Designing & Evaluating Clinical Algorithms for STI Case Management

Francis J. Ndowa
WHO
RHR/STI

Training Course in Sexual and Reproductive Health Research
Geneva, 2010

World Health Organization
Reproductive Health and Research
UNDP • UNFPA • WHO • World Bank
Special Programme of Research, Development and Research Training in Human Reproduction

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:

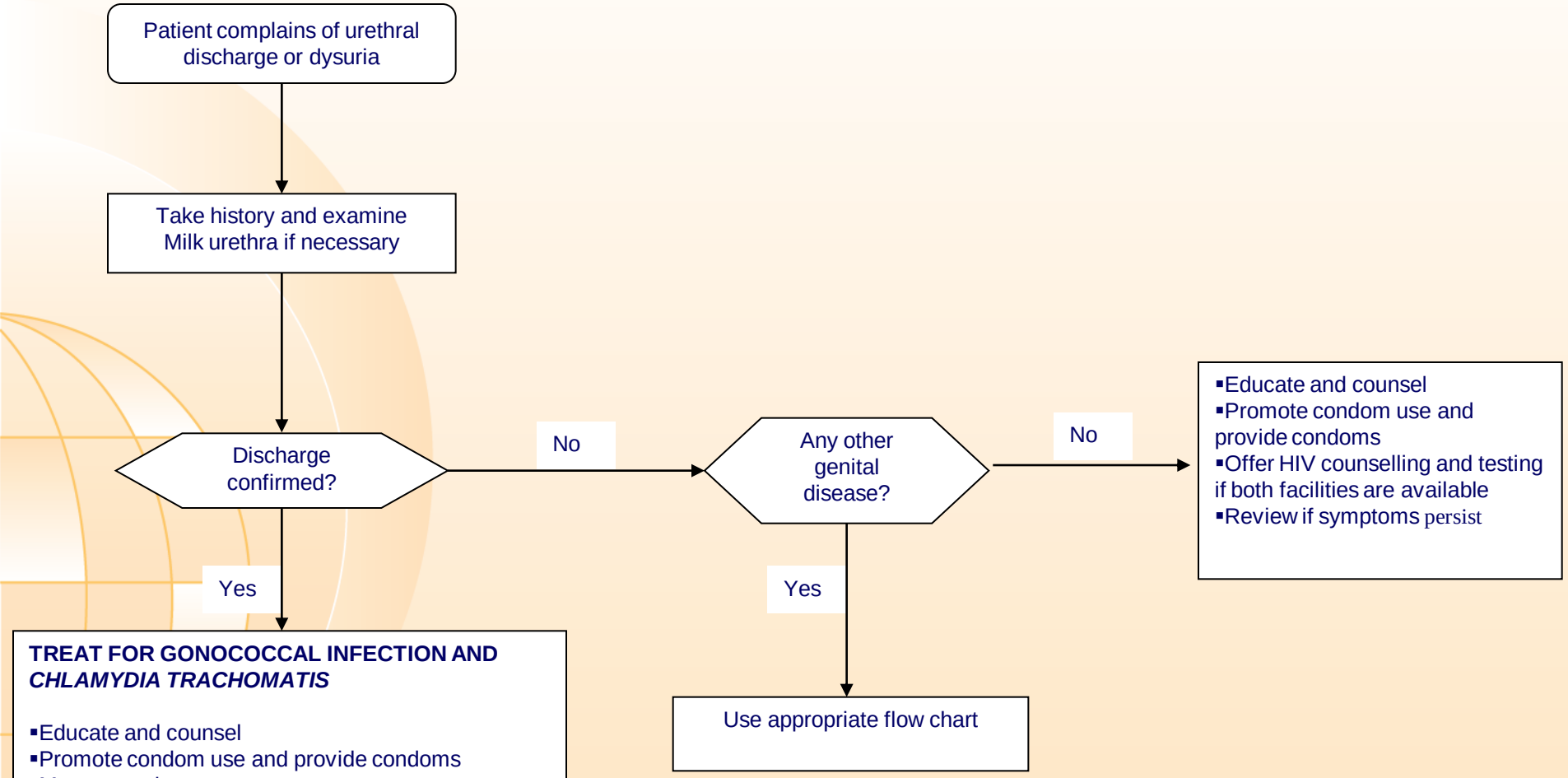
  treat the main organisms responsible for causing the syndrome

How syndromic management works

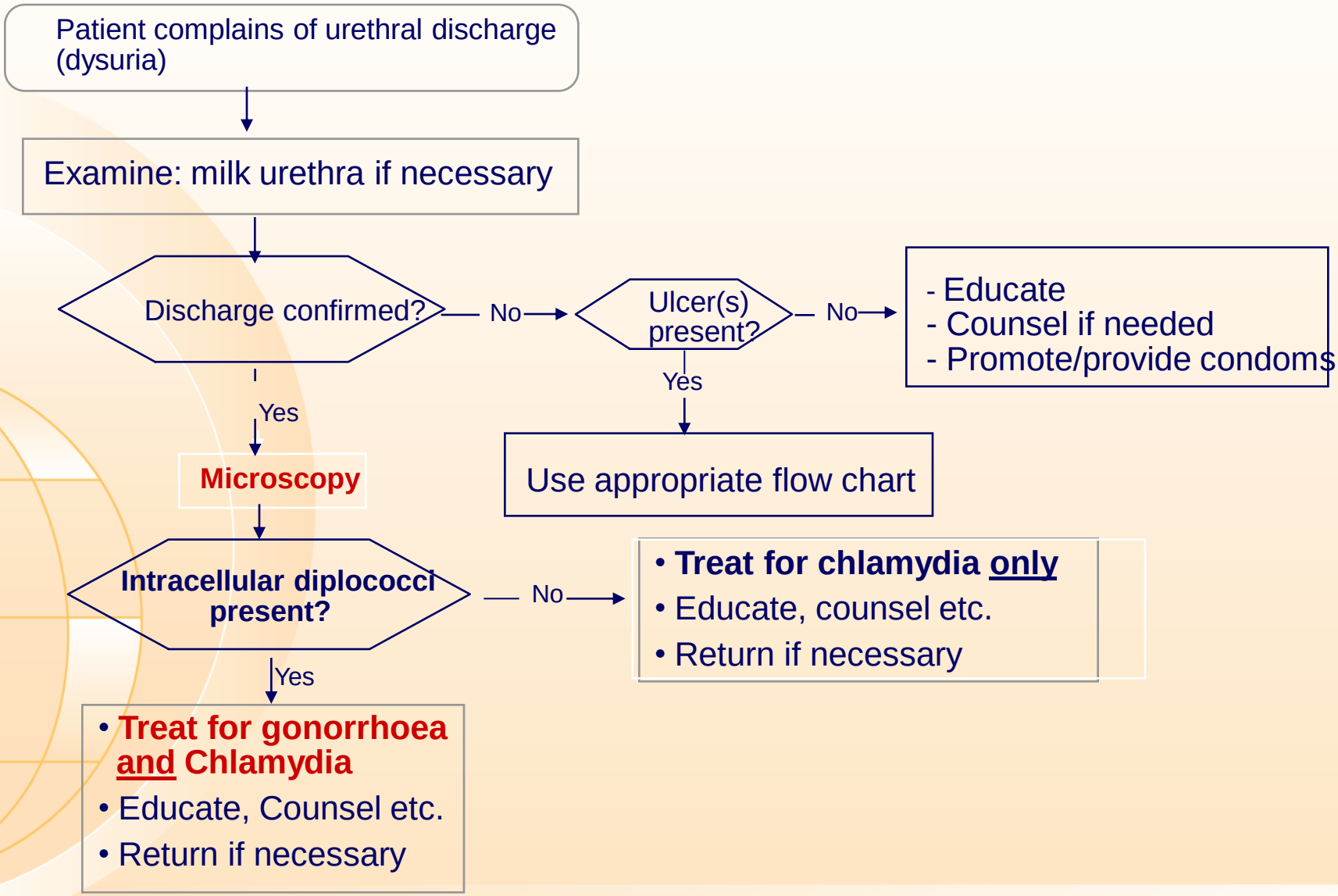
Through a series of flow-charts:

- 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

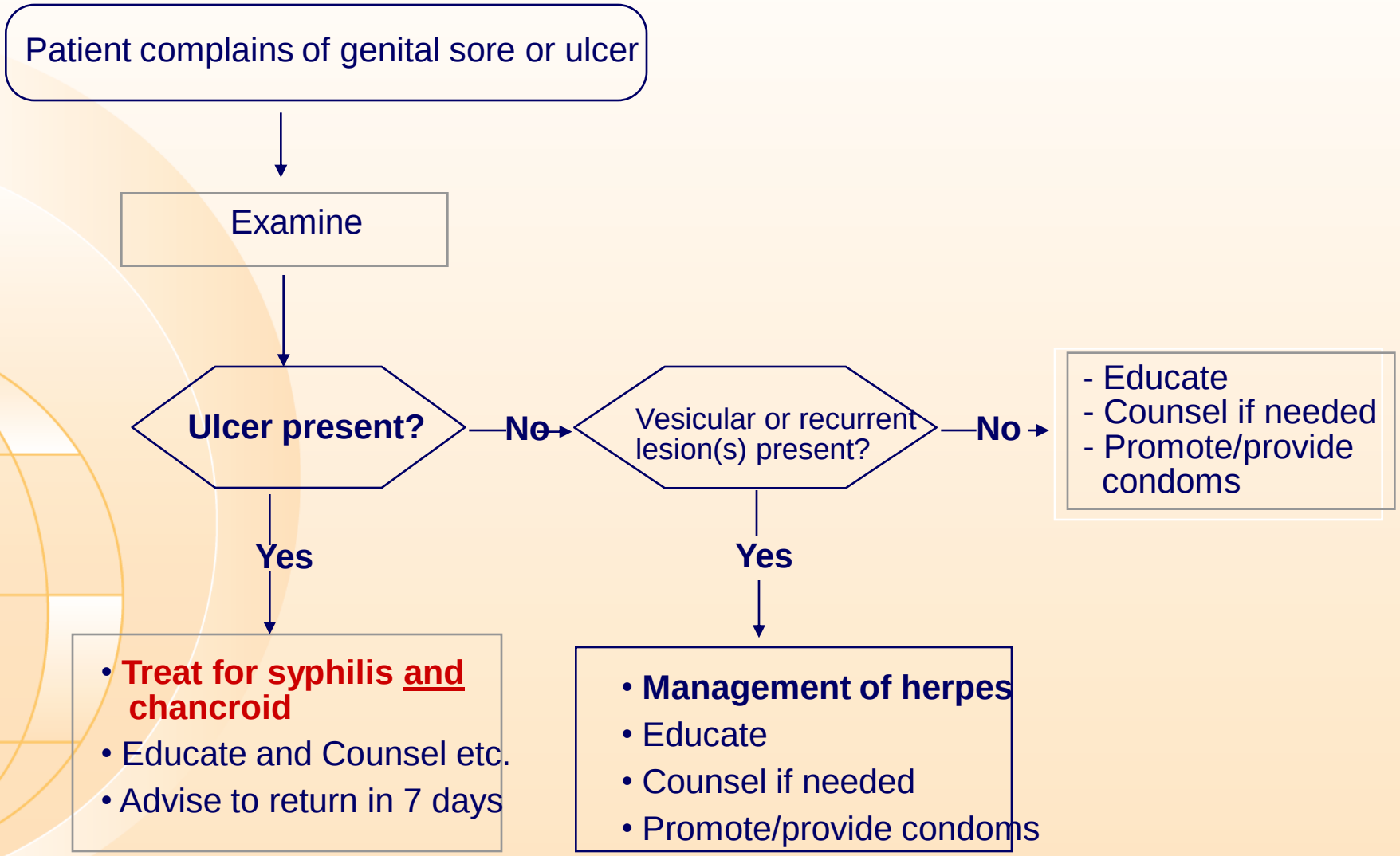
Urethral Discharge



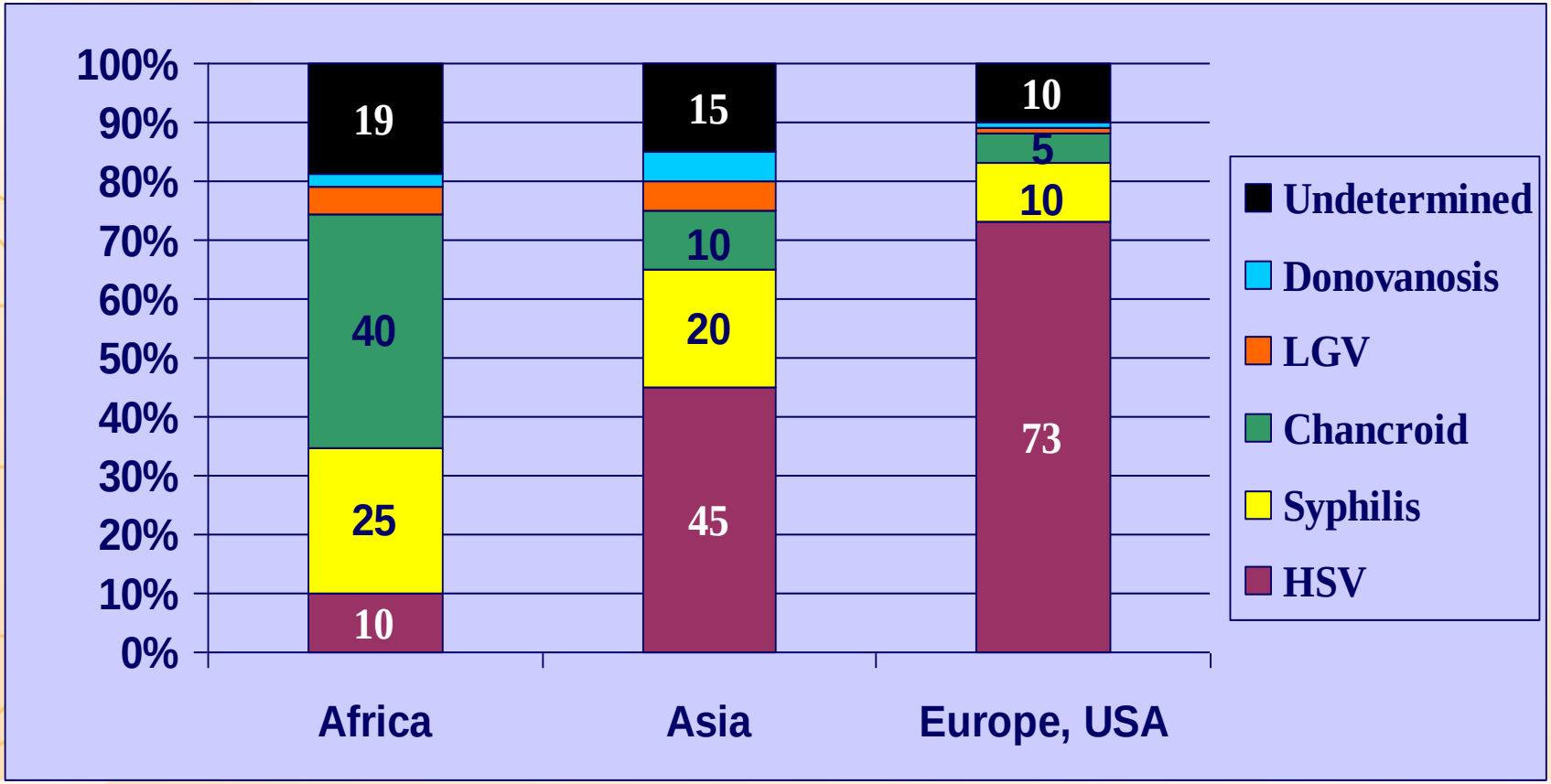
Urethral discharge (with microscope)



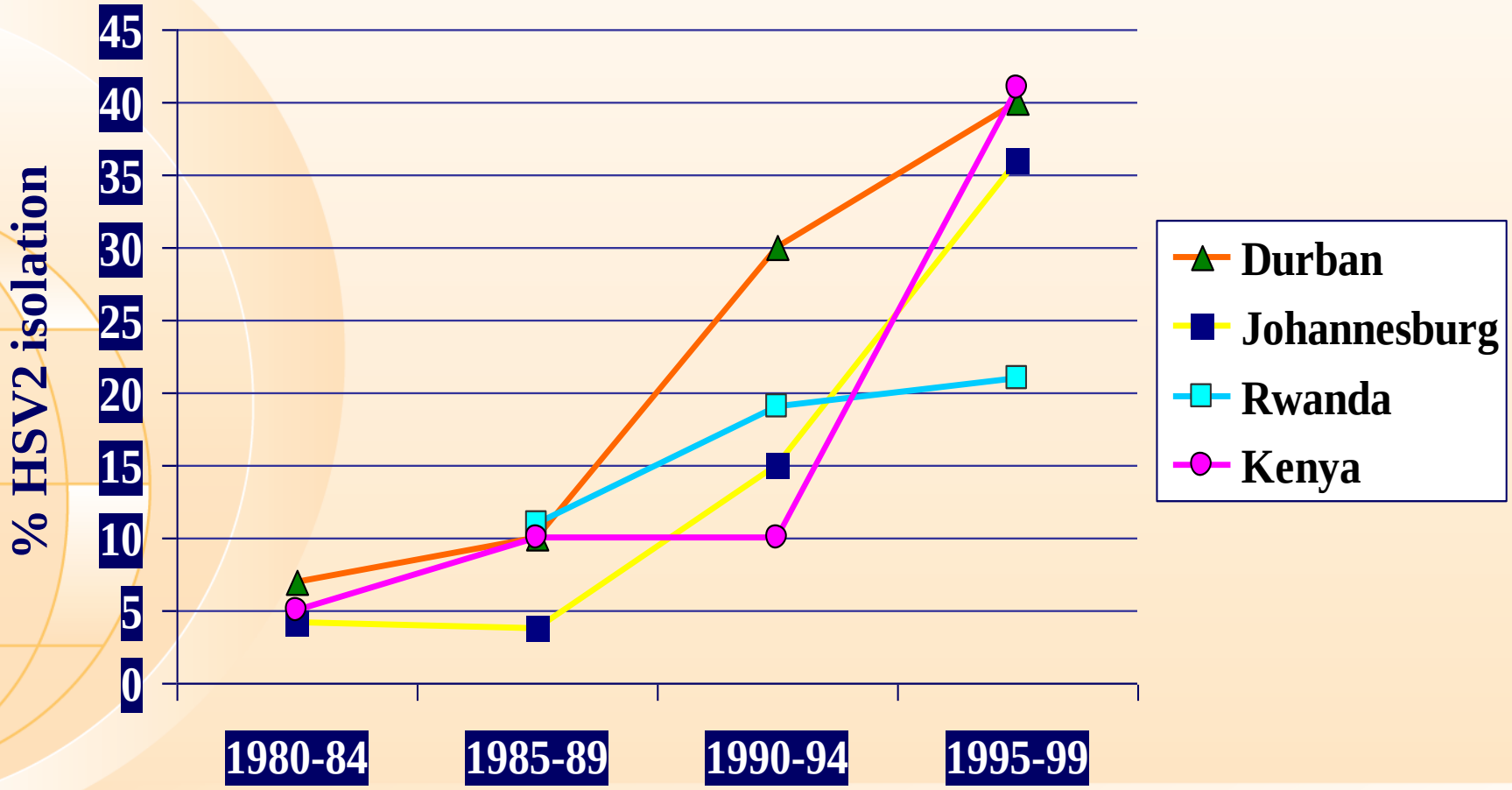
Genital ulcers



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



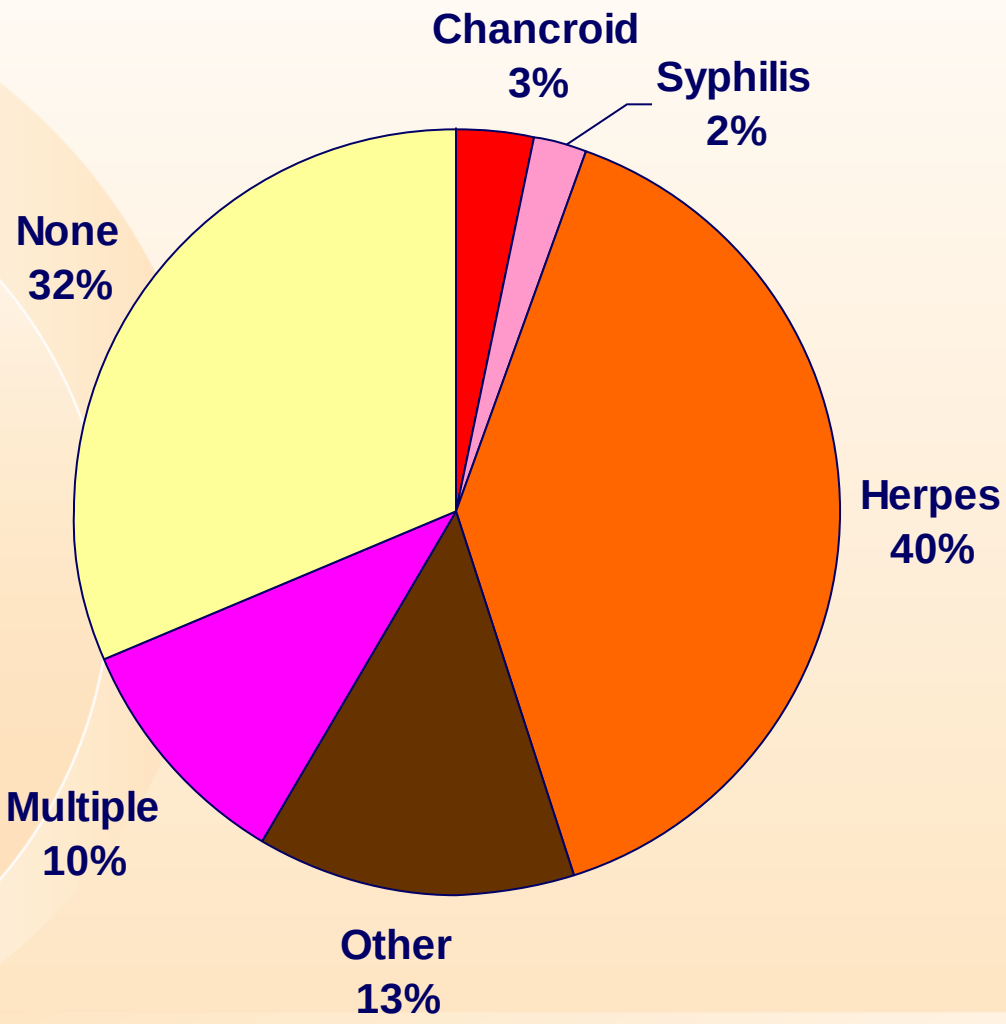
World Health Organization

Reproductive Health and Research

UNDP • UNFPA • WHO • World Bank
Special Programme of Research, Development and Research Training in Human Reproduction

Mayaud & Mc Cormick, Br Med Bull 2001

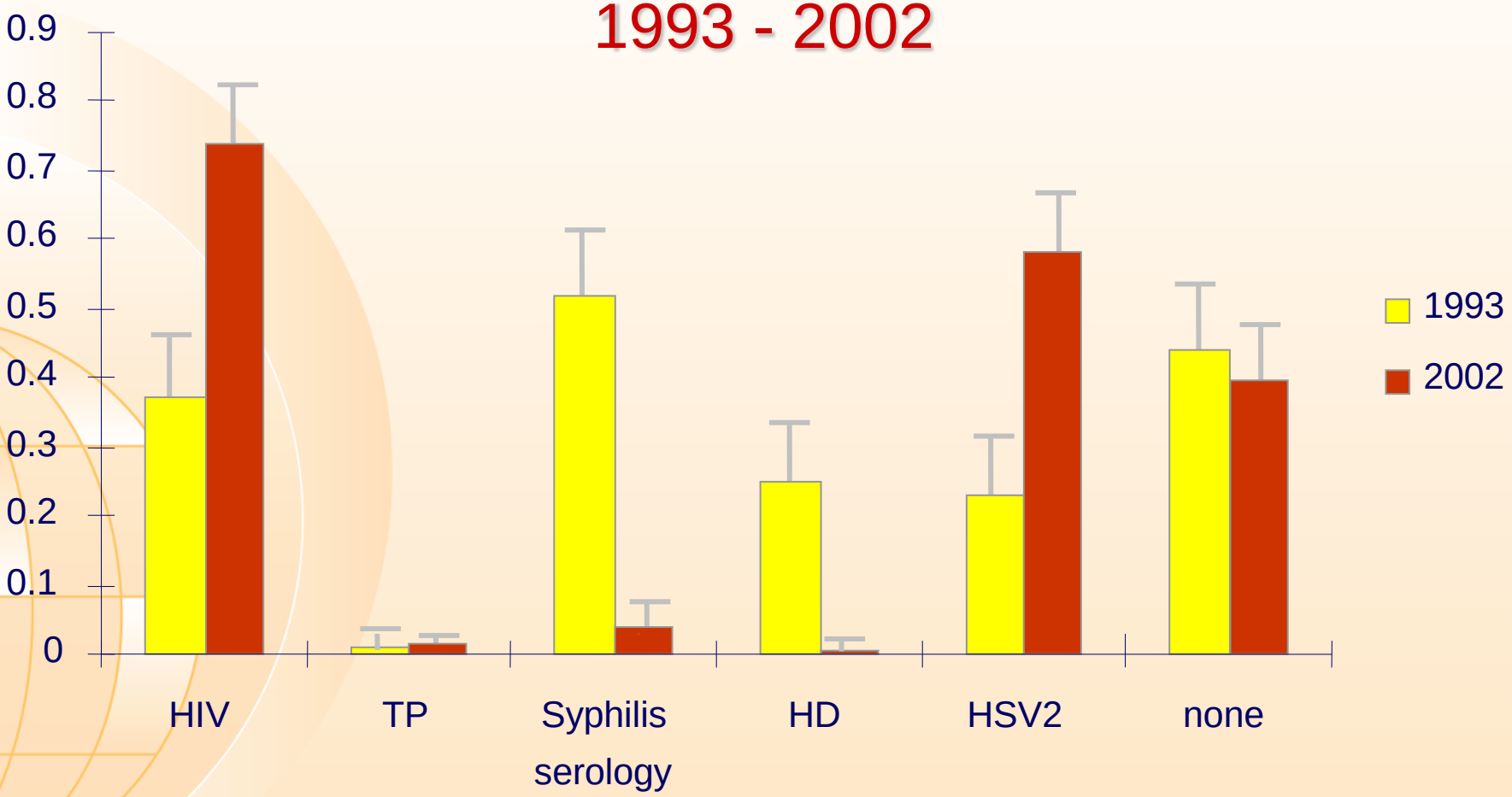
Aetiology of GUS by M-PCR and culture in Masaka, Uganda



TPHA/RPR - 15%
HIV - 30%

Source: Dr. Anatoli Kamali, Uganda

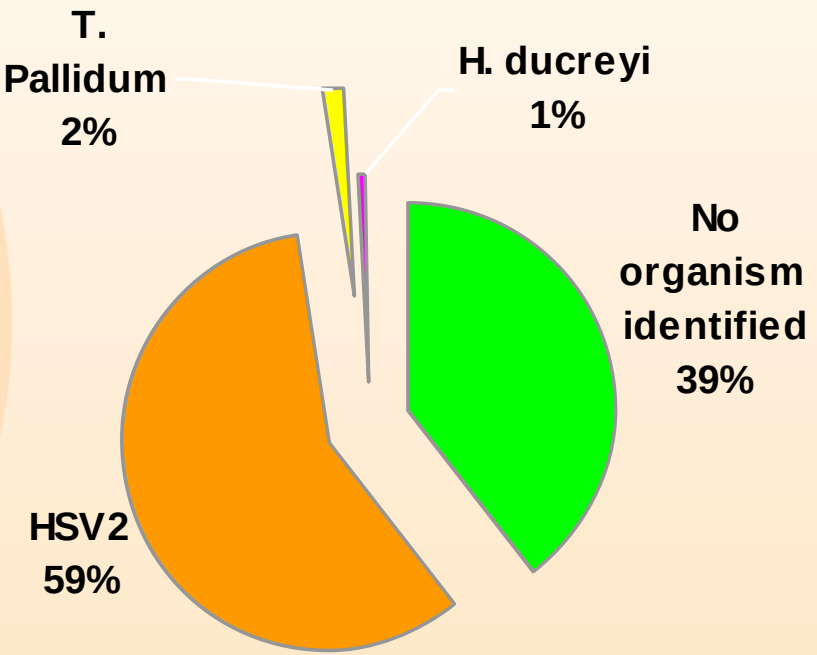
Botswana
Changes in the aetiology of GUD
1993 - 2002



*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

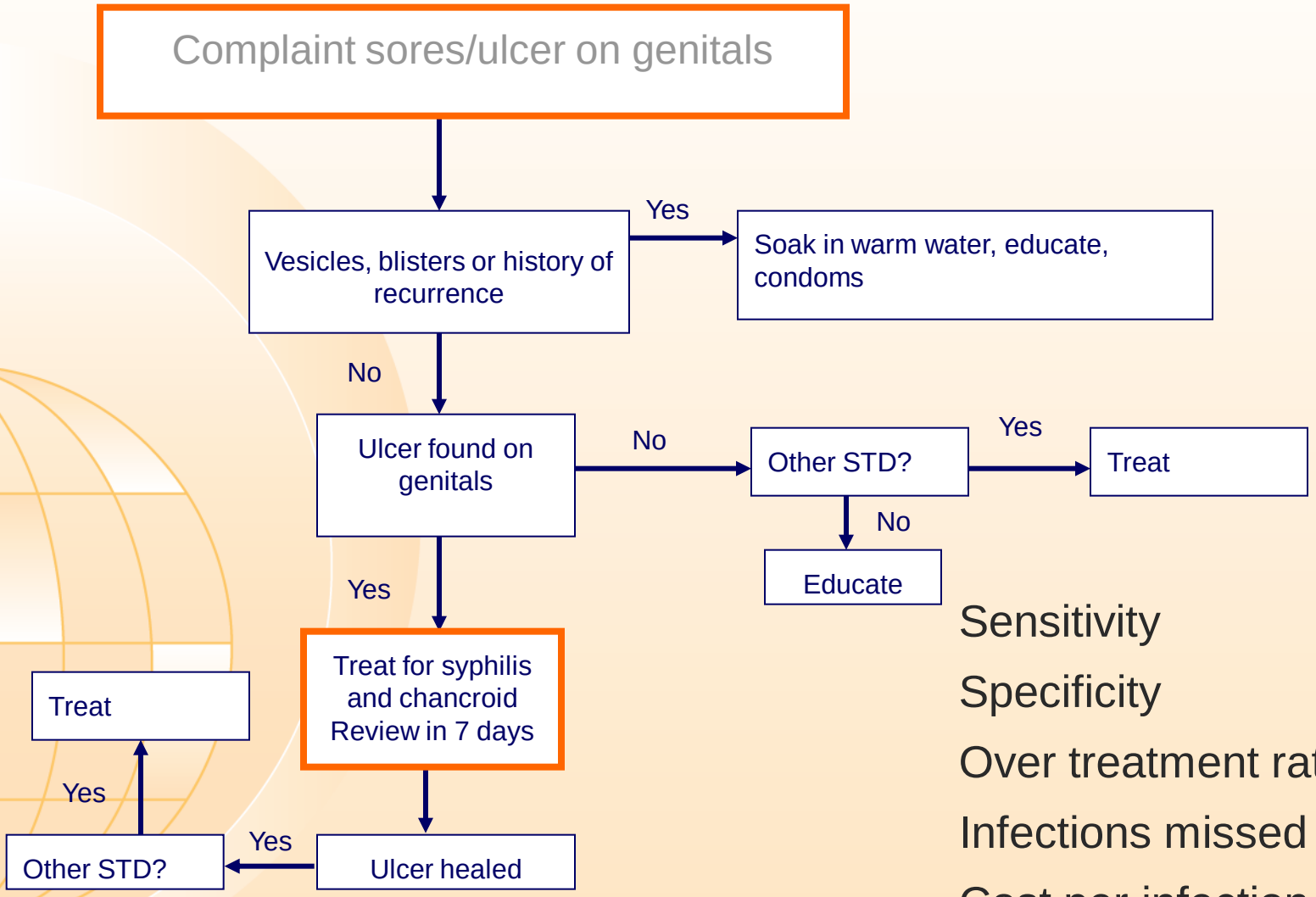


N=137

TPHA/RPR - 15%
HIV - 30%

Source: M. Rahman, ISSTDR, Ottawa 2003

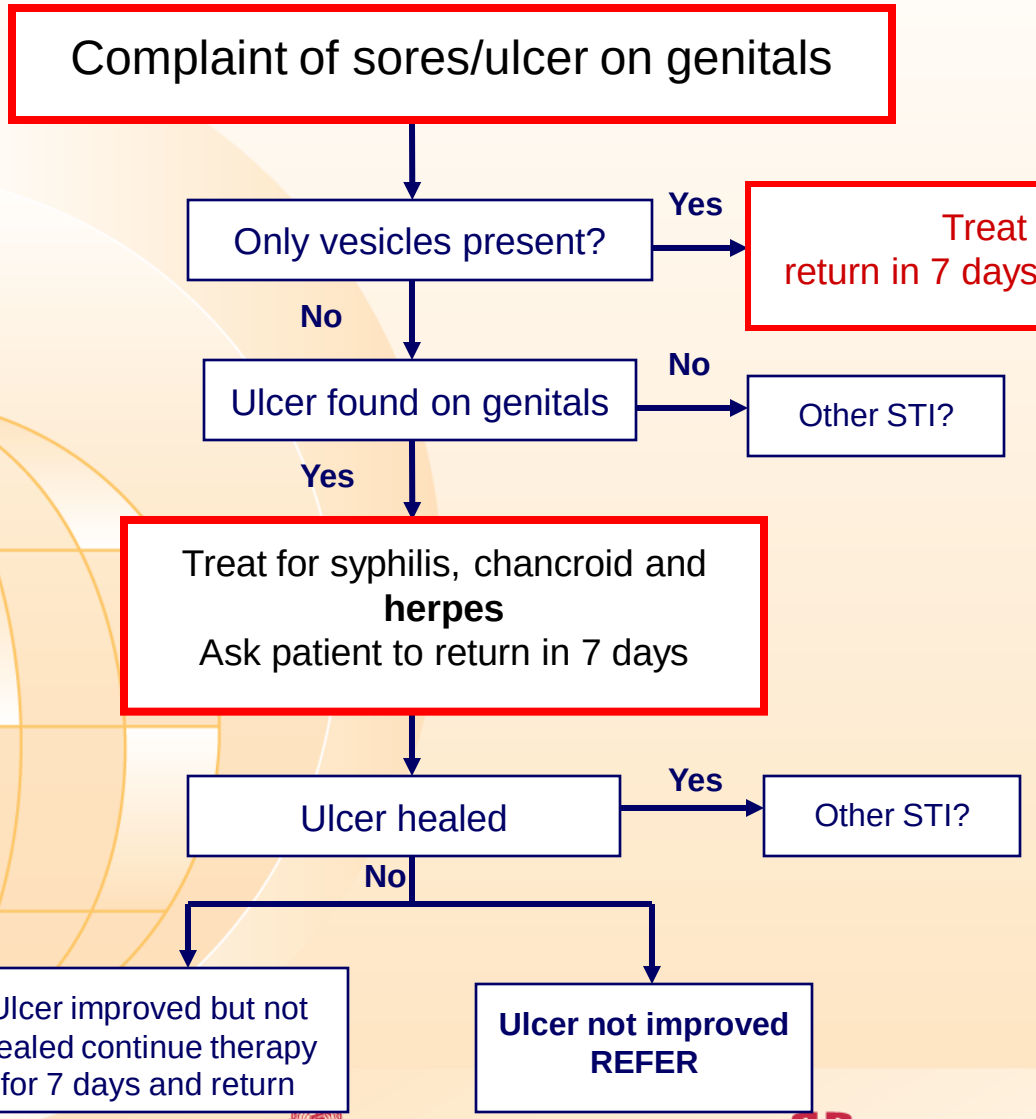
Current genital ulcer algorithm in Botswana



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

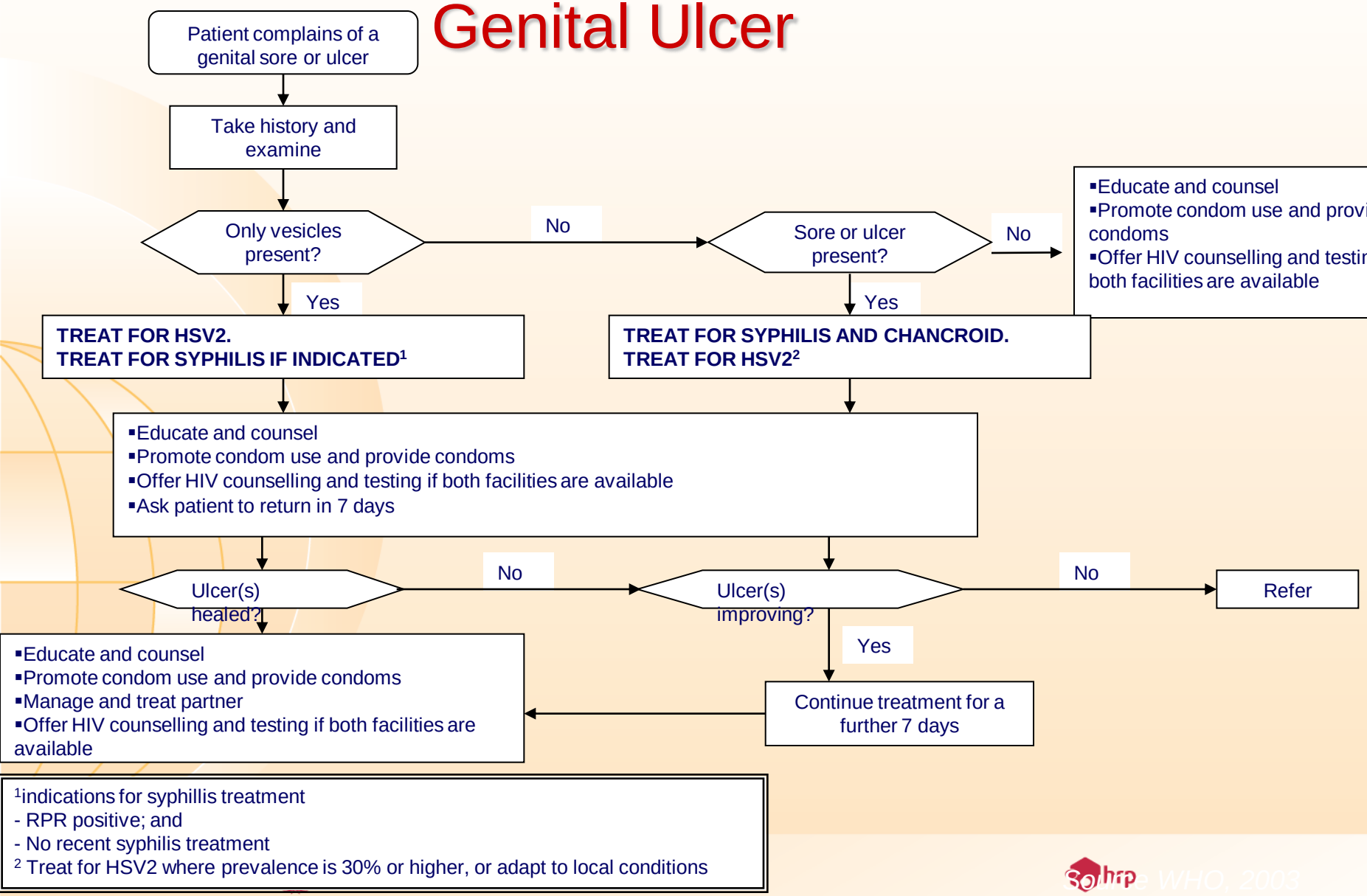
World Health Organization

Reproductive Health and Research

UNDP • UNFPA • WHO • World Bank
Special Programme of Research, Development and Research Training in Human Reproduction

Source: M. Rahman, ISSTDR, Ottawa 2003

Genital Ulcer

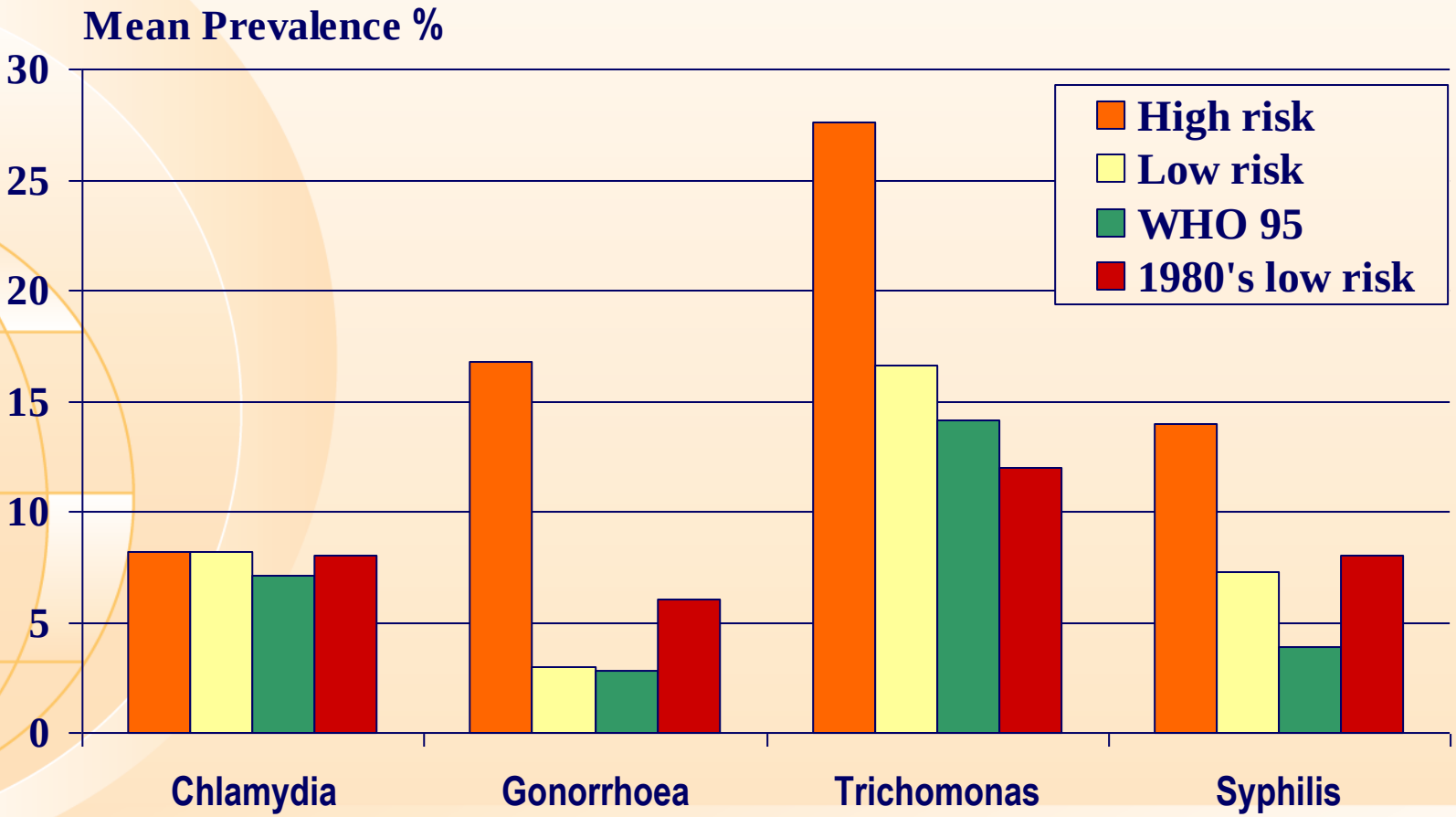


[1]indications for syphillis treatment
- RPR positive; and
- No recent syphilis treatment

[2] Treat for HSV2 where prevalence is 30% or higher, or adapt to local conditions

UNDP • UNFPA • WHO • World Bank
Special Programme of Research, Development and Research Training in Human Reproduction

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



World Health Organization

Reproductive Health and Research

UNDP • UNFPA • WHO • World Bank
Special Programme of Research, Development and Research Training in Human Reproduction

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

Vaginal discharge syndrome

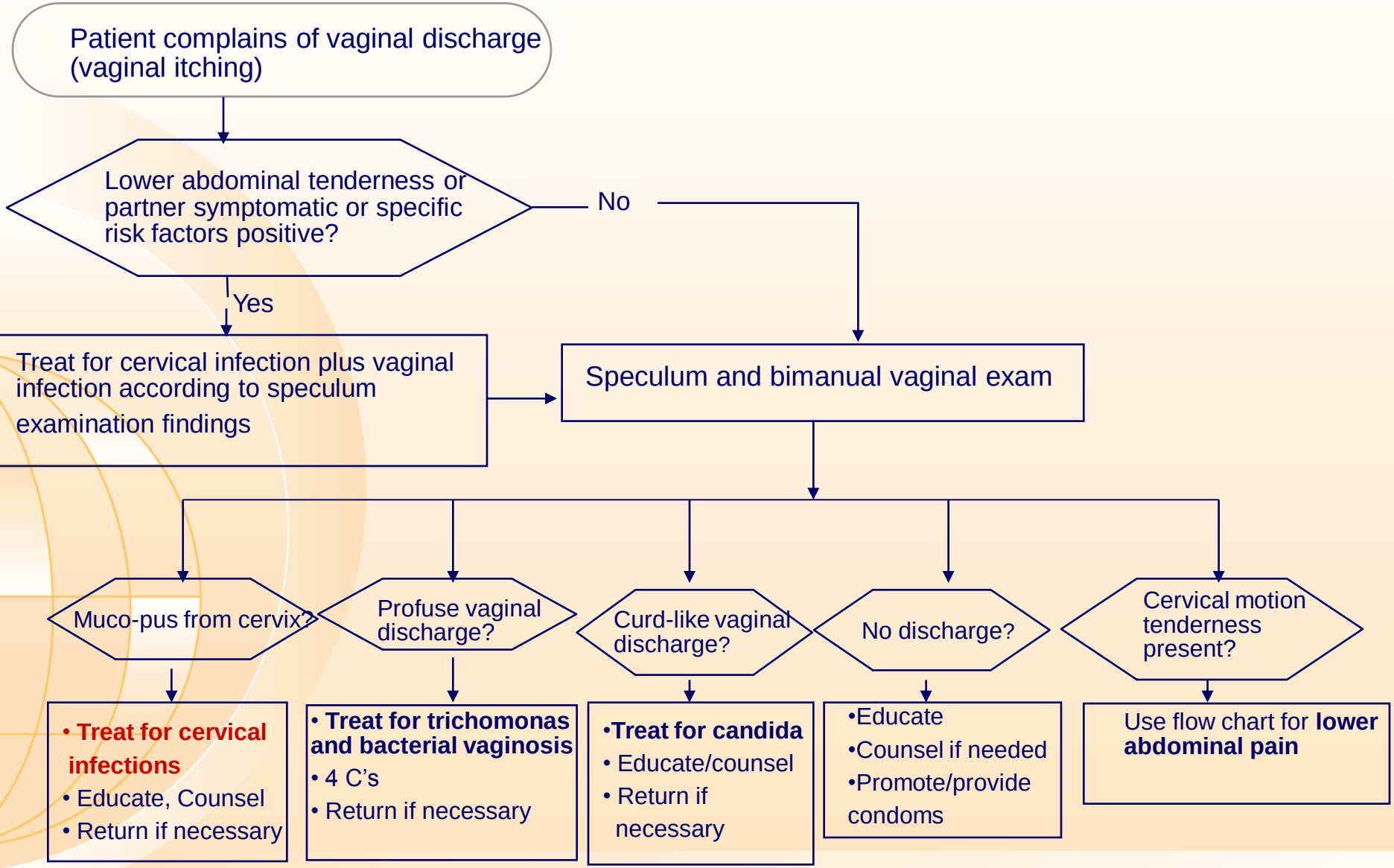
VAGINITIS

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

CERVICITIS

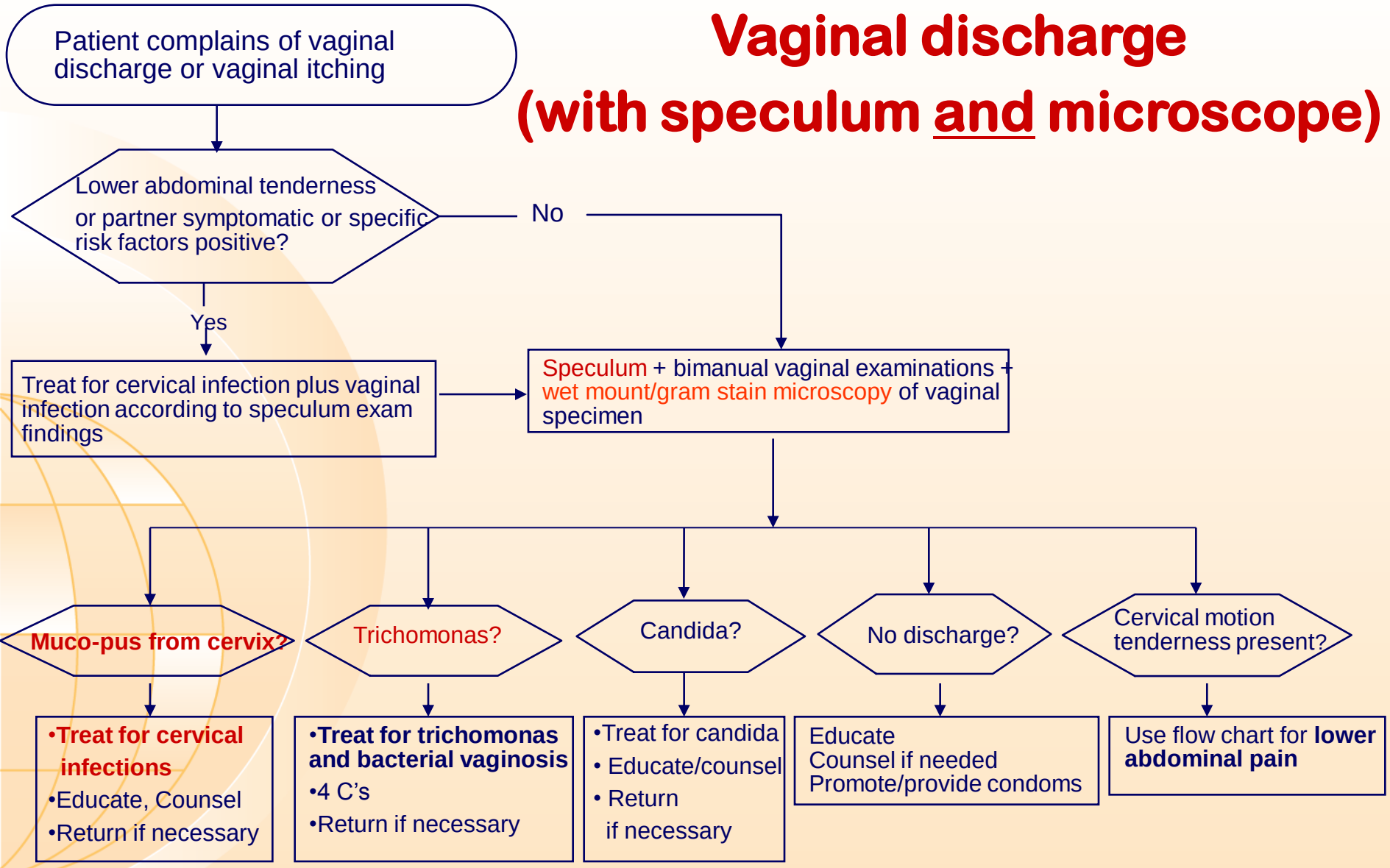
- less common causes
- not easy to diagnose
  - no simple tests
- complications ++
  - PID
  - ectopic pregnancy
  - infertility

Vaginal discharge (with speculum only)



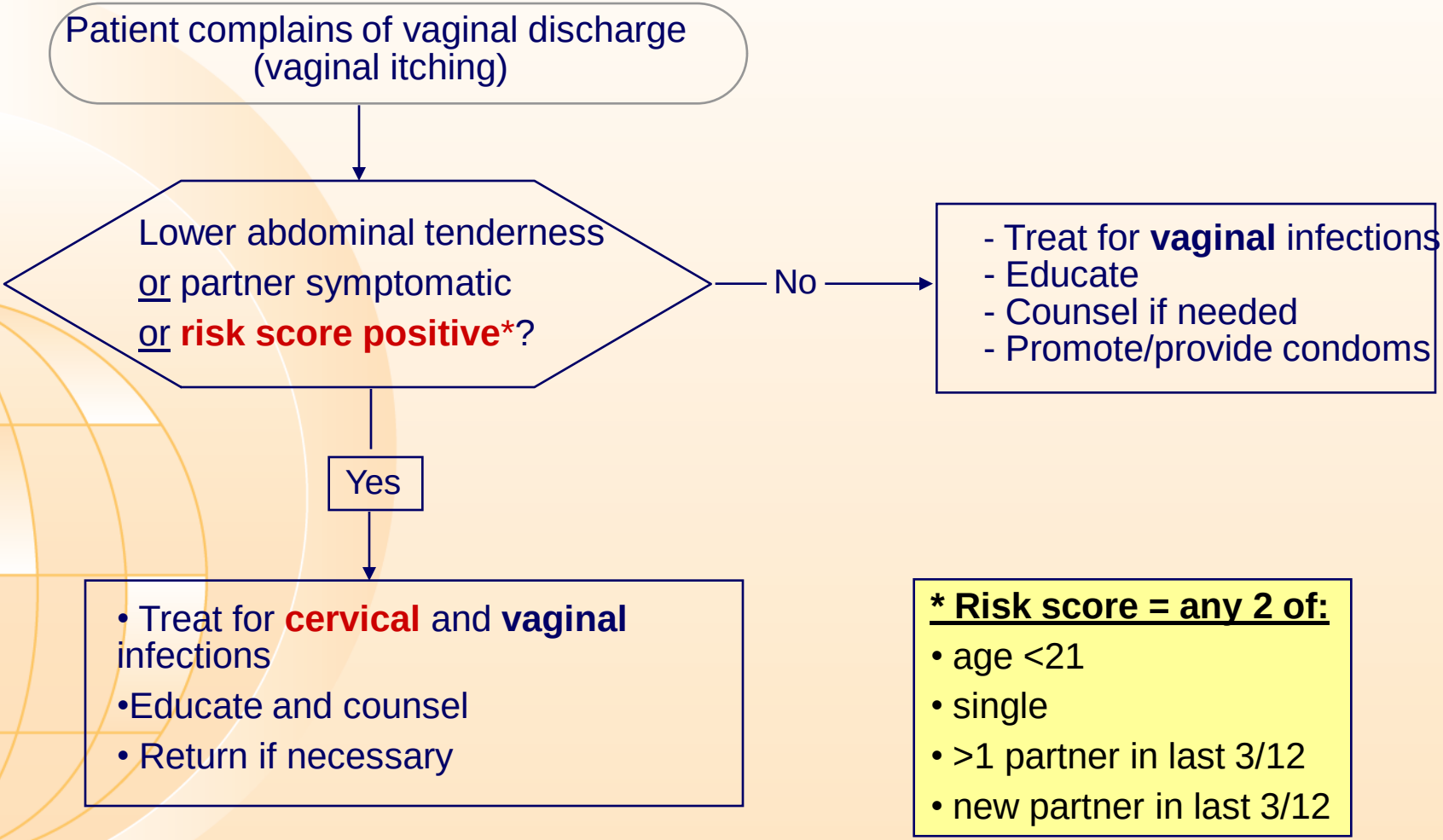
World Health Organization
Reproductive Health and Research
hrp
UNDP • UNFPA • WHO • World Bank
Special Programme of Research, Development and Research Training in Human Reproduction

Vaginal discharge (with speculum and microscope)

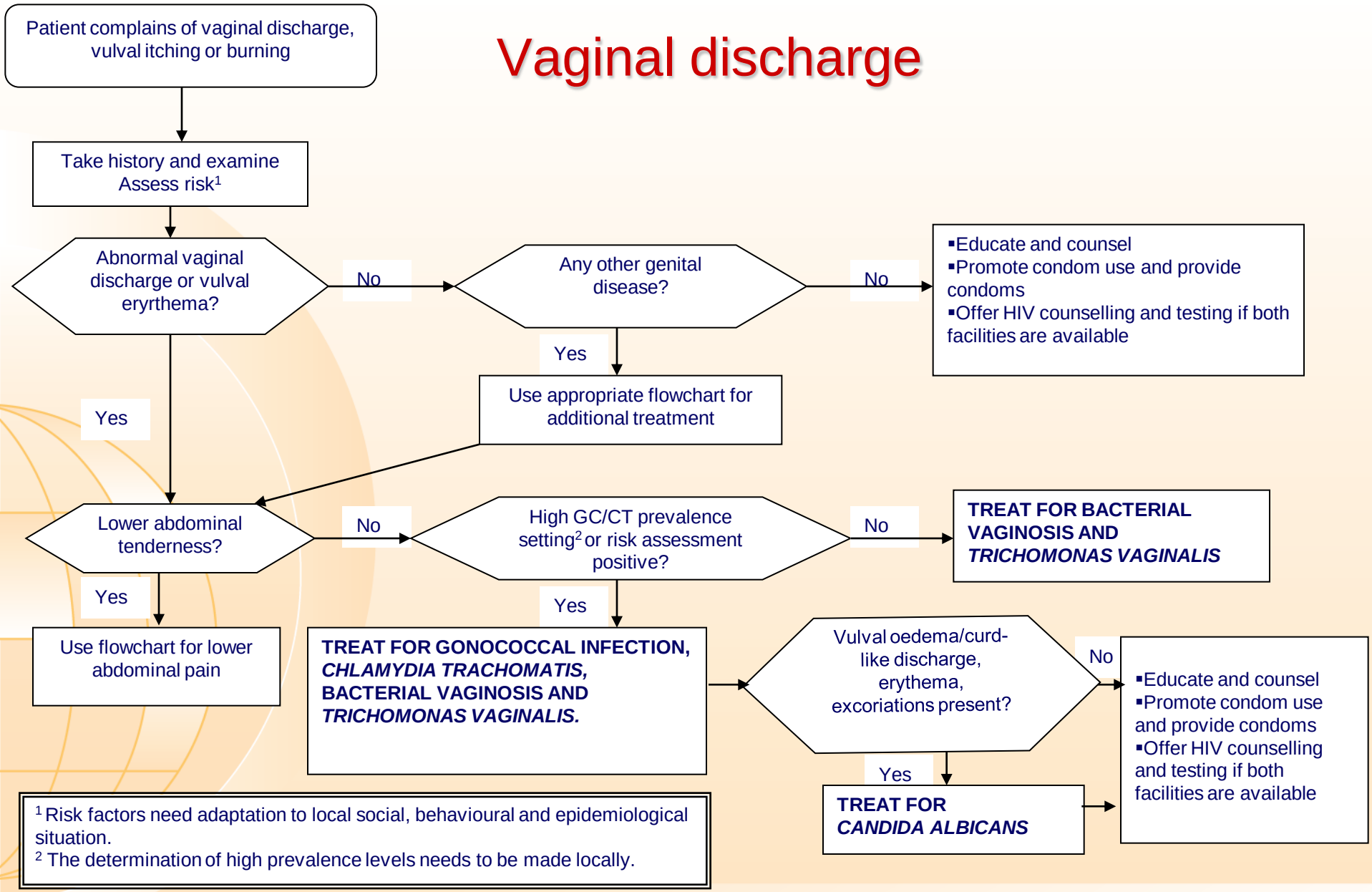


World Health Organization
Reproductive Health and Research
UNDP • UNFPA • WHO • World Bank
Special Programme of Research, Development and Research Training in Human Reproduction

Vaginal discharge (without microscope, using risk score)

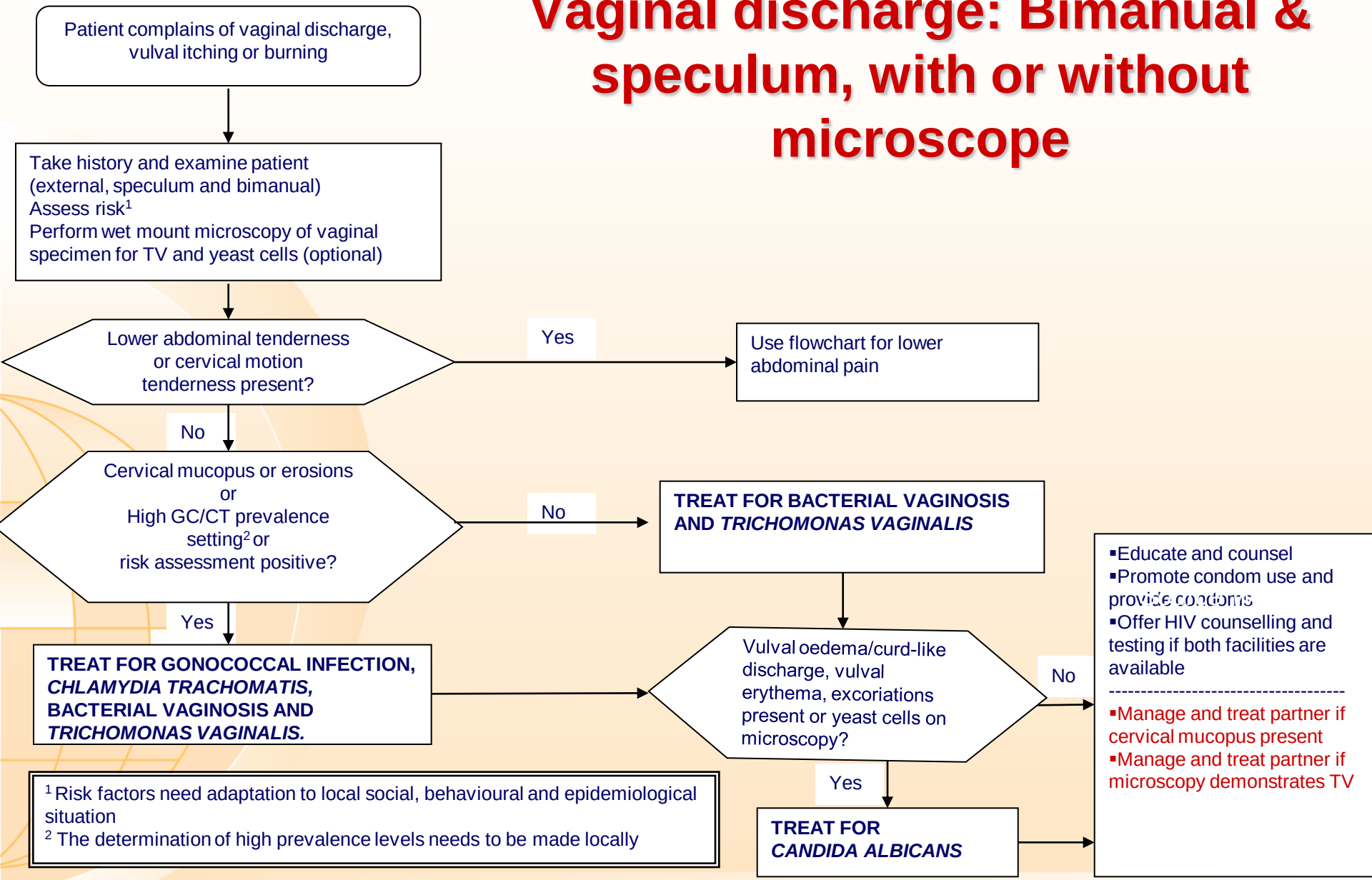


Vaginal discharge



[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



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

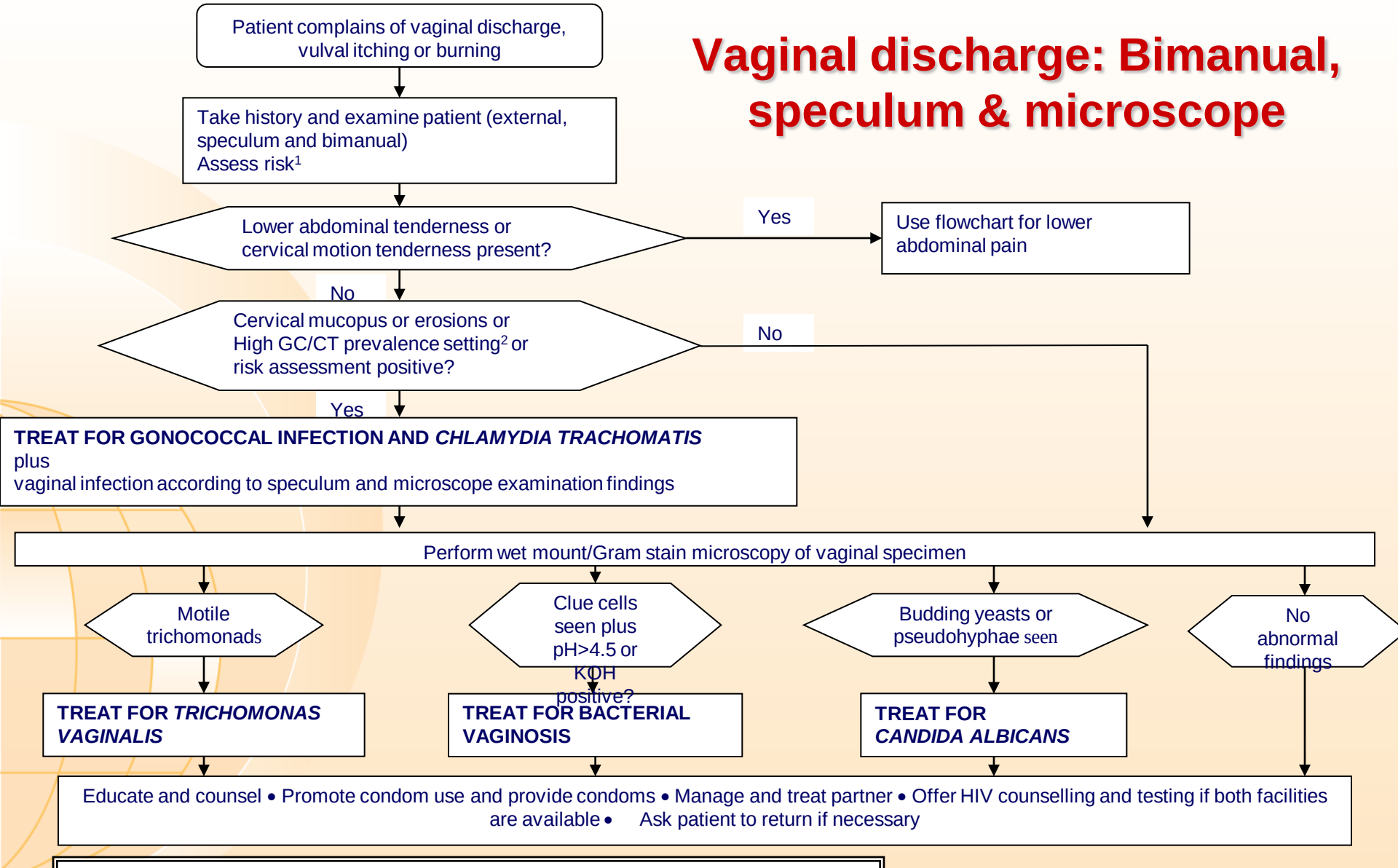
[2] The determination of high prevalence levels needs to be made locally

World Health Organization

Reproductive Health and Research

UNDP • UNFPA • WHO • World Bank
Special Programme of Research, Development and Research Training in Human Reproduction

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

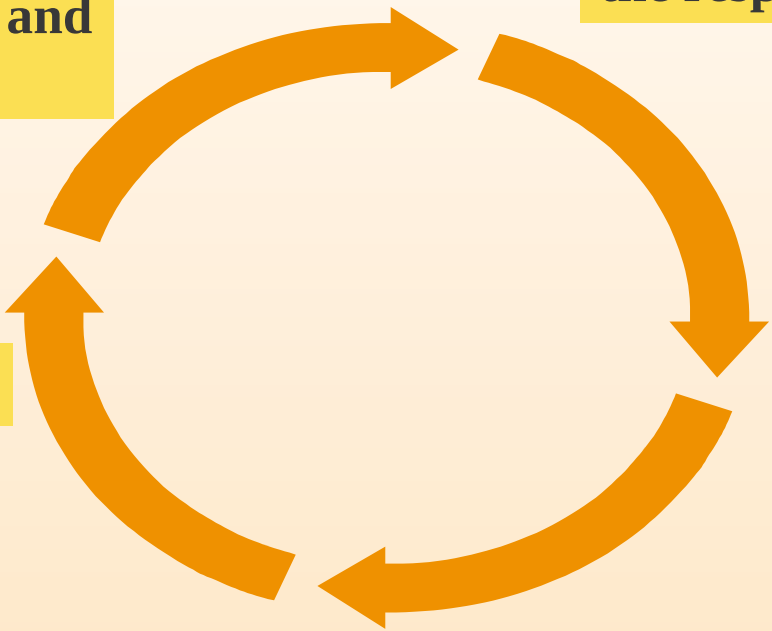
IMPLEMENTATION

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

Total cost of all diagnoses + treatments

Number of cases cured

Cost per case cured decreases if

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

END

World Health Organization

Reproductive Health and Research

UNDP • UNFPA • WHO • World Bank
Special Programme of Research, Development
and Research Training in Human Reproduction