

# Designing & Evaluating Clinical Algorithms for STI Case Management

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# Session outline

- STI case management
- STI syndromic case management
- Algorithms development
- Implementation
- Algorithms evaluation
- Exercise (Group + presentation)



# Objectives of an STI programme

- to interrupt the transmission of sexually transmitted infections
- to prevent development of disease, complications and sequelae
- to reduce the risk of HIV infection



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# Objectives of STI case management

- to provide appropriate antimicrobial therapy in order to:
  - obtain cure of infection
  - decrease infectiousness
- to limit or prevent high risk behaviour
- to ensure that sexual partners are treated in order to interrupt the chain of transmission



# STI case management: Requirements

- **Accurate diagnosis**
- **Treat at first encounter**
- **Rapid cure with effective drugs**
- **Simplicity**
- **Integrated approach**
- **Condom promotion**
- **Education/Counselling**
- **Partner notification**



# Comprehensive STI case management

- History taking (symptoms)
- Examination (signs)
- Treatment
  - Client and sexual partner(s)
- Counselling for STIs and PITC for HIV  
(provider initiated testing and counselling for HIV)
- Condom promotion



# Factors that influence patients' choice of facility

- **Accessibility**

- proximity
- affordability

- **Acceptability**

- non-stigmatising
- non-judgmental staff attitudes
- convenient opening hours
- affordable fees

- **Quality of services**

- efficiency of service delivery
- competence of staff
- effectiveness of therapy
- availability of drugs



# Diagnostic approaches to STI

- clinical

- laboratory

- syndromic

## Disadvantages

- neither sensitive nor specific
  - mixed infections cannot be detected
- 
- simple tests not available/do not exist
  - cost: existing rapid test expensive
  - delay: results not readily available
- 
- costs of over-treatment
  - side-effects of over-treatment





# STI syndromic case management: definition

- Syndromic diagnosis:  
identification of consistent group of symptoms and easily recognised signs (syndromes)
- Syndromic treatment:  
treat the main organisms responsible for causing the syndrome



# How syndromic management works

Through a series of flow-charts:

- guides the health-care worker through the correct identification and treatment of an STI-associated syndrome
- offers a package of comprehensive care from history taking, examination, to counselling/education on risk reduction and partner notification and treatment



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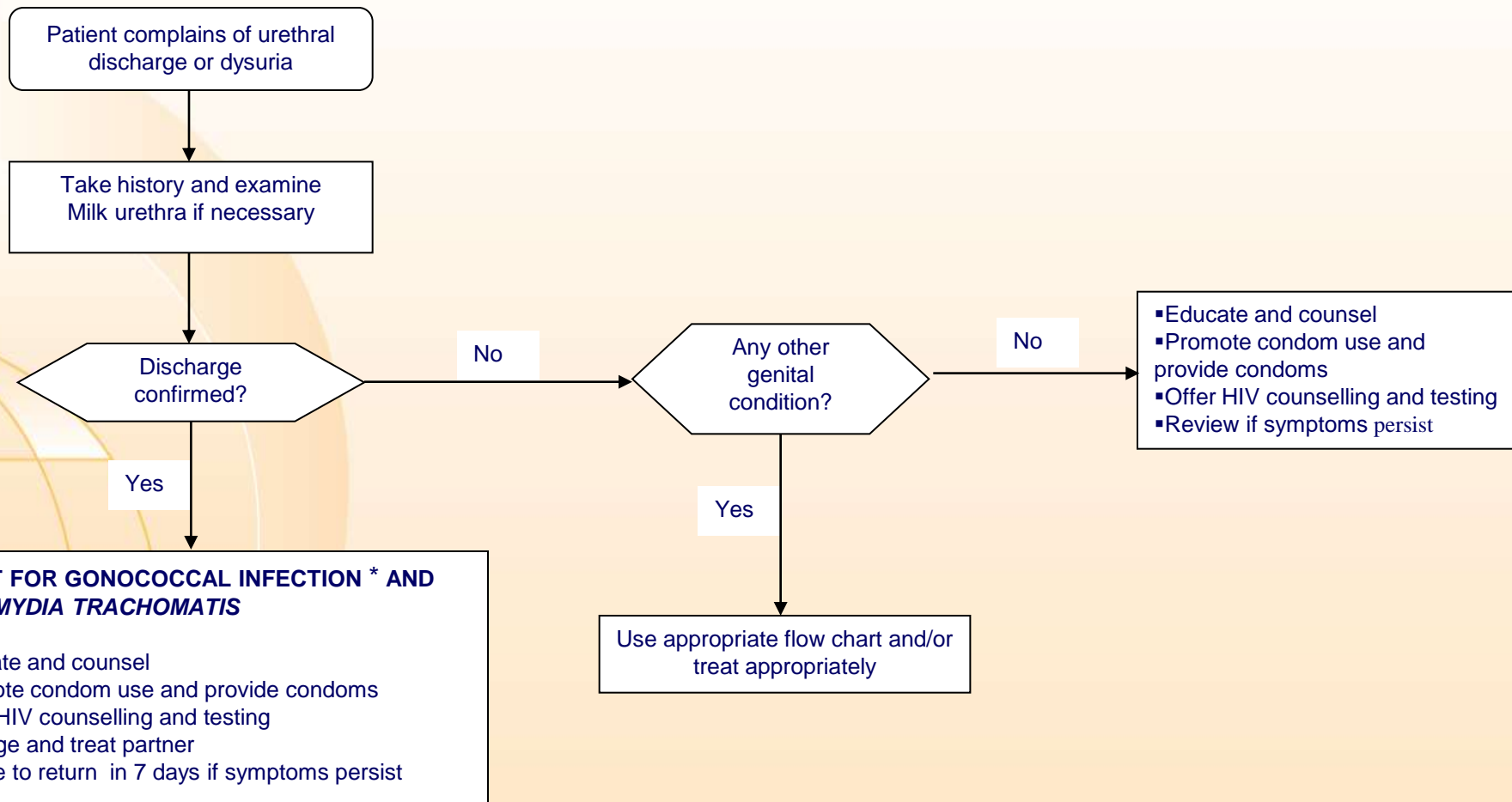


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# Urethral Discharge



\*If microscopy is available, do Gram stain smear of urethral exudates. If no intra-cellular Gram-negative diplococci are seen, treatment for chlamydial infection only may be considered.

Source WHO, 2011



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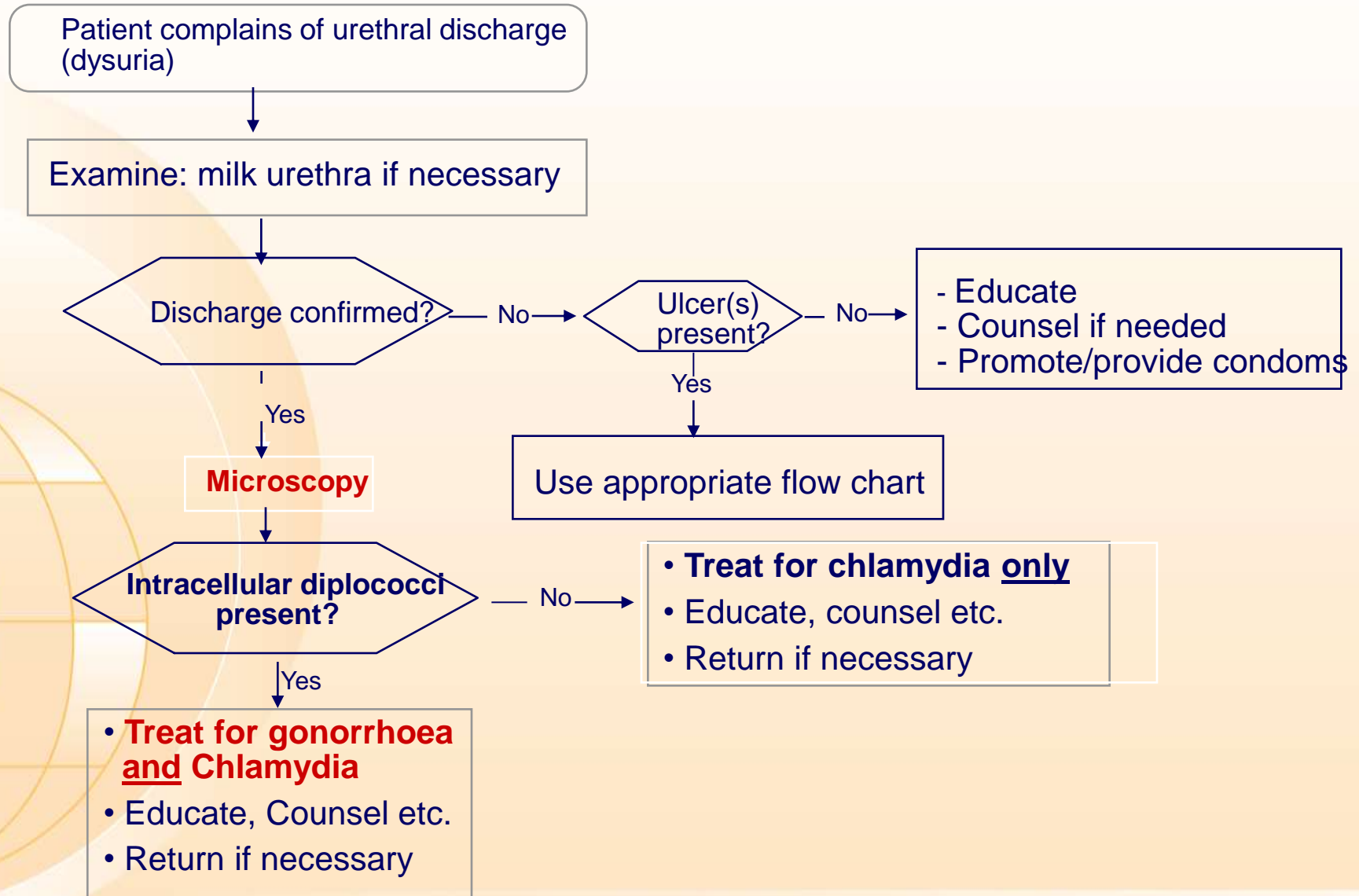


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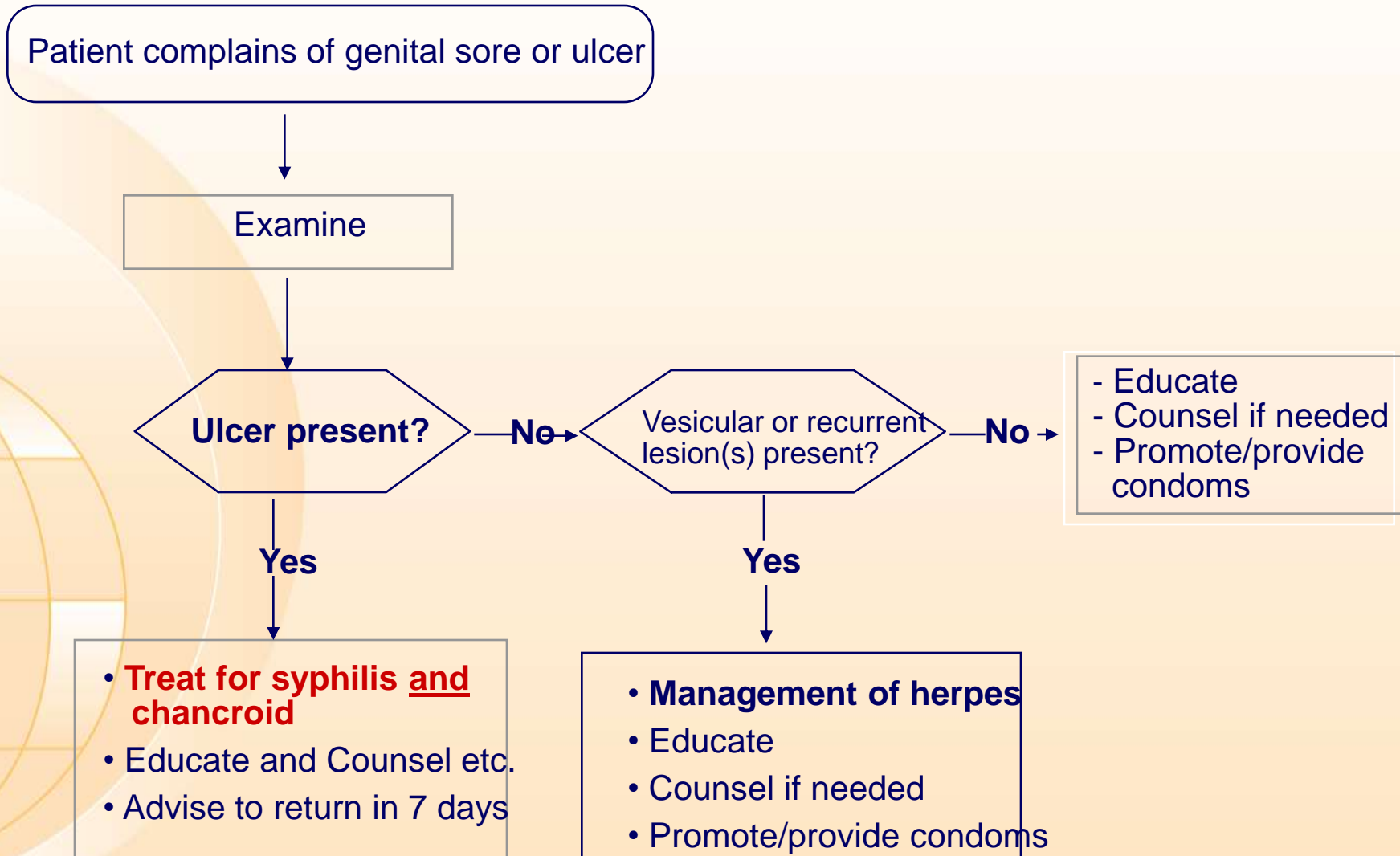


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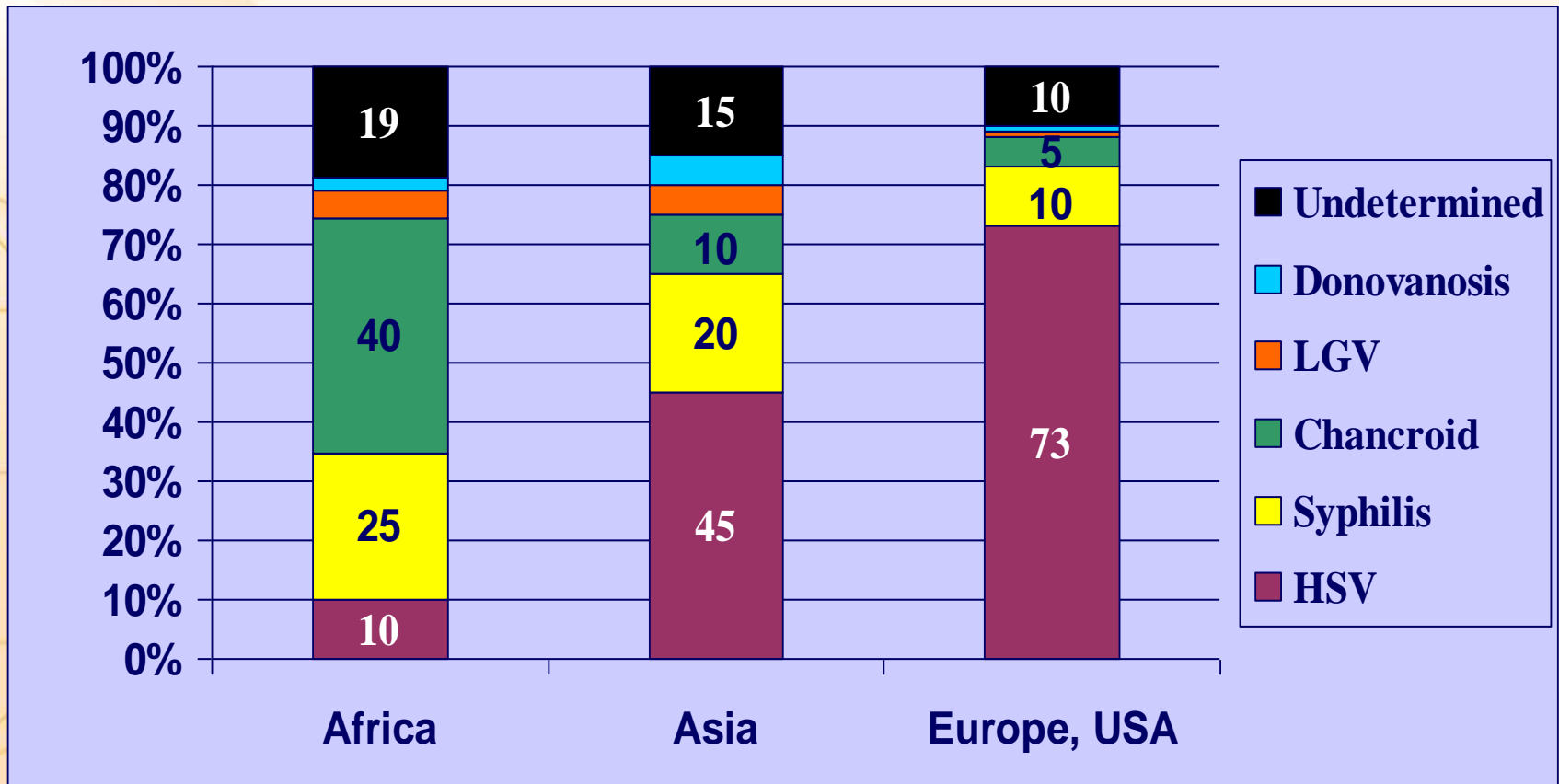
# Urethral discharge (with microscope)



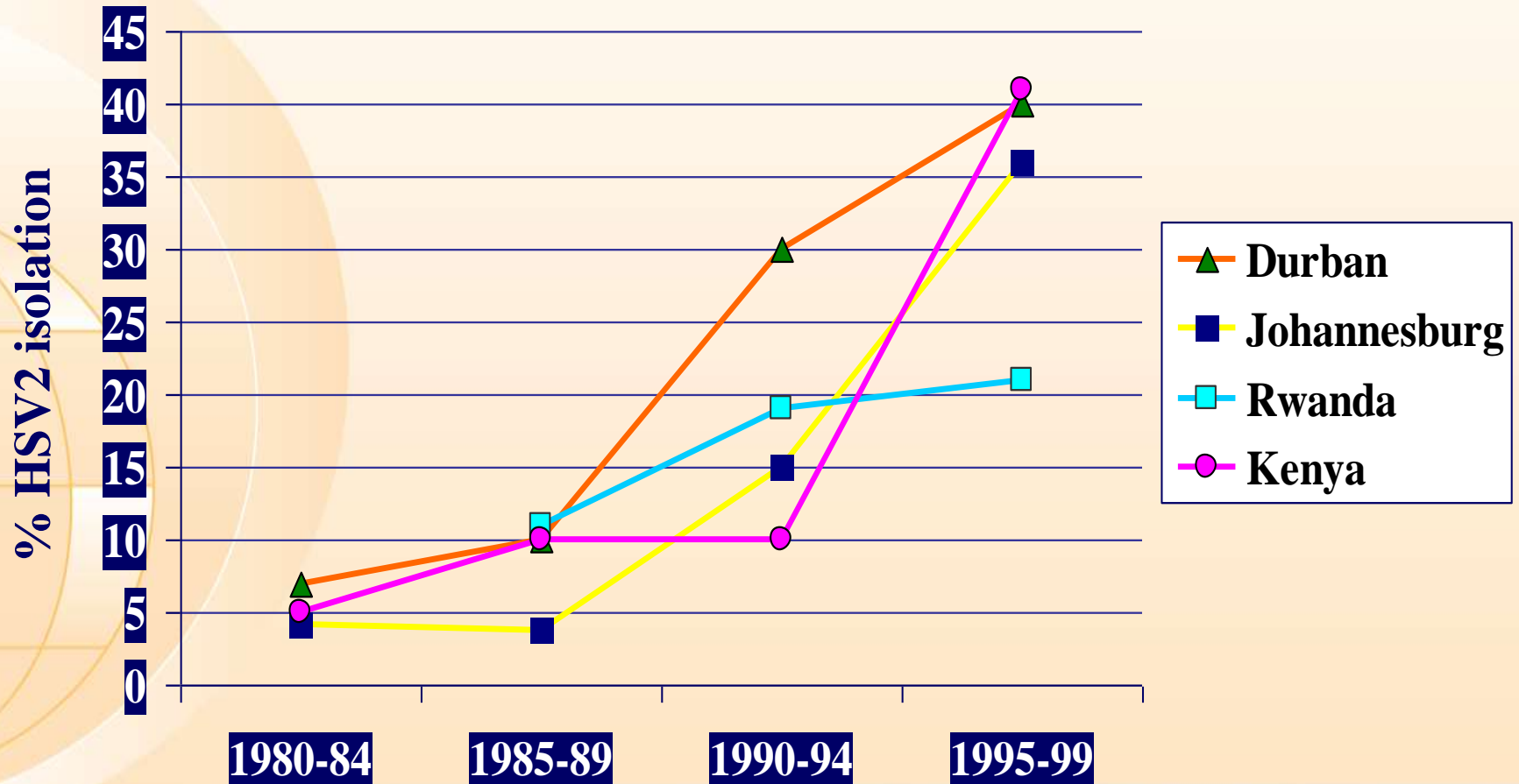
# Genital ulcers



# Agents causing genital ulcer disease (GUD) by Region until 1990's



# Proportion of genital ulcers in which HSV-2 was isolated in Africa over time



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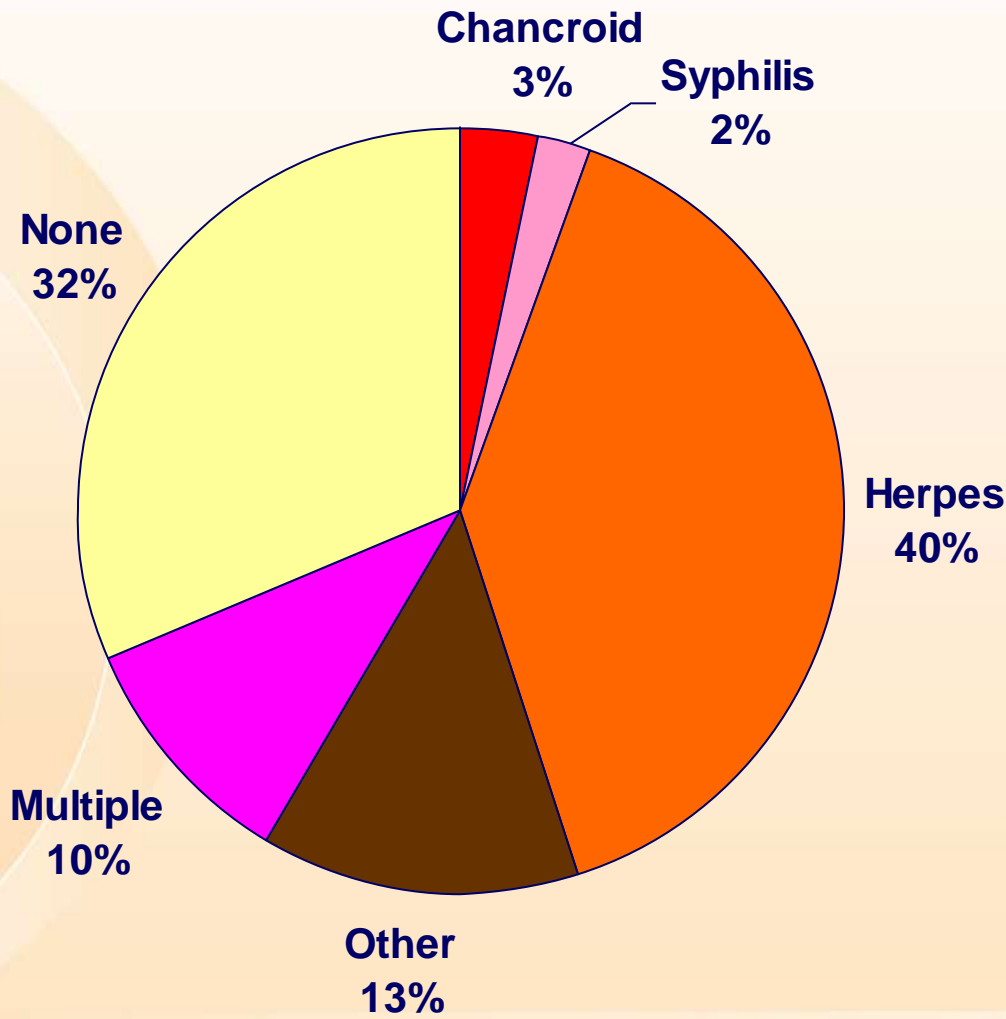


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# Aetiology of GUS by M-PCR and culture in Masaka, Uganda



**TPHA/RPR - 15%**  
**HIV - 30%**



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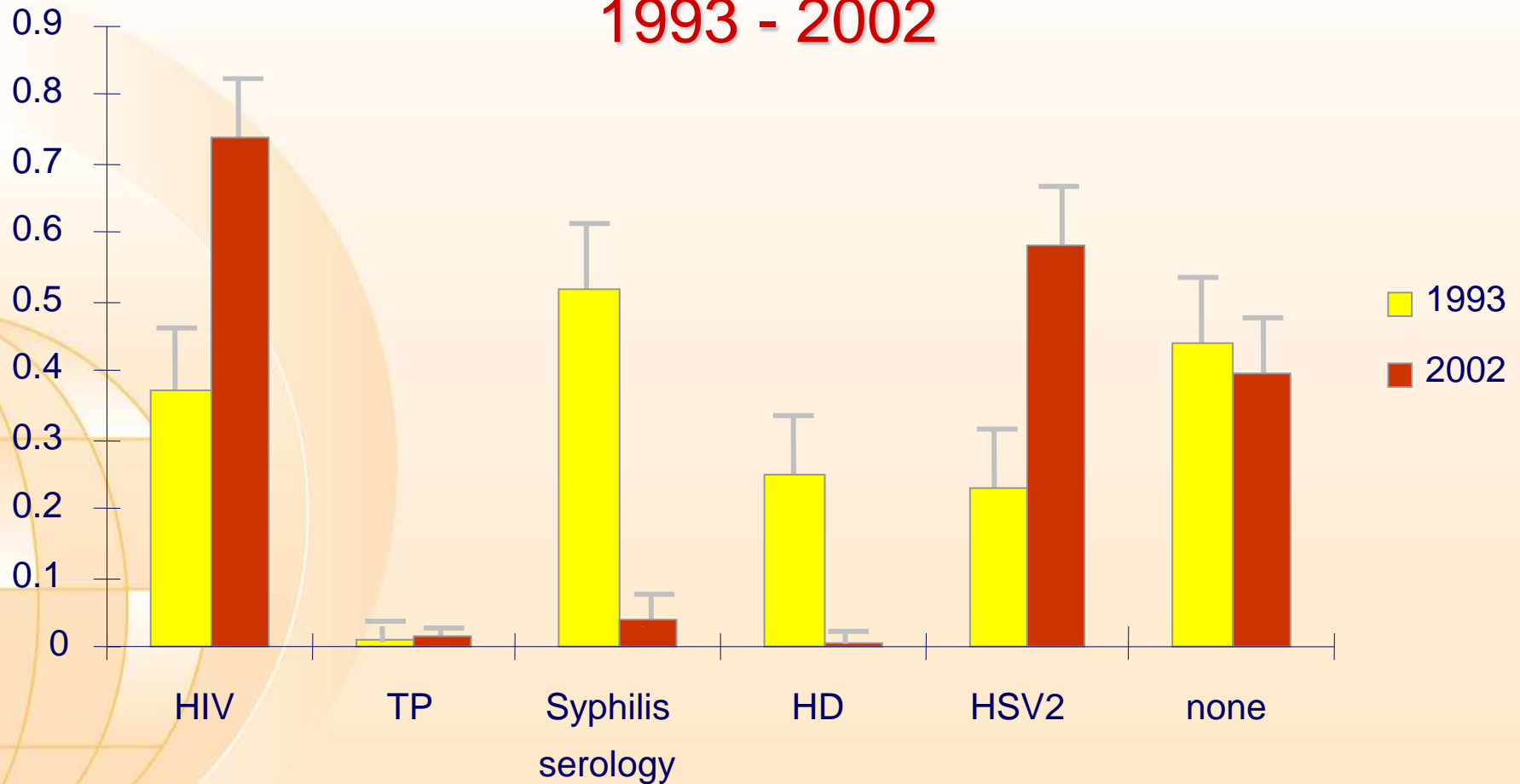
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Source: Dr. Anatoli Kamali, Uganda



# Botswana

## Changes in the aetiology of GUD 1993 - 2002



\*In 1993 a study was done by the National AIDS Control Program in Botswana in collaboration with the STD Research Unit, South African Institute for Medical Research, Johannesburg among 108 GUD patients.

Source: M. Rahman, ISSTD, Ottawa 2003



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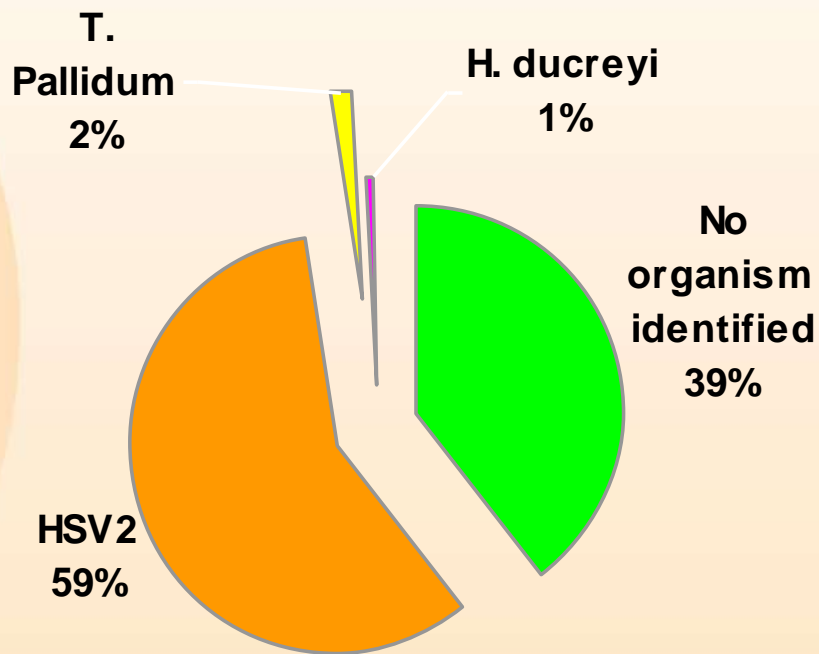
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# Botswana

## Aetiology of genital ulcer disease 2002



**N=137**

**TPHA/RPR - 15%**  
**HIV - 30%**

Source: M. Rahman, ISSTD, Ottawa 2003



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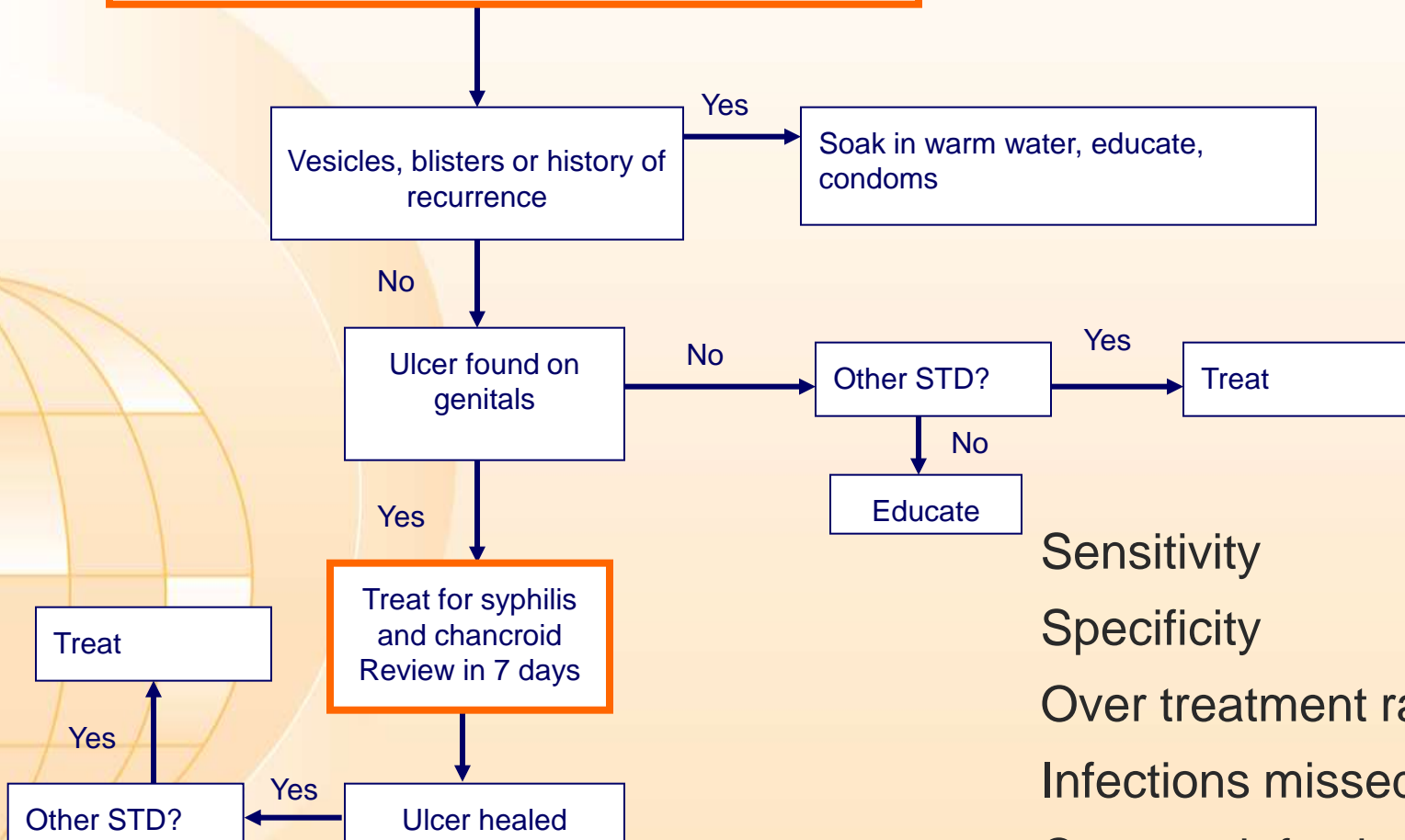
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# Current genital ulcer algorithm in Botswana

Complaint sores/ulcer on genitals



Sensitivity	33%
Specificity	45%
Over treatment rate	99%
Infections missed	67%
Cost per infection Tx.	\$88.0



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# Piloted genital ulcer algorithm in Botswana

Complaint of sores/ulcer on genitals

Only vesicles present?

Yes

Treat for **herpes**  
return in 7 days if symptoms persist

No

Ulcer found on genitals

No

Other STI?

Yes

Treat for syphilis, chancroid and  
**herpes**  
Ask patient to return in 7 days

Ulcer healed

Yes

Other STI?

No

Ulcer improved but not  
healed continue therapy  
for 7 days and return

Ulcer not improved  
**REFER**

Sensitivity	99%
Specificity	13%
Over treatment rate	36%
Infections missed	1%
Cost per infection Tx.	\$4.5



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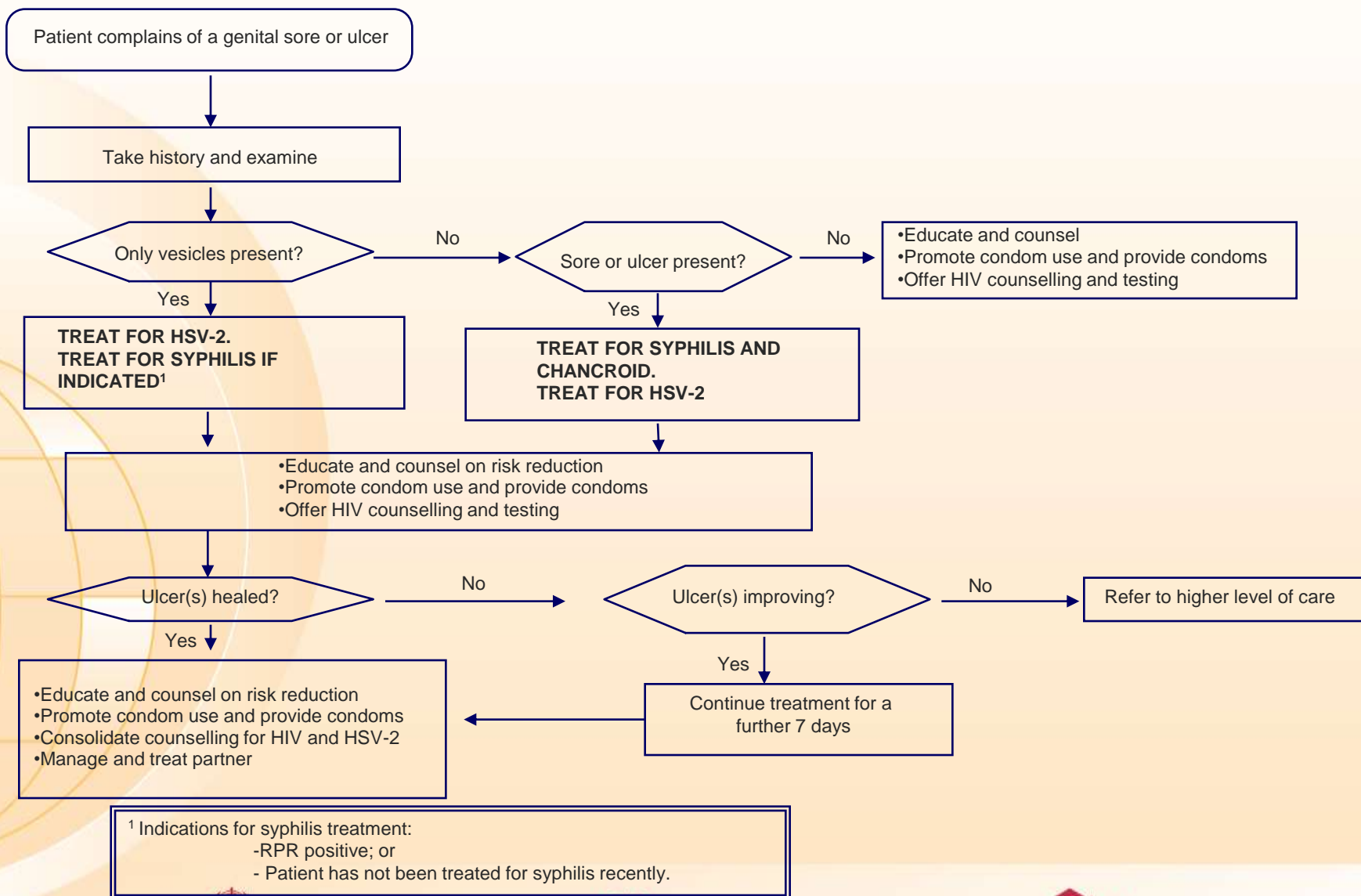


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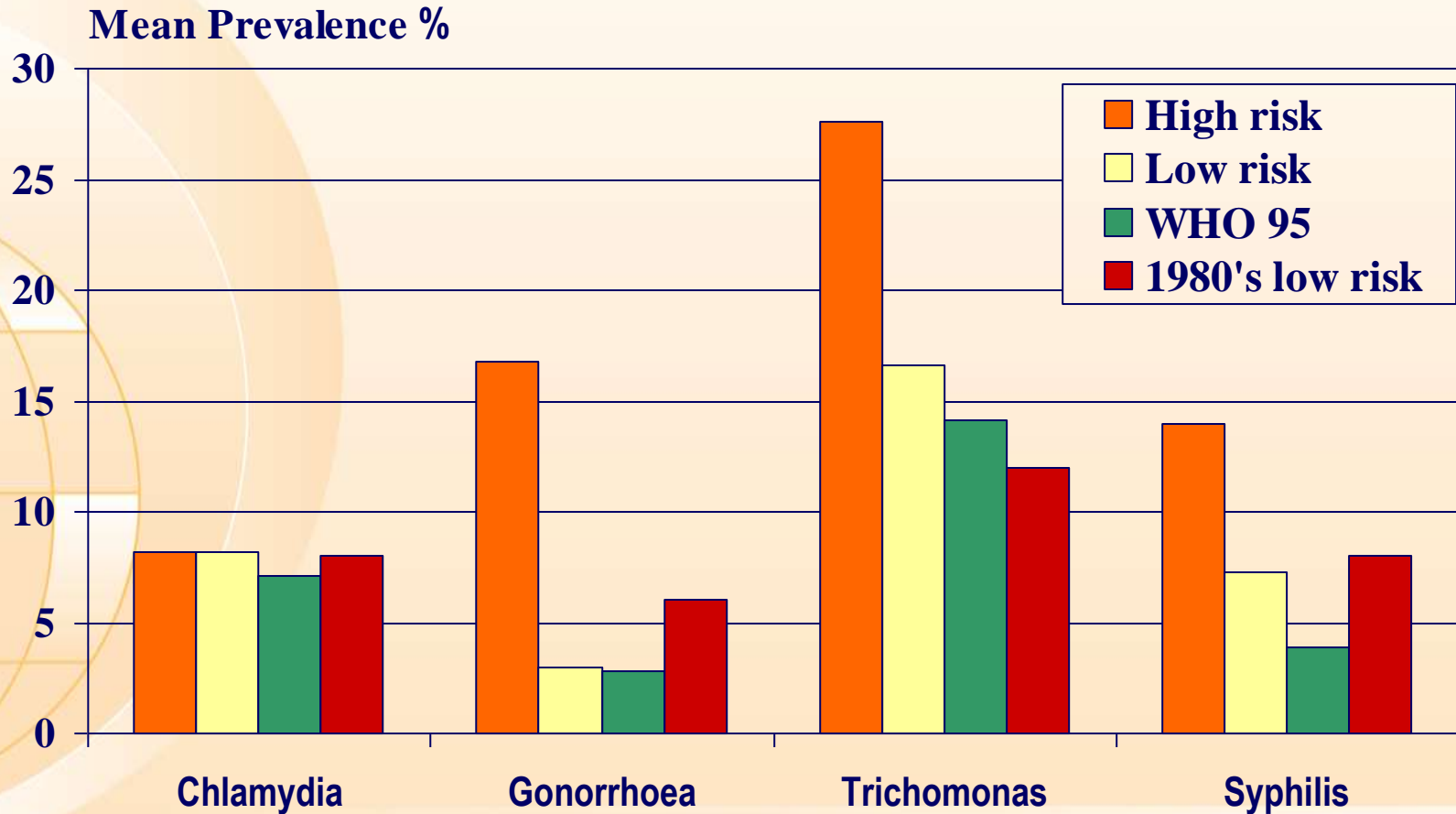
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# Genital ulcer disease



<sup>1</sup> Indications for syphilis treatment:  
 -RPR positive; or  
 - Patient has not been treated for syphilis recently.

# Prevalence of Selected STIs among Female Populations in Africa in the 1980's and 1990's



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Table of selected 1990's studies; Wasserheit & Holmes, 1992; Gerbase et al, Lancet 1998

# Vaginal discharge syndrome

## VAGINITIS

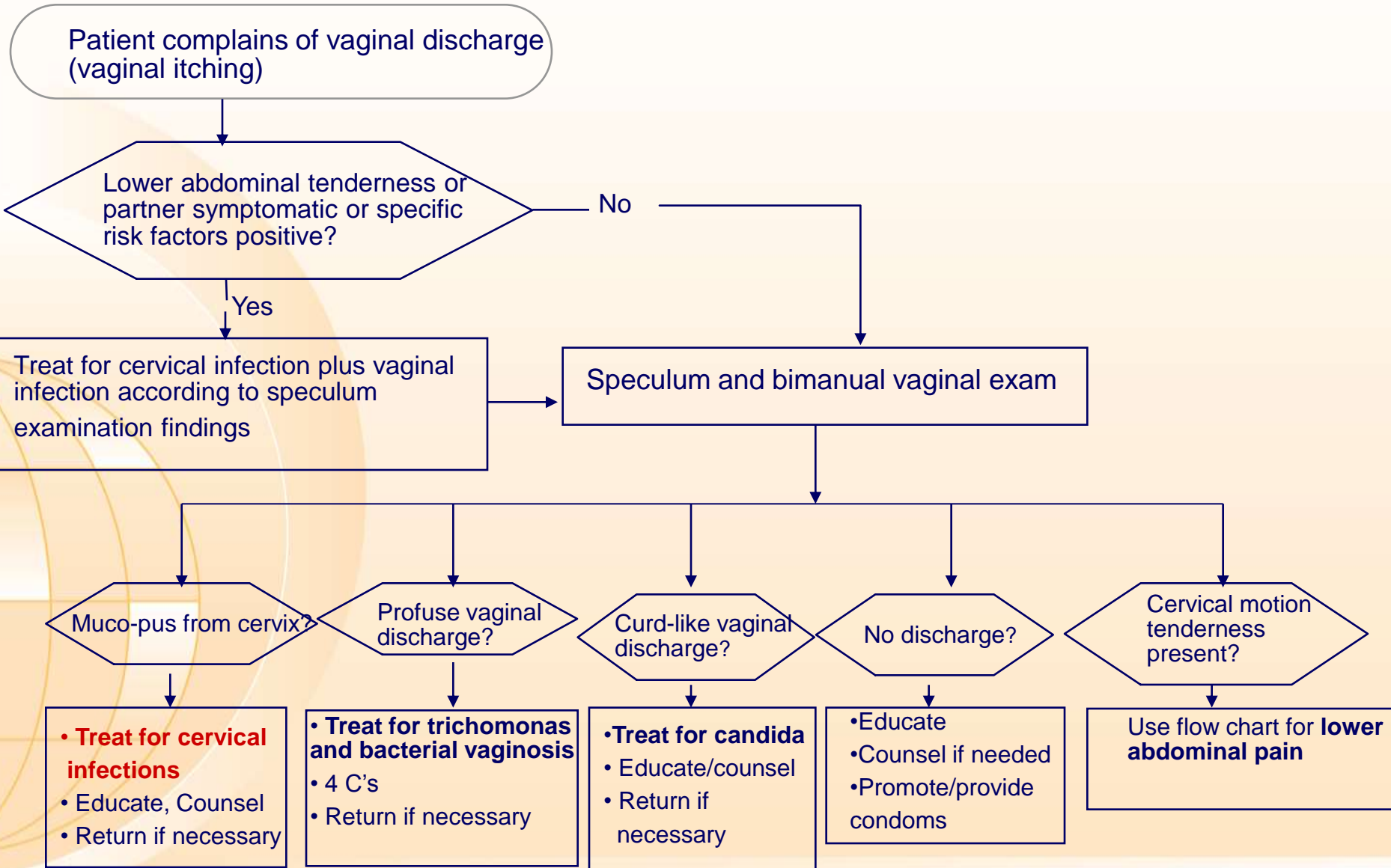
- most common causes
- easy to diagnose
  - lab tests
  - clinically
- serious complications?
  - (pregnancy)
  - (endometritis, PID)

## CERVICITIS

- less common causes
- not easy to diagnose
  - no simple tests
- complications ++
  - PID
  - ectopic pregnancy
  - infertility

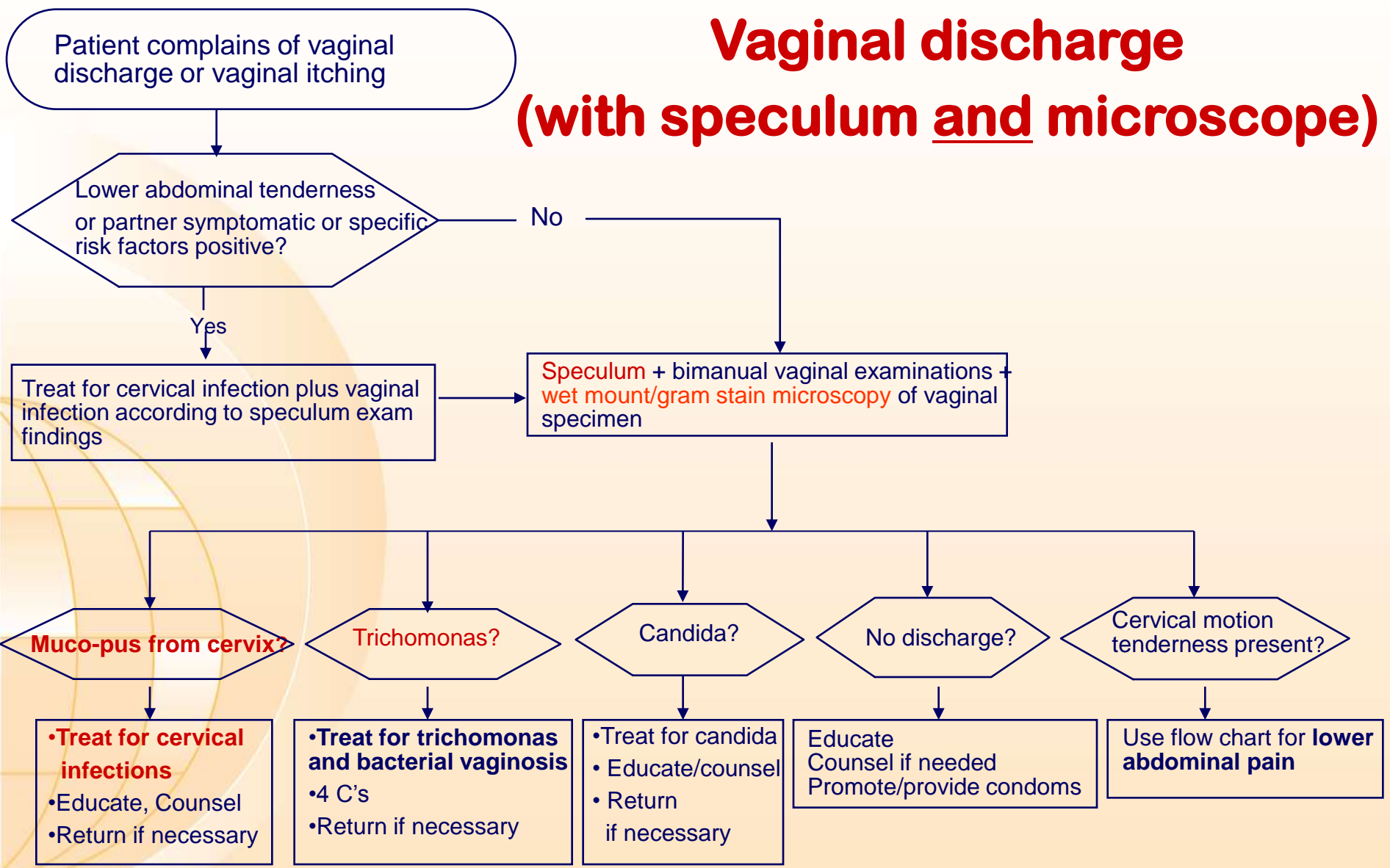


# Vaginal discharge (with speculum only)





# Vaginal discharge (with speculum and microscope)



# Vaginal discharge (without microscope, using risk score)

Patient complains of vaginal discharge  
(vaginal itching)

Lower abdominal tenderness  
or partner symptomatic  
or **risk score positive**\*?

No

- Treat for **vaginal** infections
- Educate
- Counsel if needed
- Promote/provide condoms

Yes

- Treat for **cervical** and **vaginal** infections
- Educate and counsel
- Return if necessary

**\* Risk score = any 2 of:**

- age <21
- single
- >1 partner in last 3/12
- new partner in last 3/12



# Vaginal discharge

Patient complains of vaginal discharge, vulval itching or burning

Take history and examine  
Assess risk<sup>1</sup>

Abnormal vaginal discharge or vulval erythema?

No

Any other genital disease?

No

- Educate and counsel
- Promote condom use and provide condoms
- Offer HIV counselling and testing if both facilities are available

Yes

Use appropriate flowchart for additional treatment

Yes

Lower abdominal tenderness?

No

High GC/CT prevalence setting<sup>2</sup> or risk assessment positive?

No

**TREAT FOR BACTERIAL VAGINOSIS AND TRICHOMONAS VAGINALIS**

Yes

Yes

Use flowchart for lower abdominal pain

**TREAT FOR GONOCOCCAL INFECTION, CHLAMYDIA TRACHOMATIS, BACTERIAL VAGINOSIS AND TRICHOMONAS VAGINALIS.**

Vulval oedema/curd-like discharge, erythema, excoriations present?

No

- Educate and counsel
- Promote condom use and provide condoms
- Offer HIV counselling and testing if both facilities are available

Yes

**TREAT FOR CANDIDA ALBICANS**

<sup>1</sup> Risk factors need adaptation to local social, behavioural and epidemiological situation.

<sup>2</sup> The determination of high prevalence levels needs to be made locally.



# Vaginal discharge: Bimanual & speculum, with or without microscope

Patient complains of vaginal discharge, vulval itching or burning

Take history and examine patient (external, speculum and bimanual)  
Assess risk<sup>1</sup>  
Perform wet mount microscopy of vaginal specimen for TV and yeast cells (optional)

Lower abdominal tenderness or cervical motion tenderness present?

Yes

Use flowchart for lower abdominal pain

No

Cervical mucopus or erosions or High GC/CT prevalence setting<sup>2</sup> or risk assessment positive?

No

**TREAT FOR BACTERIAL VAGINOSIS AND *TRICHOMONAS VAGINALIS***

Yes

**TREAT FOR GONOCOCCAL INFECTION, *CHLAMYDIA TRACHOMATIS*, BACTERIAL VAGINOSIS AND *TRICHOMONAS VAGINALIS*.**

Vulval oedema/curd-like discharge, vulval erythema, excoriations present or yeast cells on microscopy?

No

- Educate and counsel
  - Promote condom use and provide condoms
  - Offer HIV counselling and testing if both facilities are available
- 
- Manage and treat partner if cervical mucopus present
  - Manage and treat partner if microscopy demonstrates TV

Yes

**TREAT FOR *CANDIDA ALBICANS***

<sup>1</sup> Risk factors need adaptation to local social, behavioural and epidemiological situation

<sup>2</sup> The determination of high prevalence levels needs to be made locally



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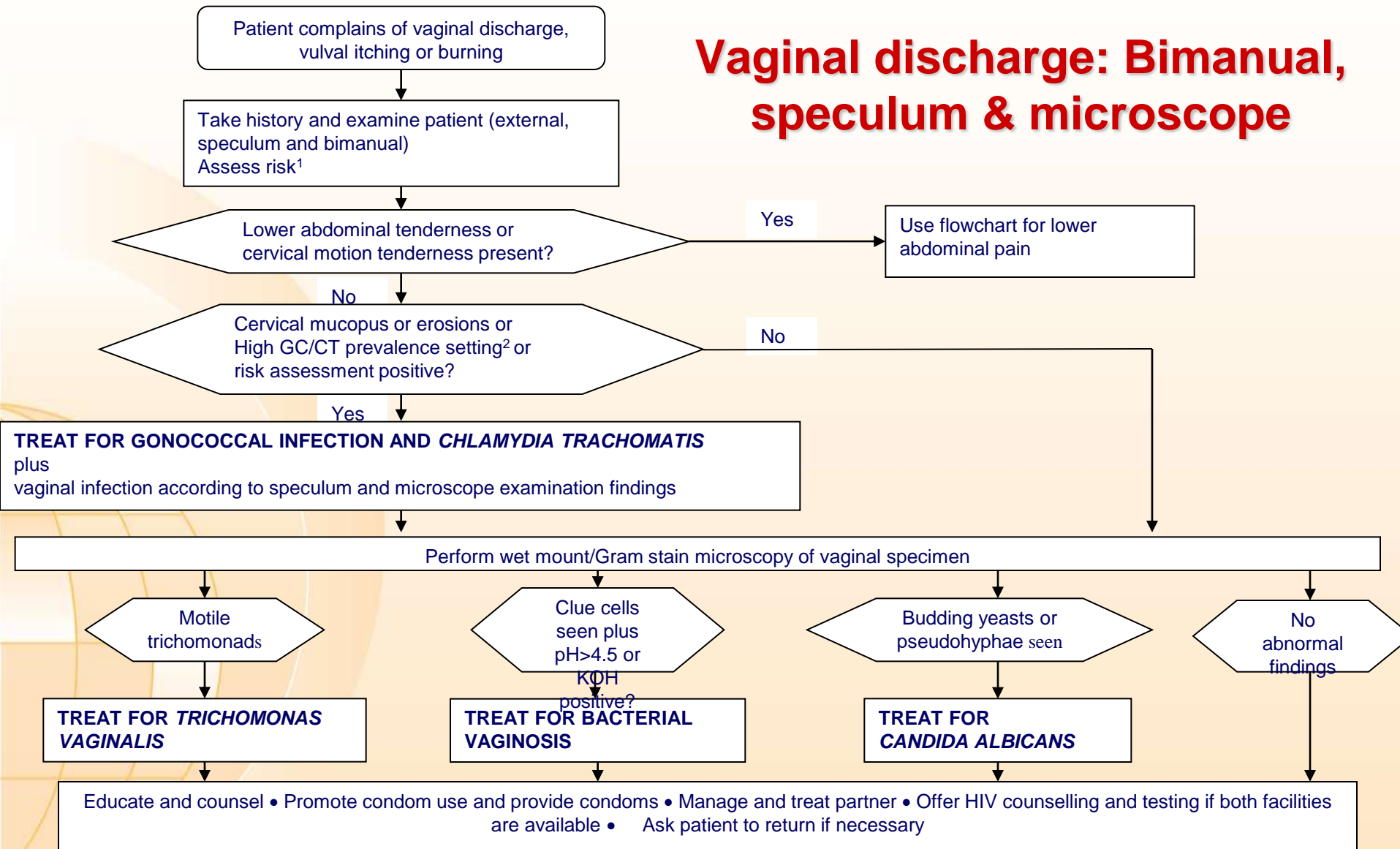


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# Vaginal discharge: Bimanual, speculum & microscope



<sup>1</sup>Risk factors need adaptation to local social, behavioural and epidemiological situation

<sup>2</sup> The determination of high prevalence levels needs to be made locally

# IMPLEMENTATION

## 1. Pre-requisite information

- Prevalence of STIs
- STI treatment-seeking behaviour
- Treatment practices & counselling (PI6 & PI7)
- Level of (and capacity for) training of implementers
- Drug policy, ordering and distribution system
- Stakeholders involvement
- Review of literature (need 'evidence criteria')



# IMPLEMENTATION

## 2. Conduct or analyse aetiological studies

- Genital ulcer syndrome
- Male genital discharge syndrome
- Female genital discharge (+/- risk-assessment)
- Resistance patterns

## 3. Assess if there is need to depart from WHO or existing national/regional algorithms

## 4. Adaptation for high/low risk environment

- high/low prevalence area
- high risk/low risk populations



# IMPLEMENTATION

## 5. Determine the role of the laboratory

- for case management (and monitoring as 'test of cure')
- for screening and case finding
- for supporting research

## 6. Determine levels of use/capacity

- will influence flowchart design & need pre-testing
- will influence choice of drugs
- depends on referral patterns





# IMPLEMENTATION

## 7. Drug selection: criteria for the choice of drugs (WHO, 2003)

- efficacy (cure at least 95% of those infected)
- safety
- cost
- compliance and acceptability
- availability (e.g. at primary health care level)
- use in pregnancy
- broad spectrum (can cover co-existing infections)
- resistance unlikely to occur rapidly



# IMPLEMENTATION

8. Printing and distribution (and translation) of flowcharts

9. Training

- post-service institutional training
- on-the-job training
- pre-service training
- what cadres to train

10. Drug procurement and distribution



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# IMPLEMENTATION

## 11. Monitoring and Supervision

- WHAT?
  - clinical outcomes on returnees and non-returnees
    - » cured/ improved/ treatment failures
    - » referral/ no follow-up
  - *Neisseria gonorrhoeae* susceptibility
  - aetiological surveys
  - quality of care (PI6, PI7)
- HOW (universal? sentinel sites? standardised protocols? consensual workshops)
- WHEN?

## 12. Evaluation scheme



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# Monitoring & Evaluation

**Evaluate programme and interventions**

**Assess the epidemic and the response**

**Train and supervise**

**Advocate for STI inclusion in the health-care agenda**

**Adopt and adapt evidence-based interventions**

**Strengthen STI programme management and intervention activities**



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# Evaluation of Algorithms

- Validity: sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV)
- Feasibility: infrastructure, personnel
- Cost: direct and indirect costs, cost/effectiveness
- Acceptability: health care provider, STI patient, programme manager



# Validity of an algorithm (1):

Comparison between:

- Outcome of the algorithm
  - Simulation studies
  - Real outcome in field conditions
- Gold standard diagnosis
  - Laboratory tests



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# Validity of an algorithm (2)

- Calculation: 2 x 2 table
  - sens, spec, PPV, NPV
- Interpretation: 2 x 2 table
  - correctly treated, over treated, missed infections



# Validity of an algorithm Interpretation

**Gold Standard test**

**+**

**-**

<b>+</b>	<b>A: (true +ve) Correctly treated</b>	<b>B: (false ve+) Over-treated</b>
<b>-</b>	<b>C: (false -ve) Missed infections</b>	<b>D: (true -ve) Correctly diagnosed as negative</b>

**Total infected**

**Total not infected**

**Algorithm**



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# Validity of an algorithm Interpretation

## Gold Standard test

+

-

<b>Algorithm</b> +	<b>A: (true +ve)</b>	<b>B: (false ve+)</b>
<b>Algorithm</b> -	<b>C: (false -ve)</b>	<b>D: (true -ve)</b>
	<b>Total infected</b>	<b>Total non infected</b>

**Sensitivity:**  $A/A+C$

**Specificity:**  $D/B+D$

**Positive Predictive Value:**  $A/A+B$

**Negative Predictive Value:**  $D/C+D$



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# COST PER CASE CURED

**Total cost of all diagnoses + treatments**

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**Number of cases cured**

**Cost per case cured decreases if**

- ▲ **prevalence increases**
- ▲ **specificity of flowchart increases**



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