Designing & Evaluating Clinical Algorithms for STI Case Management

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RHR/STI

Training Course in Sexual and Reproductive Health Research
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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

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

Disadvantages

- clinical
  - neither sensitive nor specific
  - mixed infections cannot be detected
- laboratory
  - simple tests not available/do not exist
  - cost: existing rapid test expensive
  - delay: results not readily available
- syndromic
  - 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:

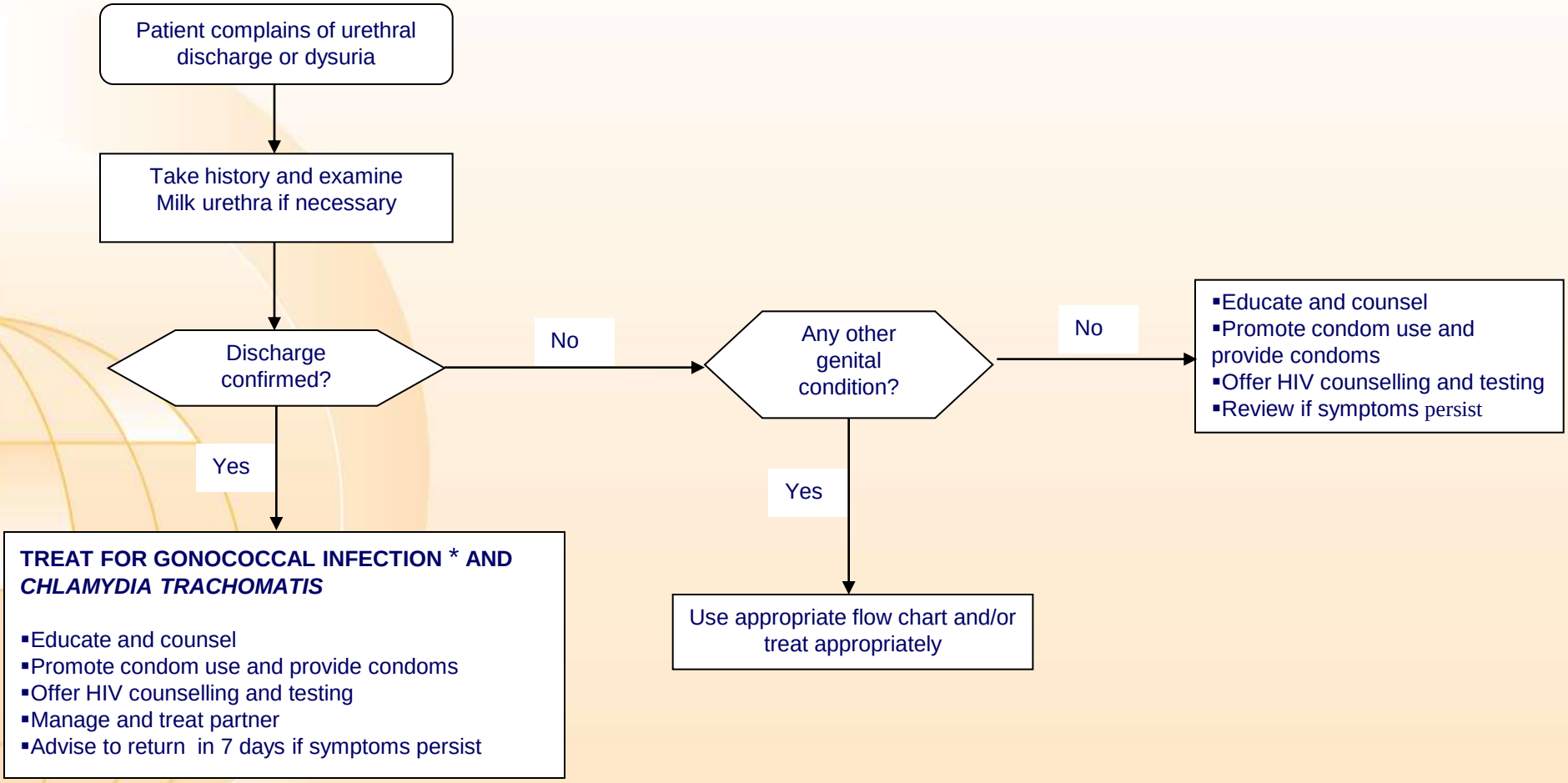
  treat the main organisms responsible for causing the syndrome

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

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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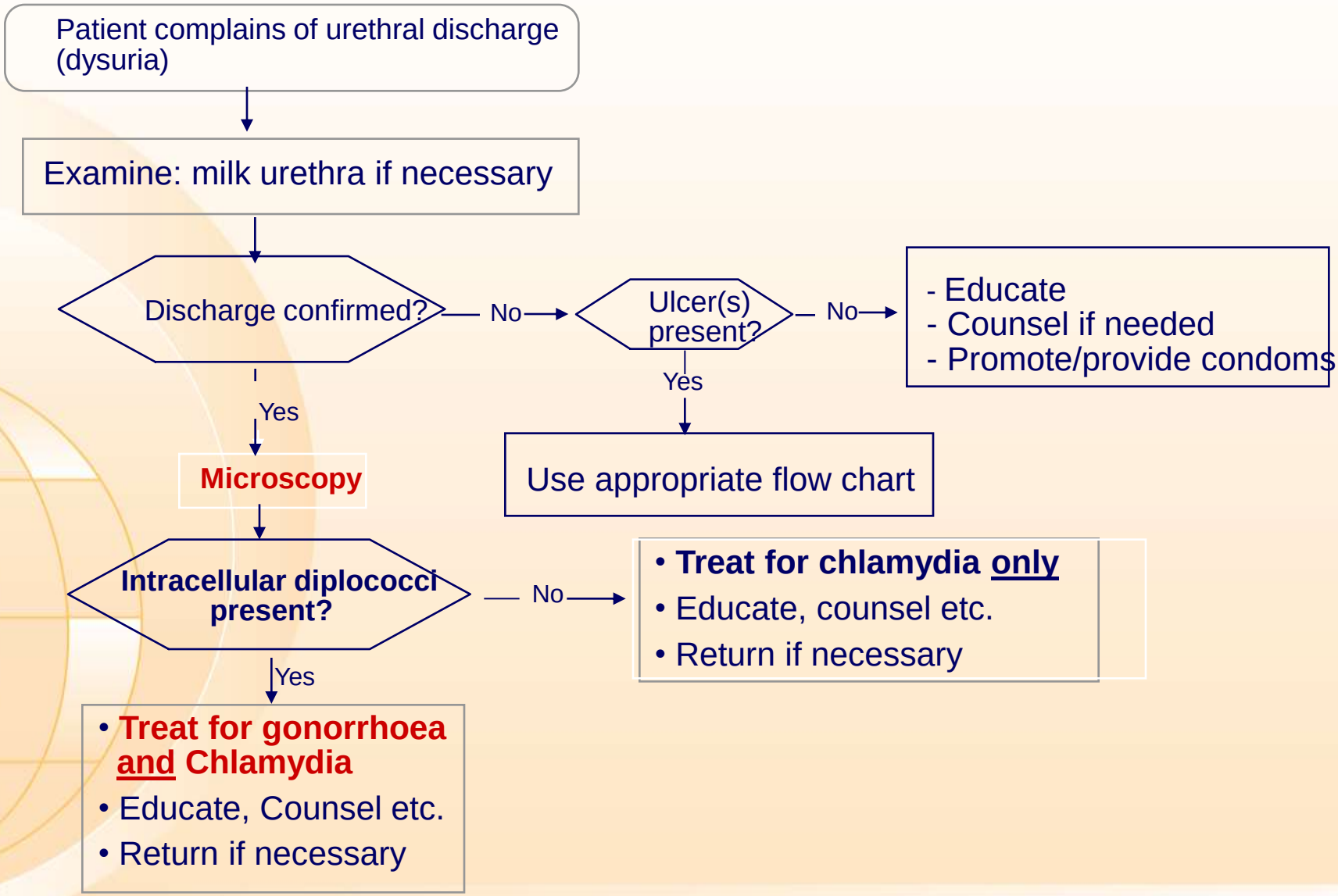
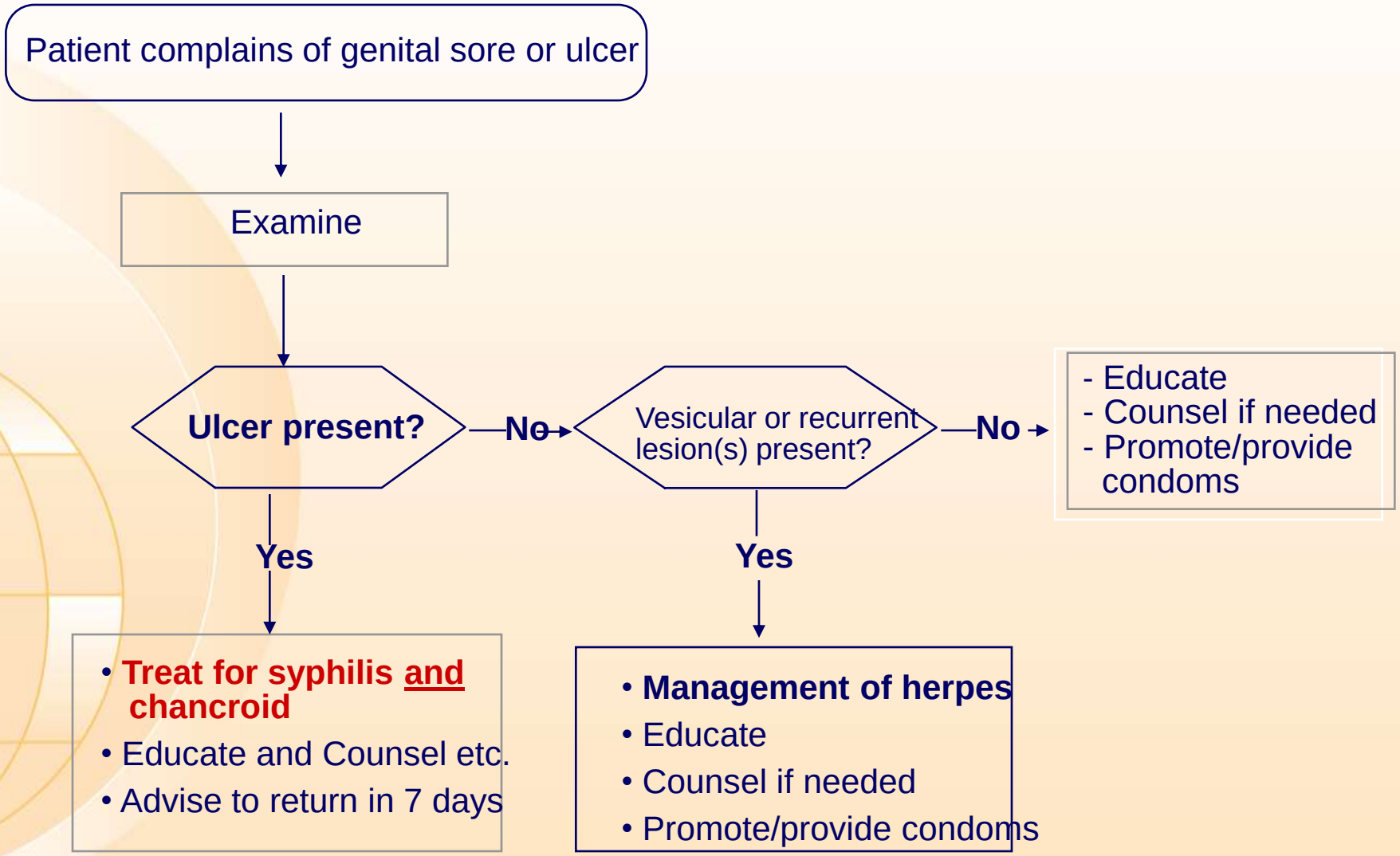
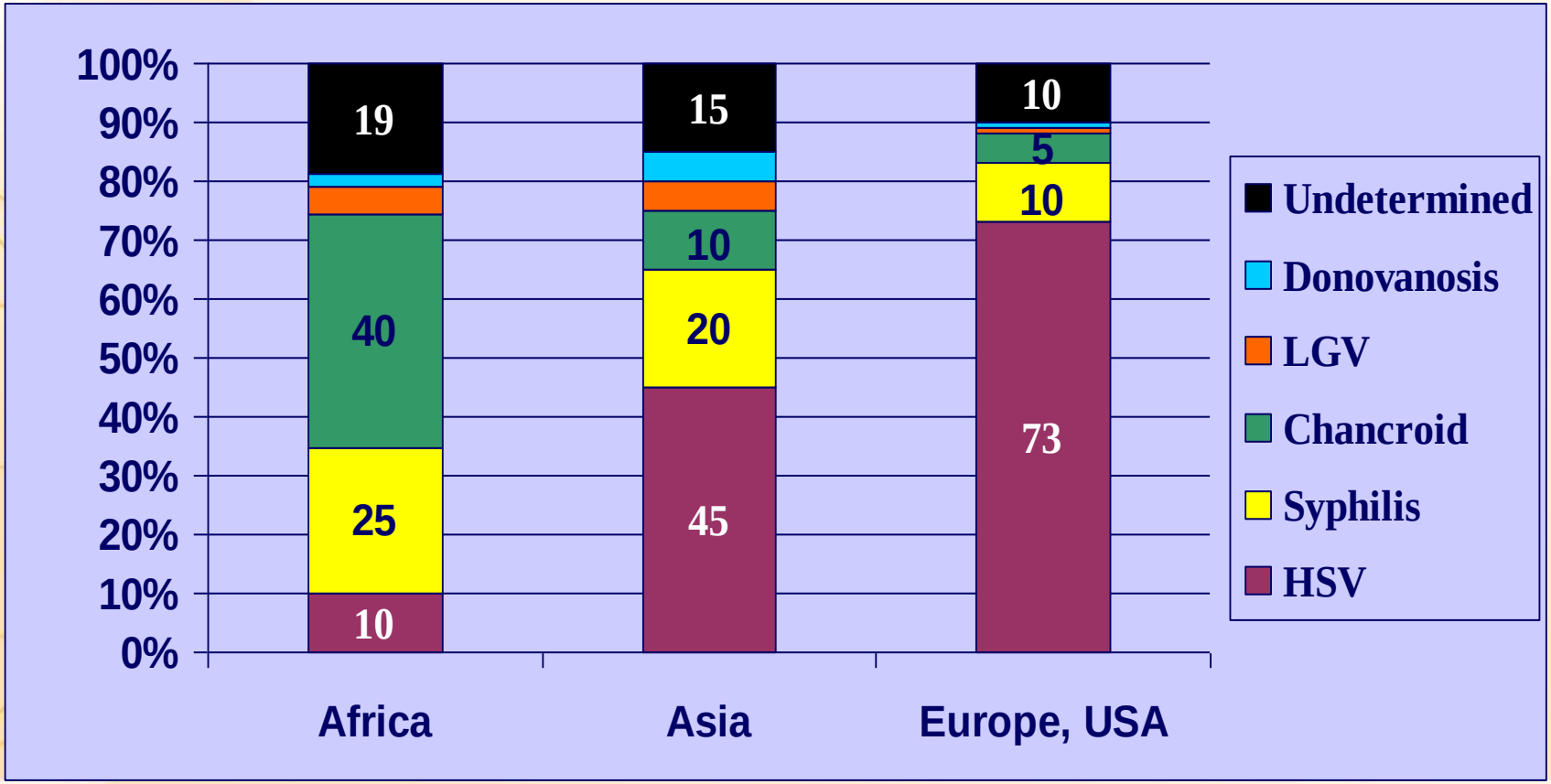
Urethral discharge (with microscope)



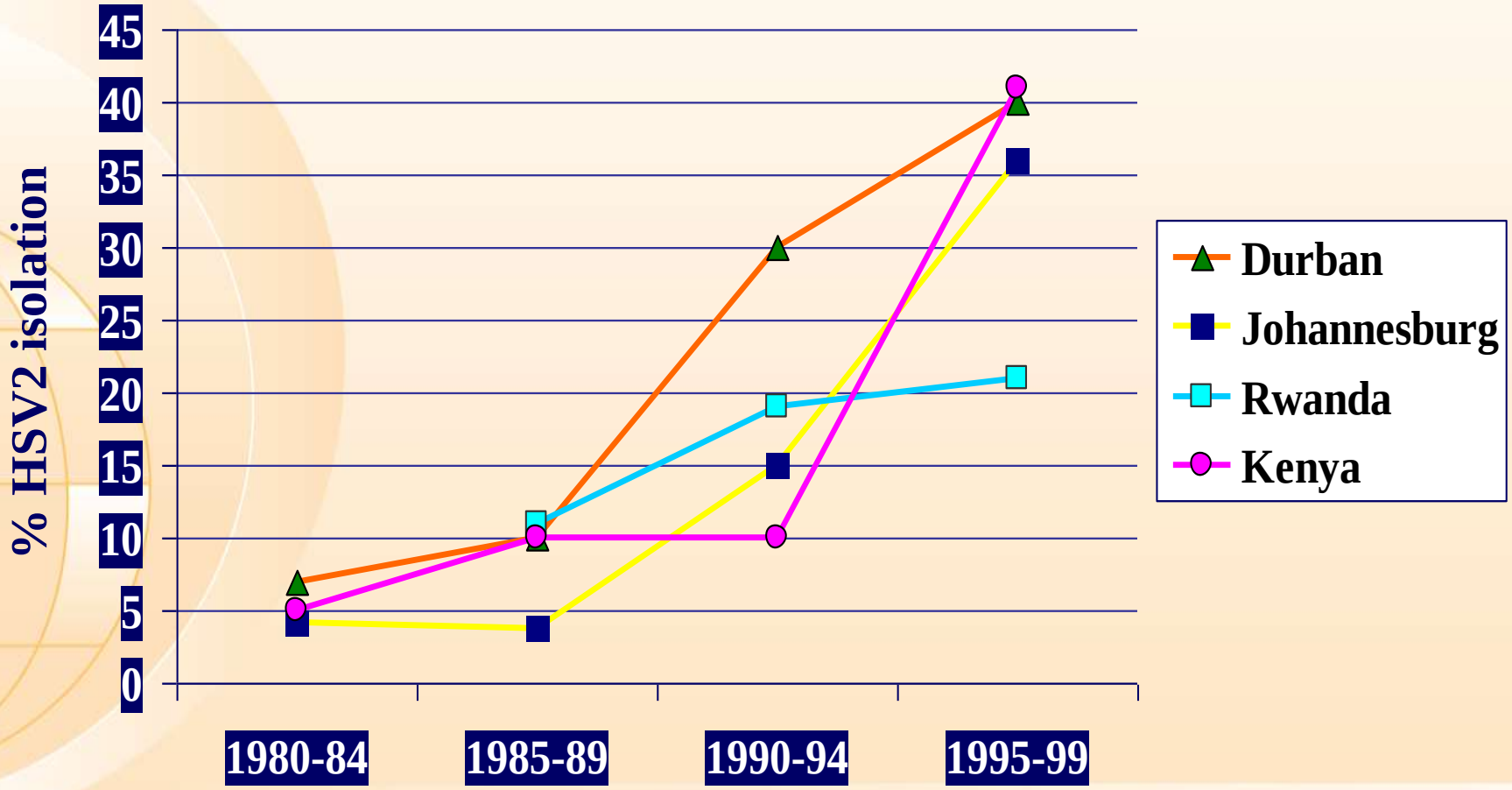
Genital ulcers



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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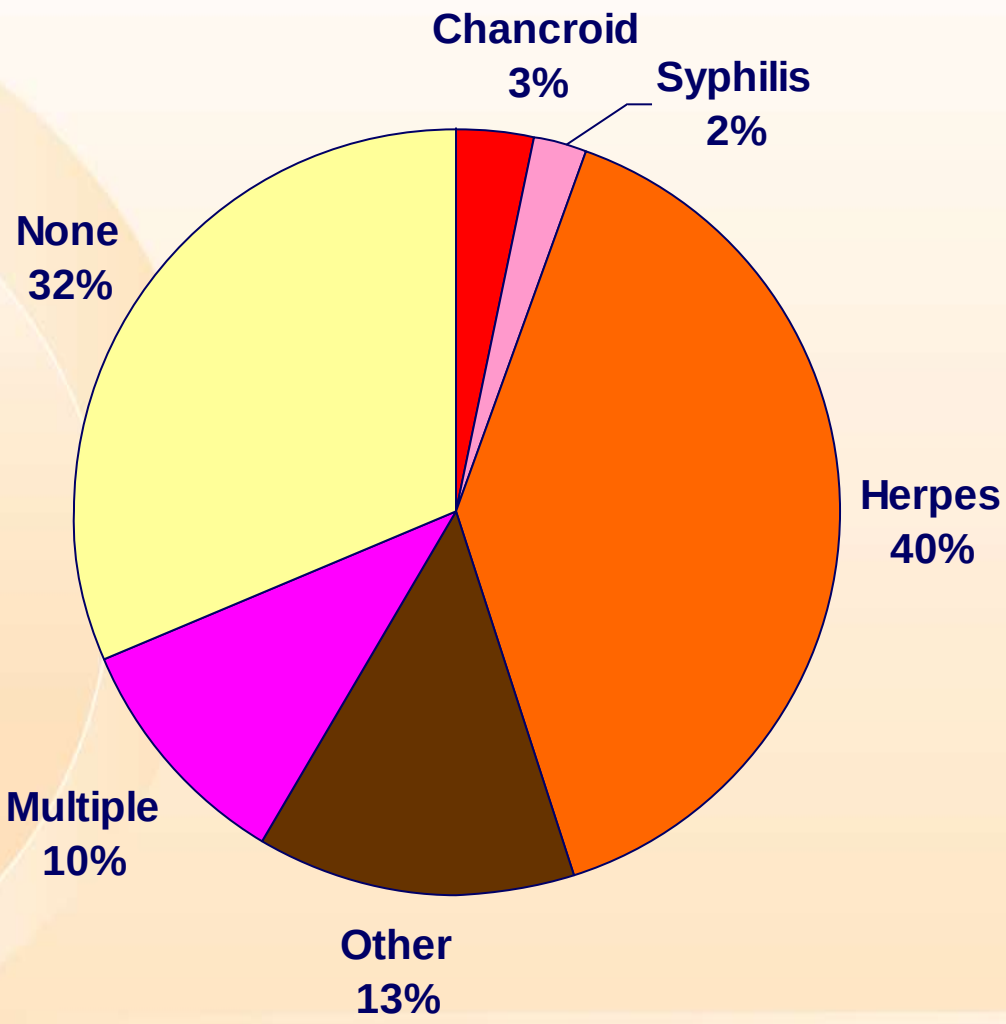
Mayaud & Mc Cormick, Br Med Bull 2001

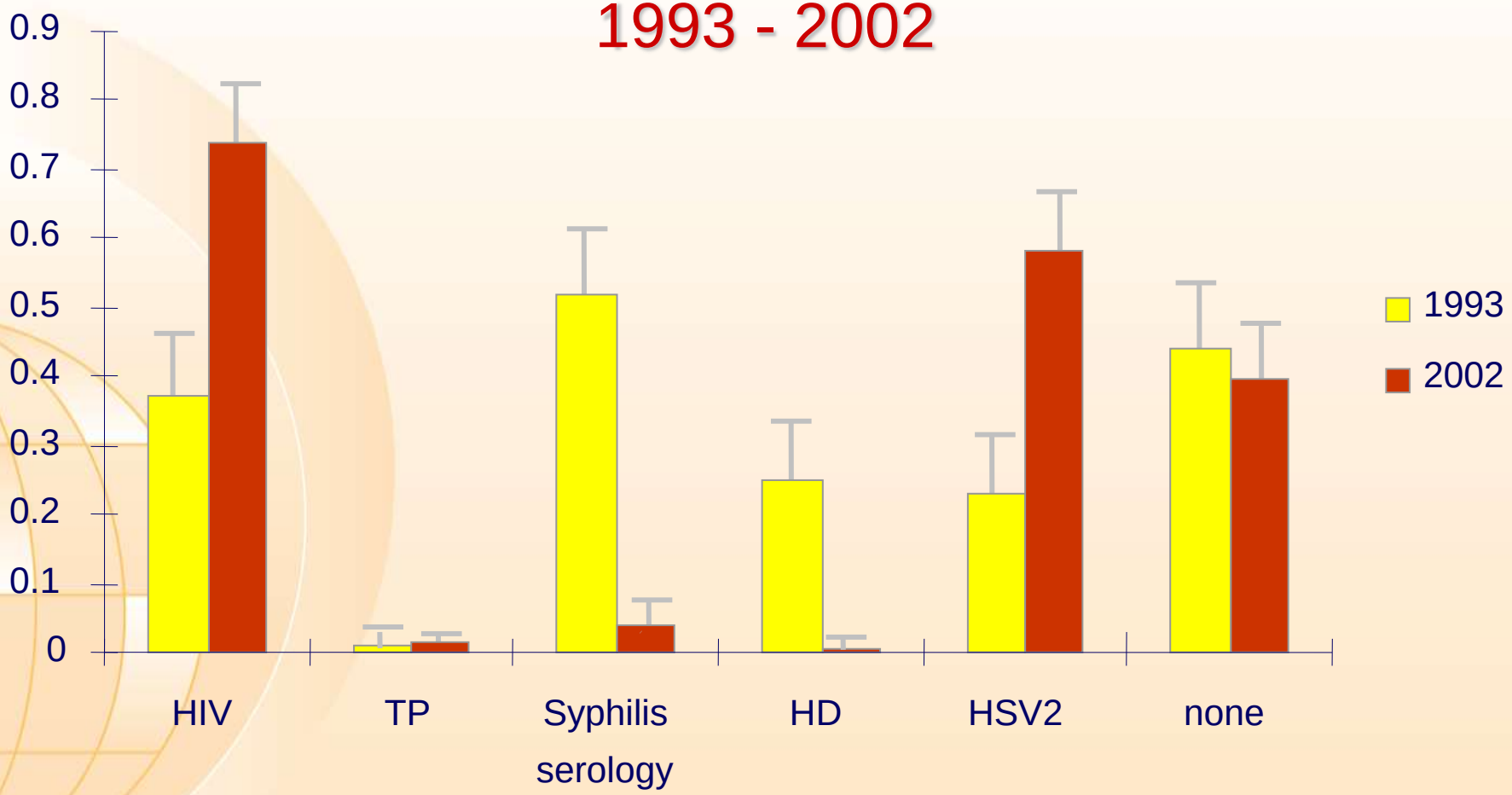
Aetiology of GUS by M-PCR and culture in Masaka, Uganda



TPHA/RPR - 15%
HIV - 30%

Source: Dr. Anatoli Kamali, Uganda

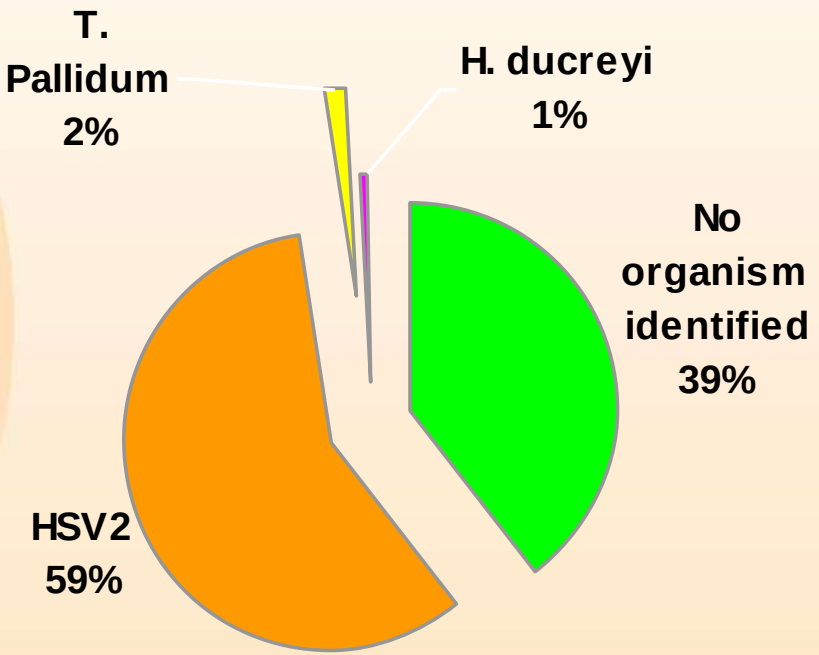
Botswana
Changes in the aetiology of GUD
1993 - 2002



*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, ISSTDR, Ottawa 2003

Botswana
Aetiology of genital ulcer disease 2002

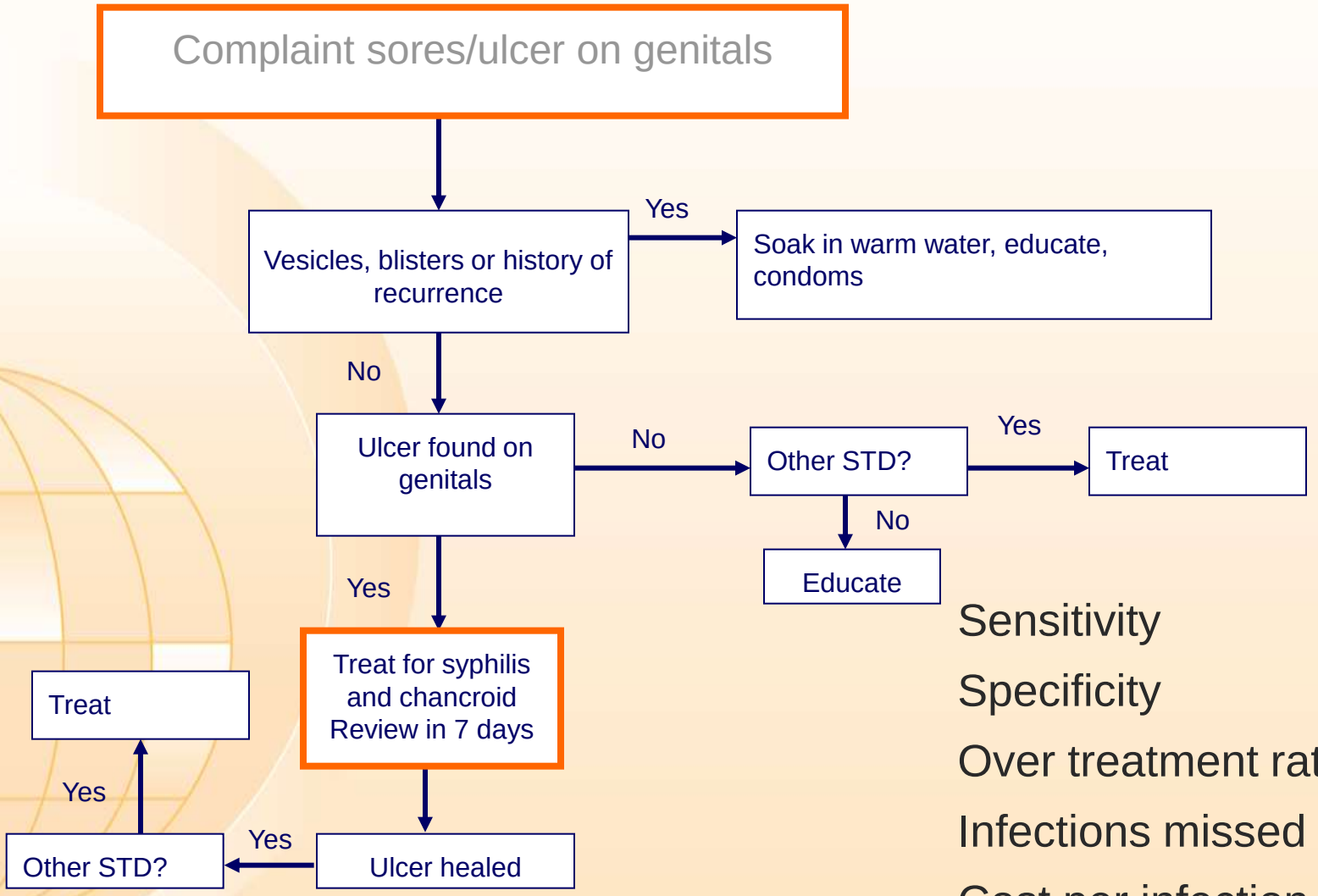


N=137

TPHA/RPR - 15%
HIV - 30%

Source: M. Rahman, ISSTDR, Ottawa 2003

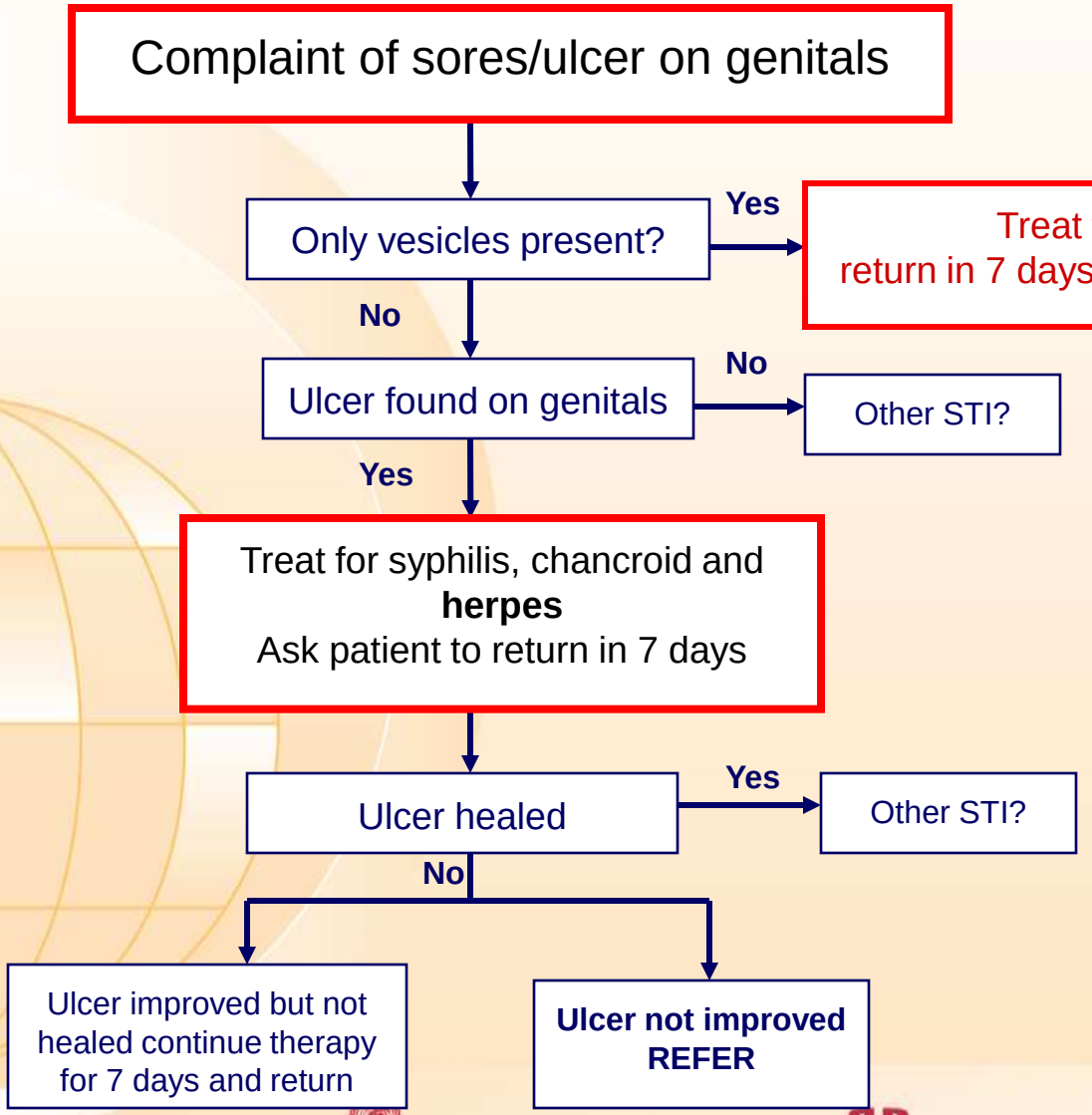
Current genital ulcer algorithm in Botswana



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

Source: M. Rahman, ISSTDR, Ottawa 2003

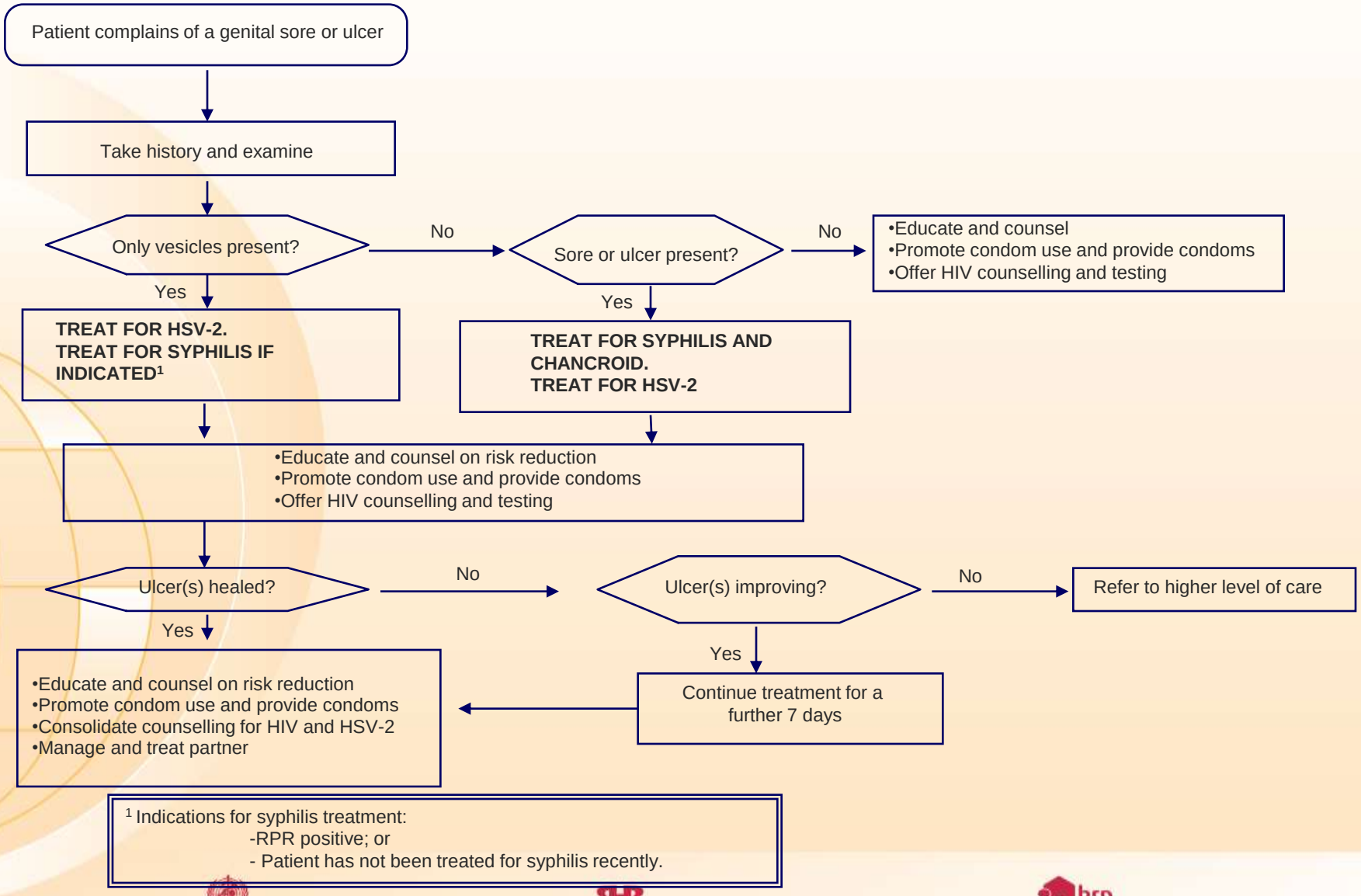
Piloted genital ulcer algorithm in Botswana



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

Source: M. Rahman, ISSTDR, Ottawa 2003

Genital ulcer disease



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

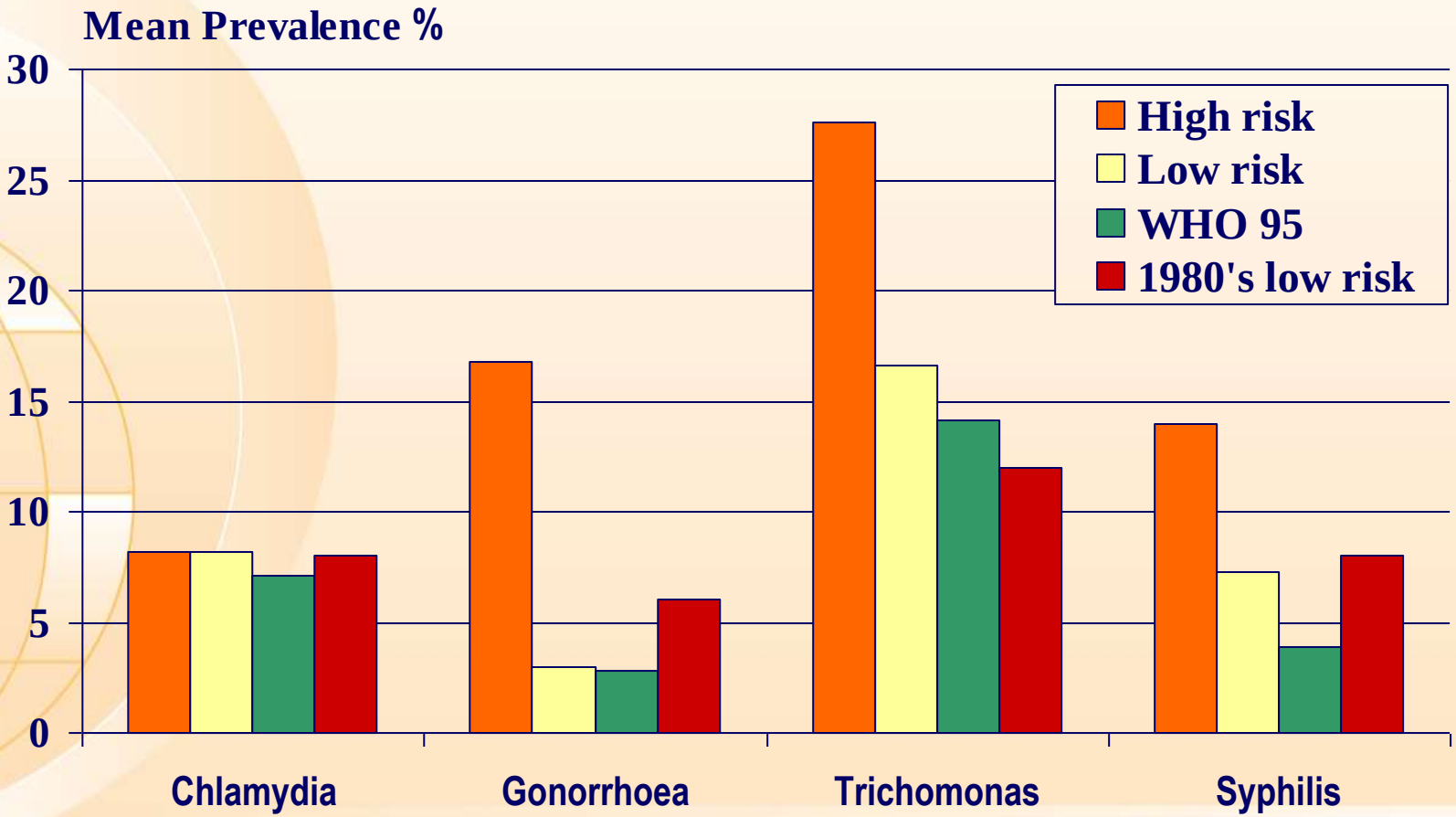

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Table of selected 1990's studies;Wasserheit & Holmes, 1992; Gerbase et al , Lancet 1998

Vaginal discharge syndrome

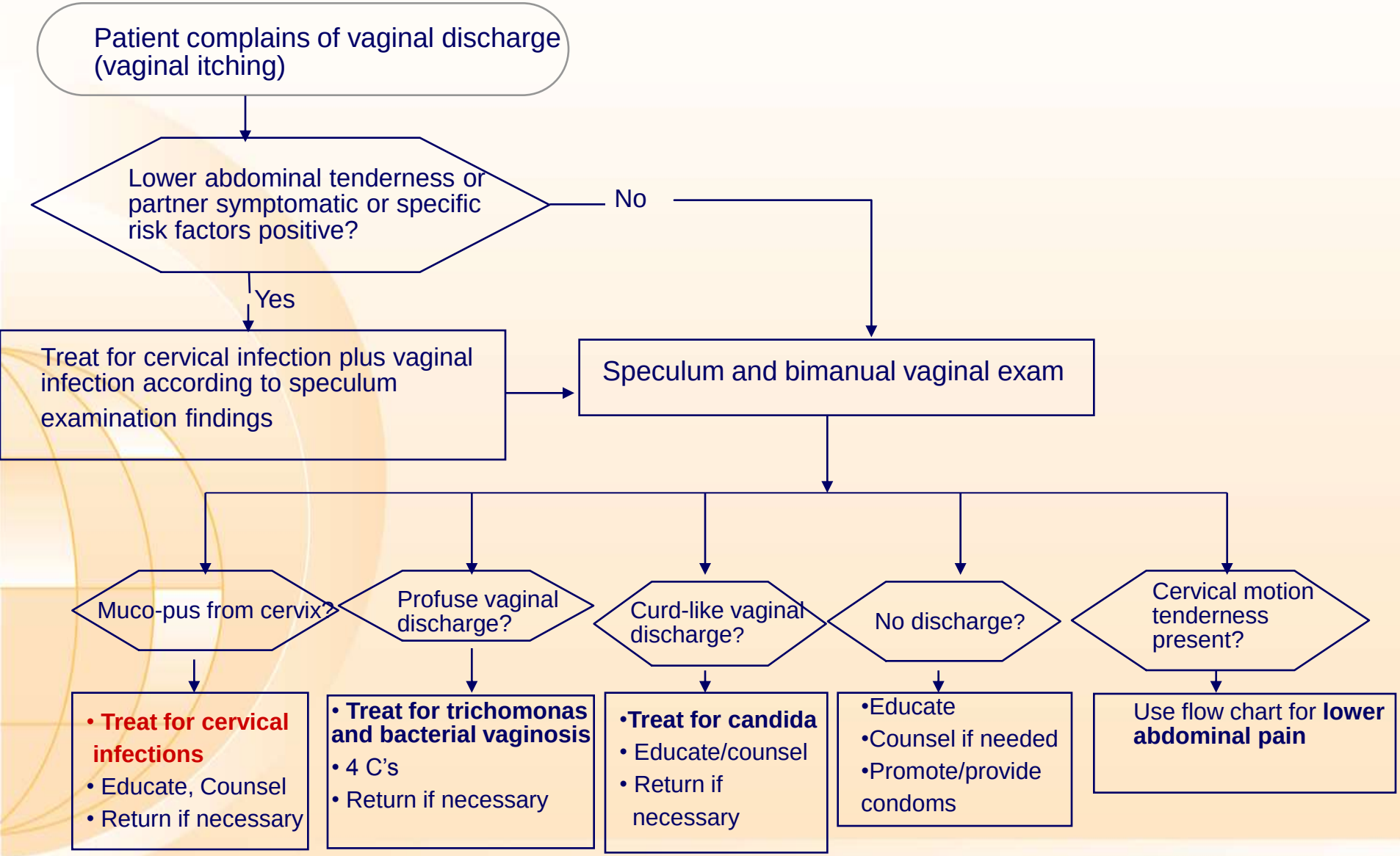
VAGINITIS

- 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)



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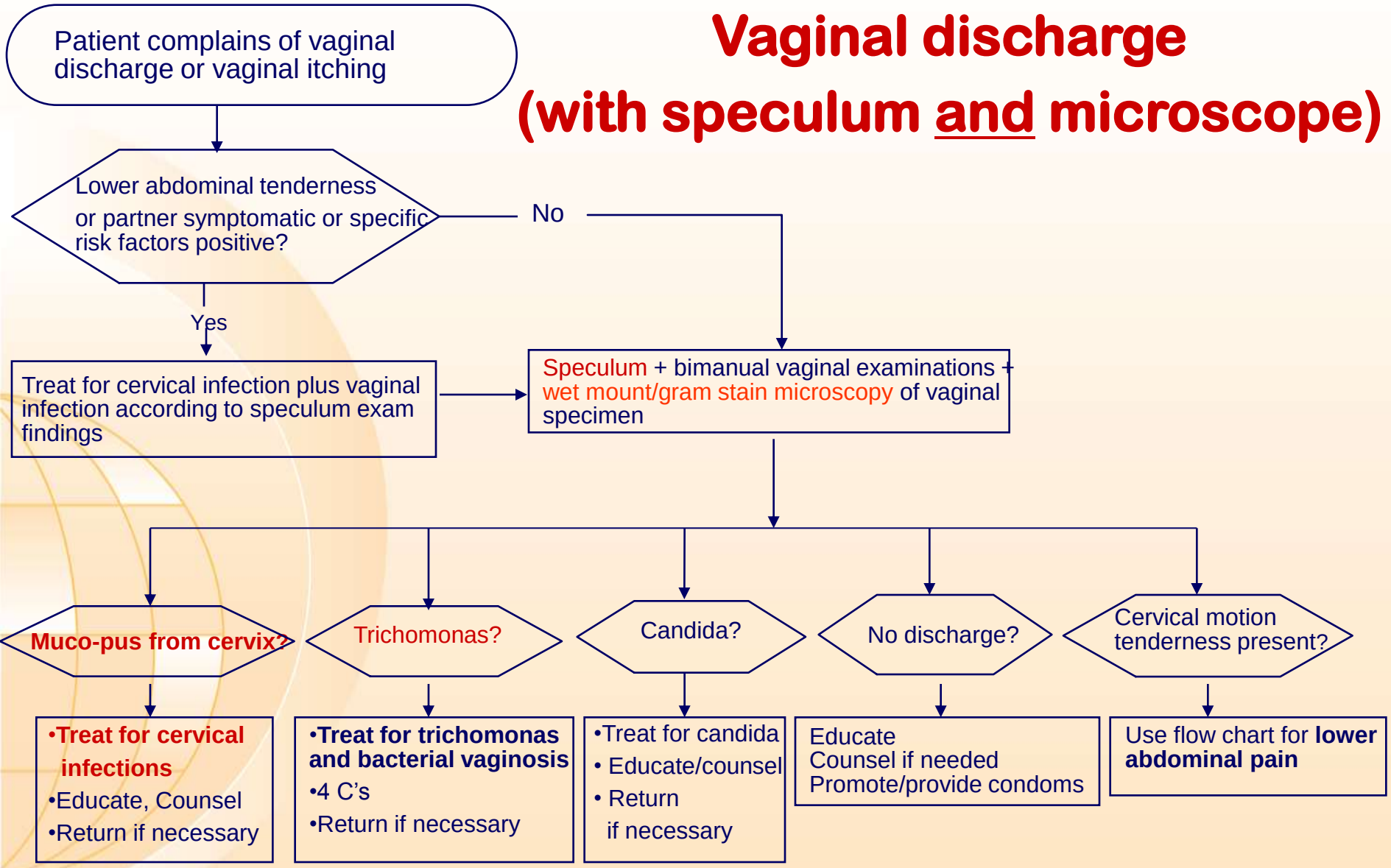
Vaginal discharge (with speculum and microscope)



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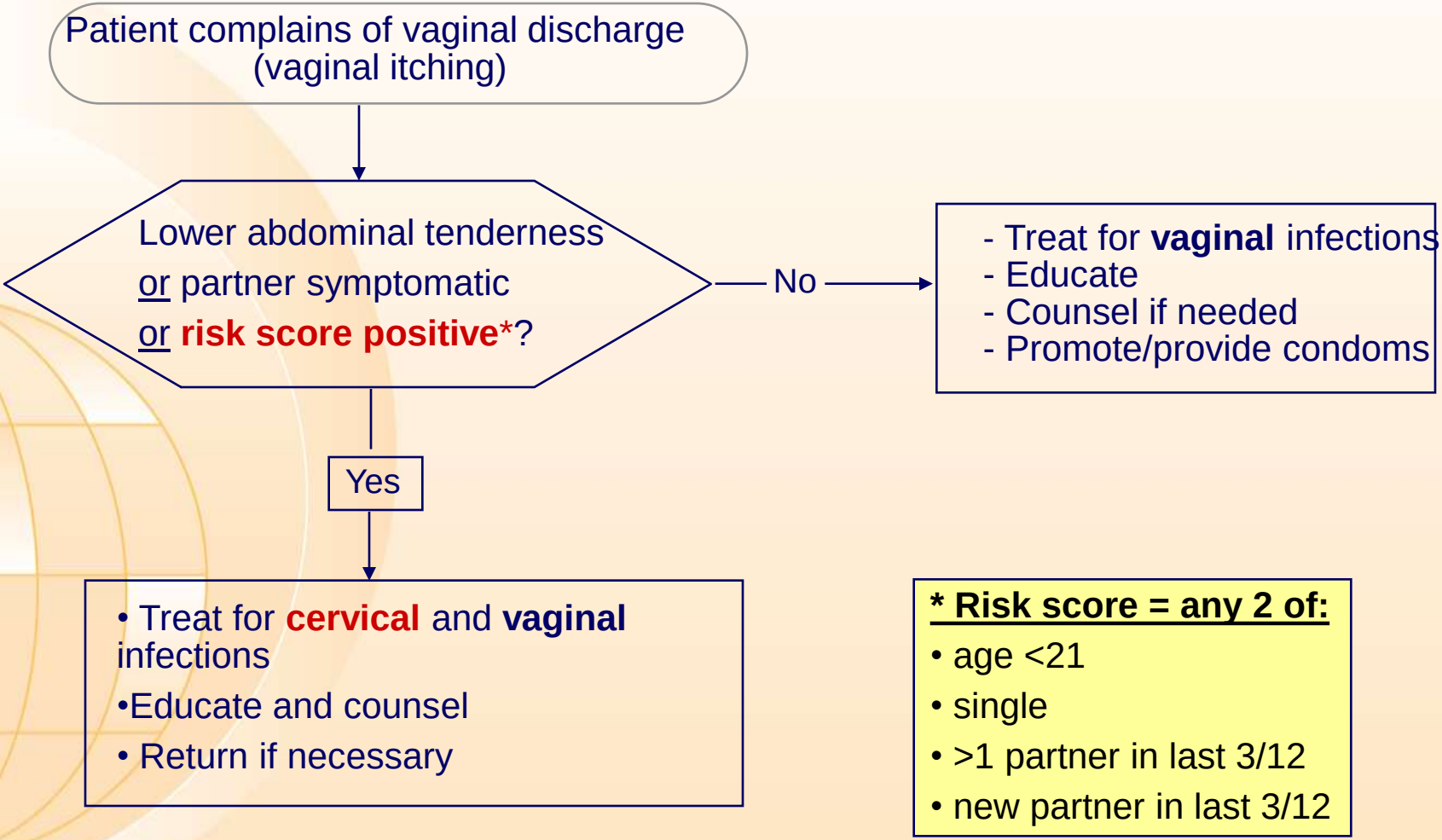
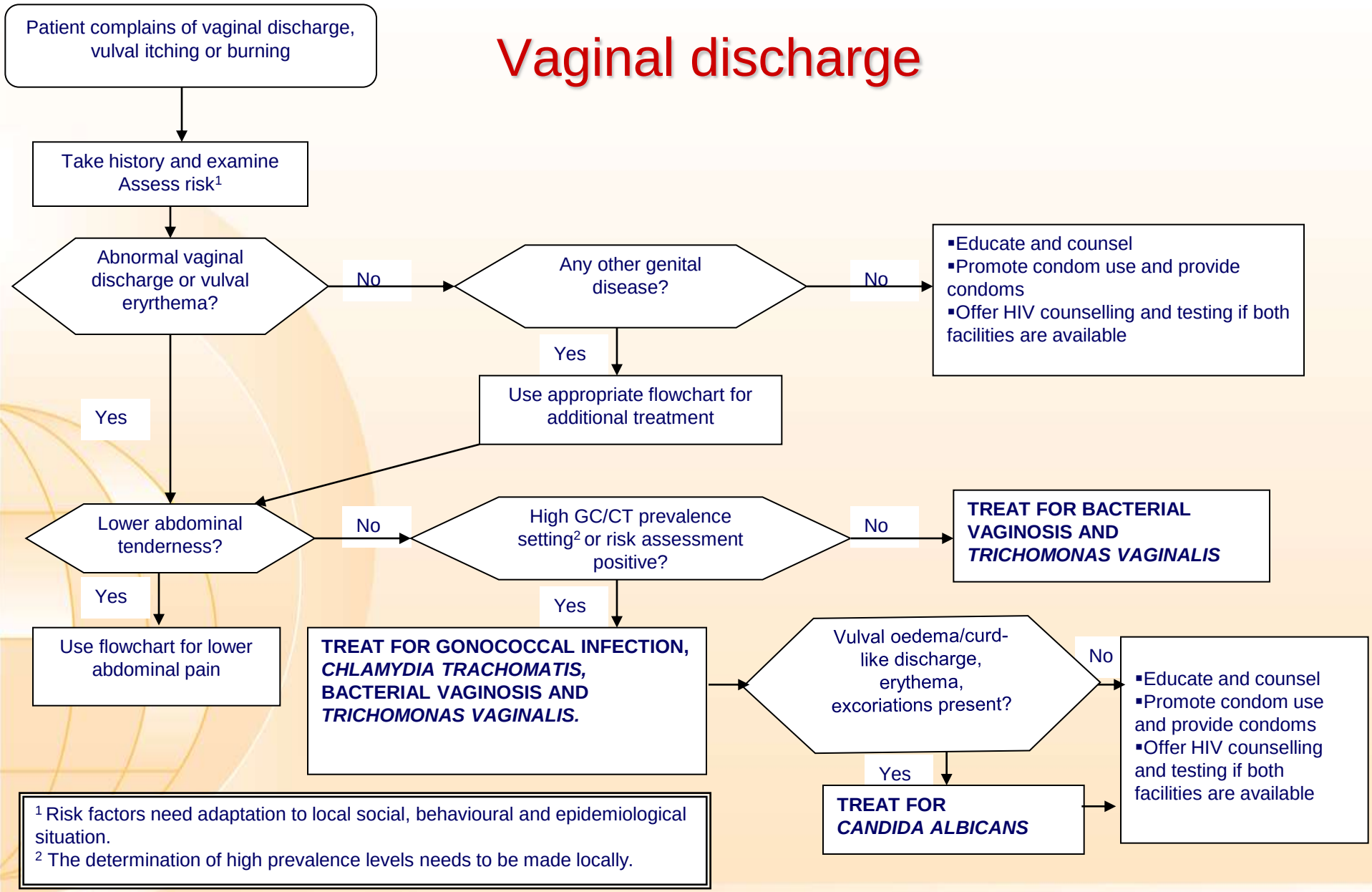
Vaginal discharge (without microscope, using risk score)

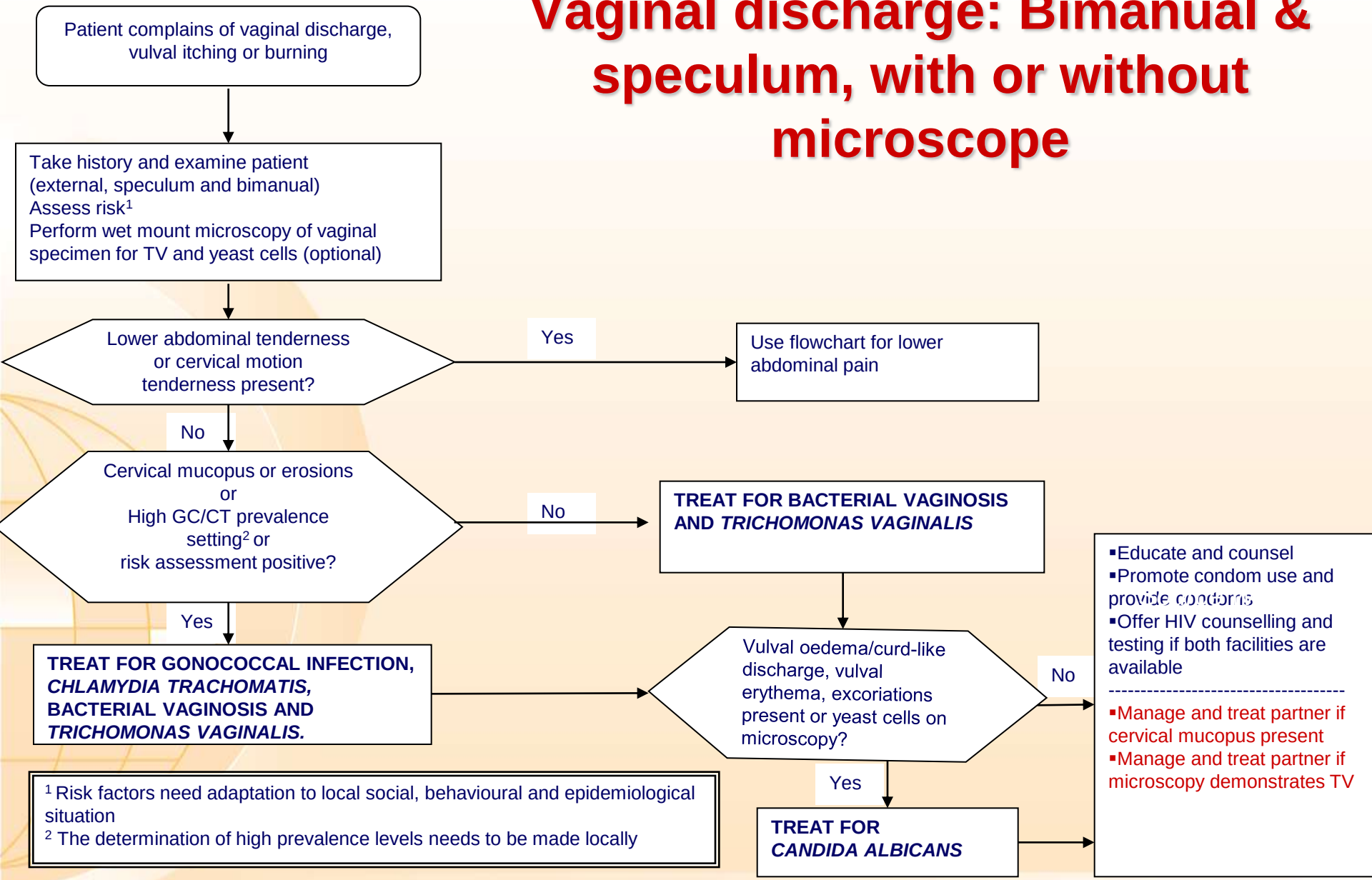


Vaginal discharge



[1] Risk factors need adaptation to local social, behavioural and epidemiological situation.
[2] The determination of high prevalence levels needs to be made locally.

Vaginal discharge: Bimanual & speculum, with or without microscope



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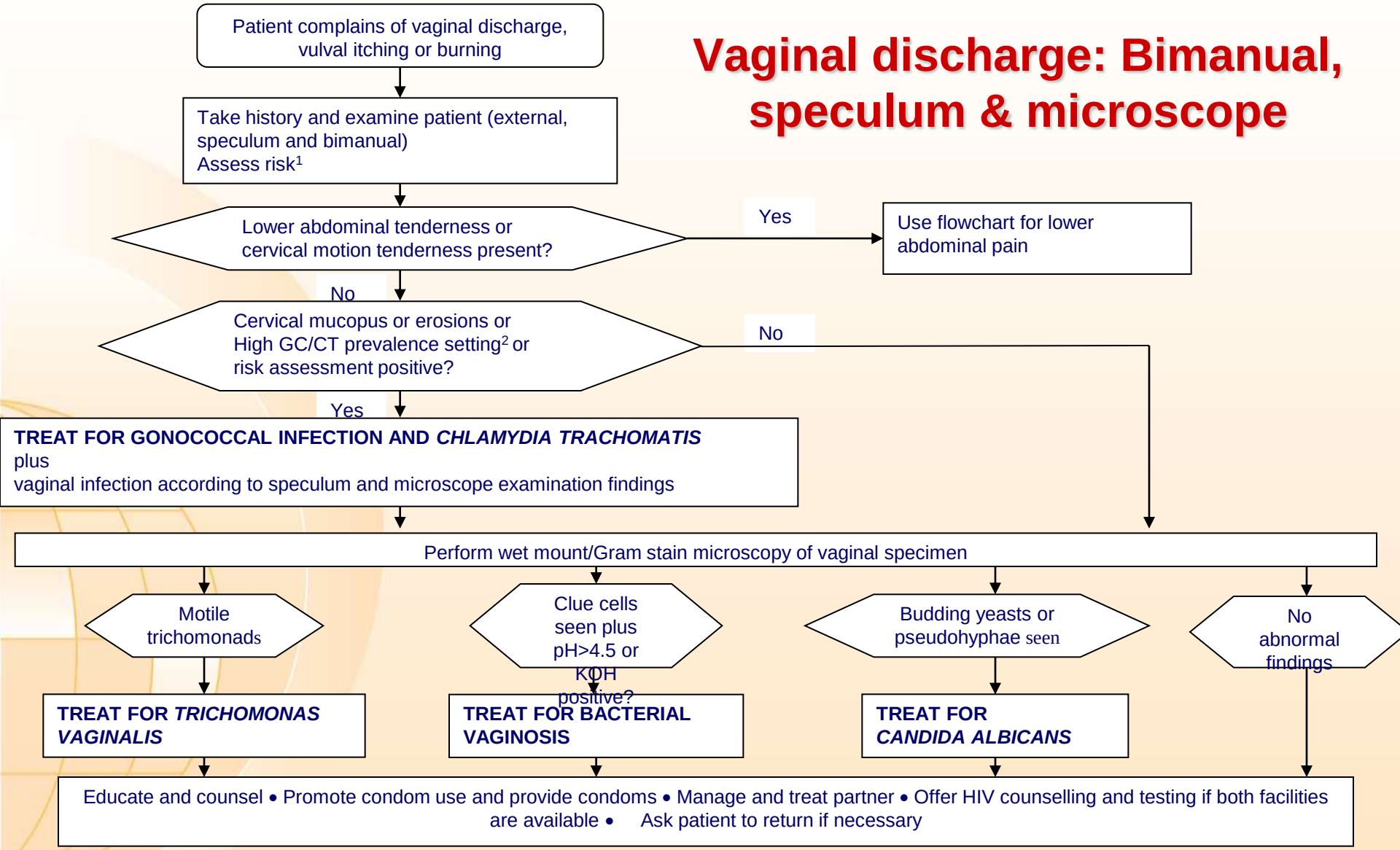
Vaginal discharge: Bimanual, speculum & microscope



[1]Risk factors need adaptation to local social, behavioural and epidemiological situation
[2] 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

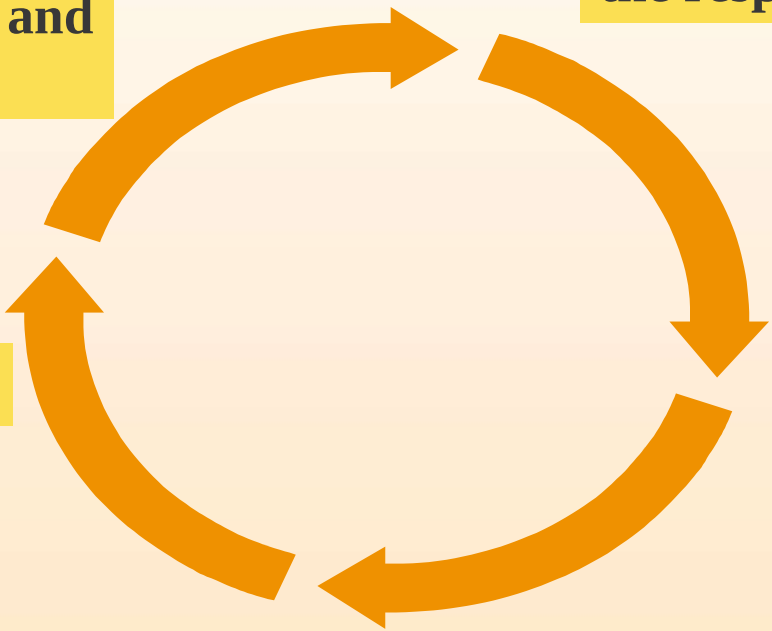
IMPLEMENTATION

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

Monitoring & Evaluation



Assess the epidemic and the response

Advocate for STI inclusion in the health- care agenda

Adopt and adapt evidence -based interventions

Strengthen STI programme management and intervention activities

Train and supervise

Evaluate programme and interventions

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

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

Algorithm	Gold Standard test +	Gold Standard test -
+	A: (true +ve) Correctly treated	B: (false ve+) Over-treated
-	C: (false -ve) Missed infections	D: (true -ve) Correctly diagnosed as negative
	Total infected	Total not infected

Validity of an algorithm Interpretation

Algorithm	Gold Standard test +	Gold Standard test -
+	A: (true +ve)	B: (false ve+)
-	C: (false -ve)	D: (true -ve)
	Total infected	Total non infected

Sensitivity: A/A+C
Specificity: D/B+D
Positive Predictive Value: A/A+B
Negative Predictive Value: D/C+D

COST PER CASE CURED

$$\frac{\text{Total cost of all diagnoses + treatments}}{\text{Number of cases cured}}$$

Cost per case cured decreases if

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

END