat for herpes simplex virus if the ulcer is recurrent or vesicular, and treat for syphilis if the person has no history of recent treatment for syphilis (in the past three months).
- Treat for chancroid only in geographical settings where cases are reported or emerging.

Good practice includes:

- performing antibody-based tests for syphilis, including an RPR-equivalent test, if available, to attempt to identify people with potentially active syphilis and to provide a baseline titre to monitor response to treatment
- referring of men with persistent anogenital ulcers to a centre with laboratory capacity and expertise to diagnose HSV or less common pathogens responsible for LGV, donovanosis and chancroid, or other genital/gastrointestinal conditions

TREATMENT OPTIONS

- Multiple-dose therapy for herpes simplex virus infection *(27)*

Plus

- Single-dose long-acting penicillin therapy or multi-dose therapy of alternatives *(26)*

Infections covered	First-line options	Effective substitutes	For pregnant and breastfeeding women and people younger than 16 years
Genital herpes	**Primary infection** **Acyclovir 400 mg,** orally, 3 times a day for 10 days *or* **Acyclovir 200 mg,** orally, 5 times a day for 10 days	**Primary infection** **Valaciclovir 500 mg,** twice a day for 10 days *or* **Famciclovir 250 mg,** orally, 3 times a day for 10 days	**Primary infection** Use acyclovir only when the benefit outweighs the risk. The dosage is the same as for primary infection in non-pregnancy.
	Recurrent infection – episodic therapy **Acyclovir 400 mg,** orally, 3 times a day for 5 days *or* **Acyclovir 800 mg,** orally, twice daily for 5 days *or* **Acyclovir 800 mg,** 3 times a day for 2 days	**Recurrent infection – episodic** **Valaciclovir 500 mg,** twice daily for days *or* **Famciclovir 250 mg,** orally, twice daily for 5 days	**Recurrent infection – episodic therapy** **Acyclovir 400 mg,** orally, 3 times a day for 5 days *or* **Acyclovir 800 mg,** orally, twice daily for 5 days *or* **Acyclovir 800 mg,** 3 times a day, for 2 days
	Suppressive therapy for recurrent herpes[a] **Acyclovir 400 mg,** orally, twice daily *or* **Valaciclovir 500 mg,** once daily	**Suppressive therapy for recurrences**[a] **Famciclovir 250 mg,** orally, twice daily	**Suppressive therapy for recurrent herpes** **Acyclovir 400 mg,** orally, twice daily *or* **Valaciclovir 500 mg,** once daily

- Multiple-dose therapy for herpes simplex virus infection *(27)*

Plus

- Single-dose long-acting penicillin therapy or multi-dose therapy of alternatives *(26)*

Infections covered	First-line options	Effective substitutes	For pregnant and breastfeeding women and people younger than 16 years
Syphilis (early) (treatment for primary, secondary and early latent [less than two years since infection] syphilis)	**Benzathine penicillin 2.4 million units,** intramuscularly in a single dose	**Doxycycline 100 mg,** orally, twice a day for 14 days *or* **Erythromycin 500 mg,** 4 times a day for 14 days	**Benzathine penicillin 2.4 million units,** intramuscularly in a single dose *or* **Erythromycin 500 mg,** orally, 4 times a day for 14 days[b]
Syphilis (late) (treatment for late latent and tertiary syphilis)	**Benzathine penicillin 2.4 million units** by intramuscular injection, once weekly for 3 consecutive weeks	**Procaine penicillin 1.2 million units** by intramuscular injection, once daily for 20 consecutive days *or* **Doxycycline 100 mg,** orally, twice daily for 30 days	**Erythromycin 500mg** orally, 4 times a day for 30 days[b]

[a] Suppressive therapy for recurrent herpes is recommended for individuals with 4–6 or more recurrent episodes per year, severe symptoms or episodes that cause distress. Increased dosages or duration of treatment are required for people living with HIV *(27)*.

[b] Although erythromycin is used to treat pregnant women, it does not cross the placental barrier completely and the fetus is not treated. The newborn infant therefore needs treatment soon after delivery.

For people living with HIV and immunosuppressed individuals, dose adjustments are recommended for valaciclovir and famciclovir (not for acyclovir).

- For recurrent episodes, valaciclovir 500 mg is recommended for five days instead of three days, and famciclovir is recommended at a dose of 500 mg twice daily for five days instead of 250 mg.
- For suppressive therapy, valaciclovir is recommended at 500 mg twice daily instead of once daily and famciclovir at 500 mg twice daily instead of 250 mg twice daily.

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Guidelines for the management of symptomatic STIs

ANAL DISCHARGE : EVIDENCE AND RECOMMENDATIONS

ANY STI (CHLAMYDIA, GONORRHOEA)

- Pooled **sensitivity** 32.4% (95% CI: 11.4–64.0)
  - Measure of how well a test can identify true positives
- Pooled **specificity** 81.7% (95% CI: 43.1–96.4)
  - Measure of how well a test can identify true negatives

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ANY STI (CHLAMYDIA, GONORRHOEA)

Pooled sensitivity : 0.32 (95% CI: 0.11 to 0.64) | **Pooled specificity** : 0.82 (95% CI: 0.43 to 0.96)

Test result	Number of results per 100 patients tested (95% CI)		Number of participants (studies)	Certainty of the Evidence (GRADE)
	Prevalence 20% Typically seen in	**Prevalence 50%** Typically seen in		
True positives	**6** (2 to 13)	**16** (6 to 32)	2010 (4)	⨁⨁⨁◯ **MODERATE** [a]
False negatives	**14** (7 to 18)	**34** (18 to 44)		
True negatives	**65** (34 to 77)	**41** (22 to 48)	2010 (4)	⨁⨁⨁◯ **MODERATE** [a]
False positives	**15** (3 to 46)	**9** (2 to 28)		

CI: Confidence interval

Explanations

a. There was high heterogeneity across studies resulting in wide confidence intervals despite adequate numbers of events

Prevalence	Sensitivity	Specificity	PPV	NPV	Number of cases	Missed cases	False Positive (Overtreated)
0.05					50	34	
0.1		0.817	0.164	0.916	100	68	
0.15		0.817	0.238	0.873	150	101	
0.2		0.817	0.307	0.829	200	135	
0.25		0.817	0.371	0.784	250	169	
0.3		0.817	0.431	0.738	300	203	
0.35		0.817	0.488	0.692	350	237	
0.4		0.817	0.541	0.644	400	270	
0.45		0.817	0.592	0.596	450	304	
0.5		0.817	0.639	0.547	500	338	
0.55		0.817	0.684	0.497	550	372	
0.6		0.817	0.726	0.446	600	406	
0.65		0.817	0.767	0.394	650	439	
0.7		0.817	0.805	0.341	700	473	
0.75		0.817	0.842	0.287	750	507	
0.8		0.817	0.876	0.232	800	541	
0.85		0.817	0.909	0.176	850	575	
0.9		0.817	0.941	0.118	900	608	
0.95		0.817	0.971	0.060	950	642	
1							

ACCURACY OF ANORECTAL SYNDROMIC MANAGEMENT

- For detection of **anorectal gonorrhoea**, five studies provided five estimates for pooling.
  - Pooled sensitivity 14.2% (95% CI: 6.1-29.7)
  - Pooled specificity 94.4% (95% CI: 84.8-98.1)
- For detection of **anorectal chlamydia**, five studies provided five estimates for pooling.
  - Pooled sensitivity 11.1% (95% CI: 2.2-40.3)
  - Pooled specificity 94.8% (95% CI: 87.1-98.0)

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	Missed cases	Unnecessary treatment
Short term consequences	Onward transmission Vulnerability to HIV	Cost of Rx (side effects) Potential stigma / relationship strain
Long term consequences	Loss of confidence in health system if inappropriately managed Burden of STIs	AMR (esp NG) Loss of confidence in health system if inappropriately managed

OTHER CAVEATS FROM THE EVIDENCE

- Majority of studies are in **MSM** (one study in TG)
  - No studies found for women with anorectal syndrome
- No data on **cost-effectiveness** of anorectal syndromic management or resource use
- Impact on **equity**
  - Cost of consultation, diagnostics, drugs may be prohibitive to some
  - Might improve access (if avoid cost of expensive diagnostics)
- No data on **acceptability** to key stakeholders
  - Is anorectal syndrome algorithm acceptable to key stakeholders?

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OTHER CAVEATS FROM THE EVIDENCE

- Is the algorithm **feasible** to provide?
  - There is a low NNT (4 (Rebe 2015, Sanders 2014); 12 (Quilter 2019)) if we follow WHO guidelines in settings with high STI prevalence in MSM
- Need for ongoing monitoring of aetiological causes (esp for **AMR**)
  - Sentinel surveillance may be helpful

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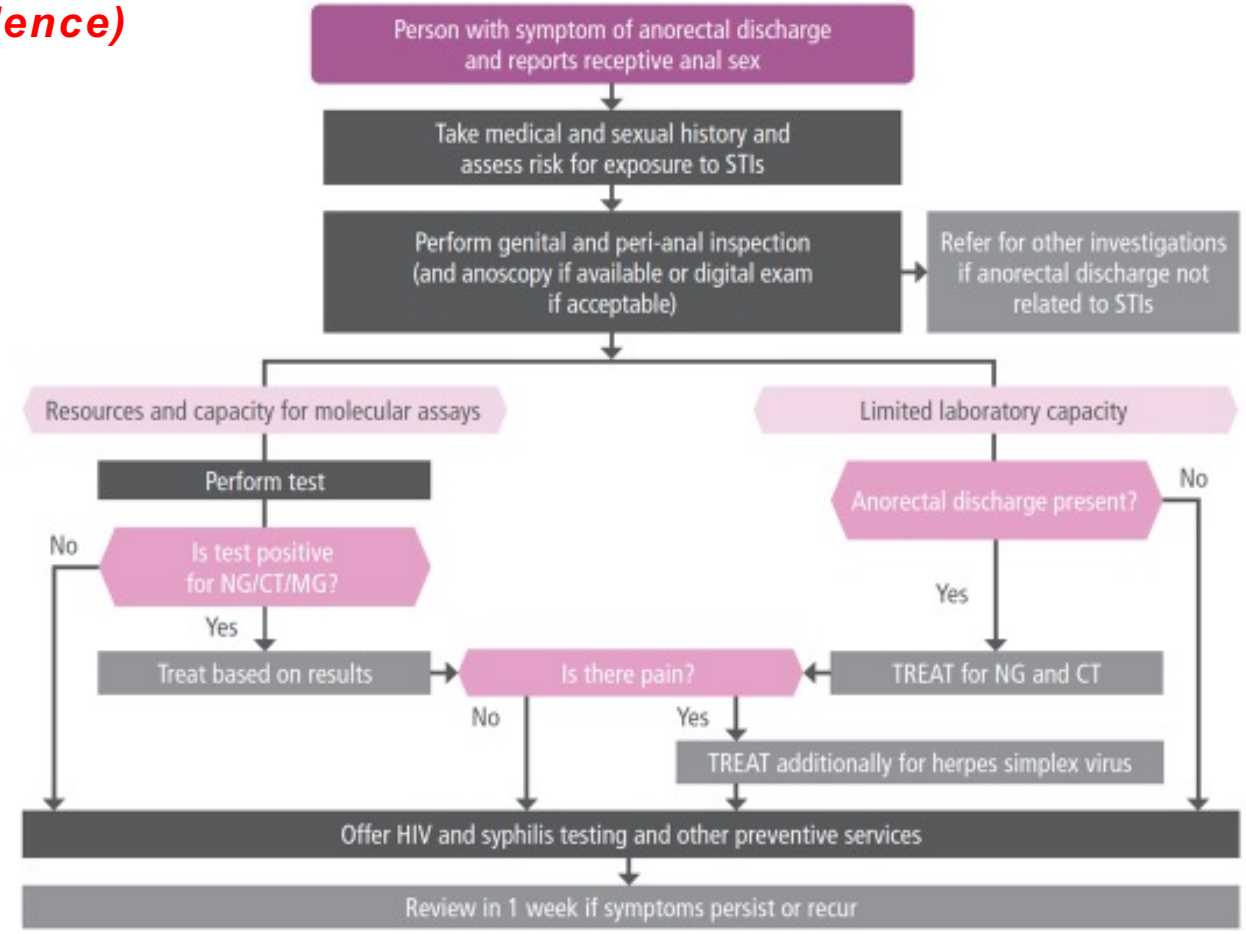
RECOMMENDATIONS FOR THE MANAGEMENT ANAL DISCHARGE

Settings with quality-assured molecular testing in a laboratory with a fully operational quality management system

(strong recommendations; moderate-certainty evidence)

WHO recommend the following:

- Perform molecular assays (nucleic acid amplification testing (NAAT)) using a self-collected or clinician-collected anorectal swab to confirm or exclude *N. gonorrhoeae* and/or *C. trachomatis*, and treat individual infections detected.
- Treat, additionally, for herpes simplex virus if there is anorectal pain.
- Follow the genital ulcer guidelines if ulceration is present.



NG, *N.gonorrhoeae*; CT, *C. trachomatis*; MG, *M. genitalium*.

RECOMMENDATIONS FOR THE MANAGEMENT OF ANAL DISCHARGE

Settings in which same-day treatment is not feasible with molecular testing or with limited or no molecular testing

(conditional recommendations; very low-certainty evidence)

WHO suggest the following:

- Treat for *N. gonorrhoeae* and *C. trachomatis*, if discharge is present.
- Treat, additionally, for herpes simplex virus if there is anorectal pain.

Good practice includes:

- Following the genital ulcer guidelines if ulceration is present.
- Referring people with persistent anorectal discharge to a centre with laboratory capacity to diagnose *N. gonorrhoeae, C. trachomatis* (including LGV serovars), *M. genitalium,* and determine antimicrobial resistance for *N. gonorrhoeae and M. genitalium.*

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Guidelines for the management of symptomatic STIs

LOWER ABDOMINAL PAIN: EVIDENCE AND RECOMMENDATIONS

ANY STI (CHLAMYDIA, GONORRHOEA, TRICHOMONAS)

- Pooled **sensitivity** 30.0% (95% CI: 17.7–46.0%)
  - Measure of how well a test can identify true positives
- Pooled **specificity** 73.3% (95% CI: 56.3–85.4%)
  - Measure of how well a test can identify true negatives

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ANY STI (CHLAMYDIA, GONORRHOEA, TRICHOMONAS)

Test result	Number of results per 1000 people tested (95% confidence interval)	Number of participants (studies)	Certainty of the evidence (GRADE)
	Prevalence of 5%		
True positives	15 (9–23)	3908 (5)	⨁⨁⨁⨁ High
False negatives	35 (27–41)		
True negatives	696 (535–811)	3908 (5)	⨁⨁⨁◯ Moderate[a,b]
False positives	254 (139–415)		

[a] Most studies showed consistent results.

[b] The threshold for unnecessary treatment was high (about 75%), and the confidence intervals cross that threshold and there is therefore some imprecision for false positives.

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LOWER ABDOMINAL PAIN +

Clinical characteristic	Sensitivity in % (95% confidence interval)	Specificity in % (95% confidence interval)
Abdominal tenderness	93.9 (90.6–96.3)	7.4 (4.8–10.7)
Cervical motion tenderness	91.6 (88.0–94.5)	12.6 (9.1–16.7)
Uterine tenderness	94.2 (91.0–96.6)	5.3 (3.1–8.2)
Adnexal tenderness	95.5 (92.6–97.5)	3.8 (2.1–6.5)
Minimal criteria of the United States Centers for Disease Control and Prevention	83.3 (78.7–87.3)	21.8 (17.5–26.5)

Single study sensitivity: 0.84 (95% CI: 0.79–0.87) | **Single study specificity**: 0.22 (95% CI: 0.17–0.27)

Source: Peipert et al. *(1)*.

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Lower abdominal pain alone

Test result	Number of results per 1000 people tested (95% confidence interval)	Number of participants (studies)	Certainty of the evidence (GRADE)
	Prevalence of 5%		
True positives	15 (9–23)	3908 (5)	⨁⨁⨁⨁ High
False negatives	35 (27–41)		
True negatives	696 (535–811)	3908 (5)	⨁⨁⨁◯ Moderate[a, b]
False positives	254 (139–415)		

Lower abdominal pain + cervical motion tenderness

Test result	Number of results per 1000 people tested (95% confidence interval)	Number of participants (studies)	Certainty of the evidence (GRADE)
	Prevalence 5%		
True positives	42 (39–44)	651 (1)	⨁⨁⨁◯ MODERATE[a]
False negatives	8 (6–11)		
True negatives	207 (166–252)	651 (1)	⨁⨁⨁◯ MODERATE[a]
False positives	743 (698–784)		

Identify more STI cases

Trade-off – higher overtreatment

RECOMMENDATIONS FOR THE MANAGEMENT OF LOWER ABDOMINAL PAIN

For sexually active women with symptom of lower abdominal pain, WHO suggests assessing for pelvic inflammatory disease and treating syndromically.

(conditional recommendation, low-certainty evidence

Good practice includes:

- taking a medical and sexual history and assessing the risk of STIs;
- performing a physical examination, including abdominal and pelvic examination, to assess for pelvic inflammatory disease, surgical conditions or pregnancy and vulvovaginal examination to visualize any lesions, overt genital discharge, vulval erythema and excoriations;
- performing a bimanual digital examination of the vagina (1) to assess for cervical motion tenderness or pain with palpation of the pelvic area to exclude pelvic inflammatory disease; and (2) to assess for the presence of vaginal discharge and the colour and consistency of the discharge on the glove; and
- offering HIV and syphilis testing and other preventive services as recommended in other guidelines.

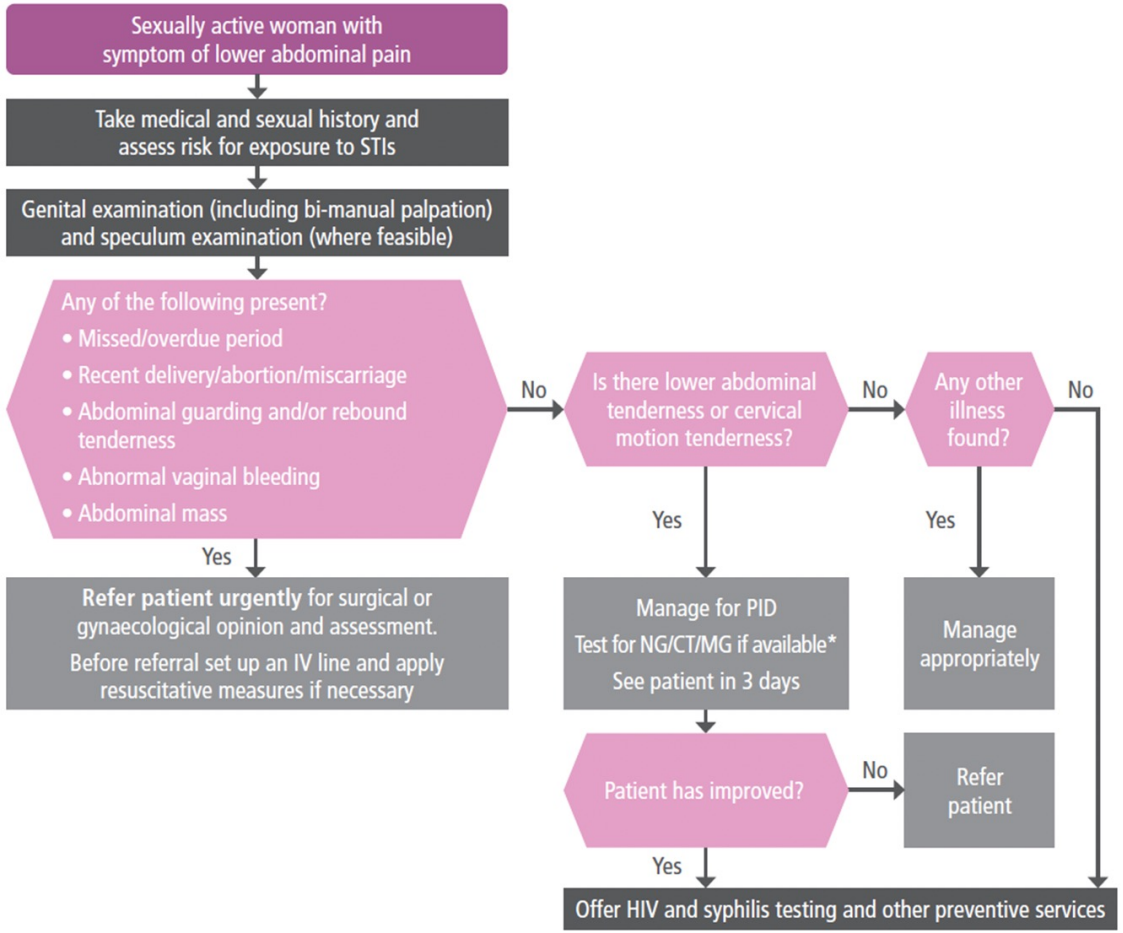
RECOMMENDATIONS FOR THE MANAGEMENT OF LOWER ABDOMINAL PAIN

For sexually active women with lower abdominal pain with either of the following features on clinical examination (bimanual palpation):

- cervical motion tenderness; or
- lower abdominal tenderness:

WHO suggests the following.

- Treat for pelvic inflammatory disease on the same visit.
- Test for infection with N. gonorrhoeae and C. trachomatis and, if available, M. genitalium, to support partner management when tests are available.
- Schedule follow-up assessment three days later to assess for clinical improvement, and if the woman has not improved, refer for further assessment.



World Health Organization

RECOMMENDATIONS FOR THE MANAGEMENT OF LOWER ABDOMINAL PAIN

For women with lower abdominal pain with any of the following conditions, good practice includes referral to surgical or gynaecological assessment:

- missed or overdue period;
- recent delivery, abortion or miscarriage;
- abdominal guarding and/or rebound tenderness;
- abnormal vaginal bleeding in excess of spotting;
- abdominal mass; and
- detection of a suspected cervical lesion.

WHAT'S NEW WITH THE CURRENT GUIDELINES COMPARED TO THE 2003 SYNDROMIC CASE MANAGEMENT GUIDELINES

Urethral discharge	• Treat based on quality assured molecular assay for NG/CT • If not feasible, treat for both NG/CT
Vaginal discharge	• Treat based on quality assured molecular assay/ POCT for NG/CT • Use of speculum exam – preferred approach compared to risk assessment - cervical infection to tx NG/CT • Treat all for TV/BV • Treat also for Candidiasis for curd-like discharge
Recurrent urethral, vaginal & ano-rectal discharge	• Repeat molecular assay after 21 days • Refer to centre with laboratory capacity to test for NG, CT, MG, TV and AMR in GC and MG

WHAT'S NEW WITH THE CURRENT GUIDELINES COMPARED TO THE 2003 SYNDROMIC CASE MANAGEMENT GUIDELINES

Genital ulcer disease (ano-rectal)	• Treat based on quality assured molecular assay for HSV/SY • Treat for HSV and syphilis • Monitor emergence of chancroid
Ano-rectal discharge	• Treat based on quality assured molecular assay for NG/CT • If not feasible, treat for both NG/CT syndromically • Pain – treat for HSV
Lower abdominal pain	• Sexually active women • Presence of lower abdominal and cervical tenderness

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