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

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 and symptoms
- Examination
- Treatment
  - Client and partner(s)

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:

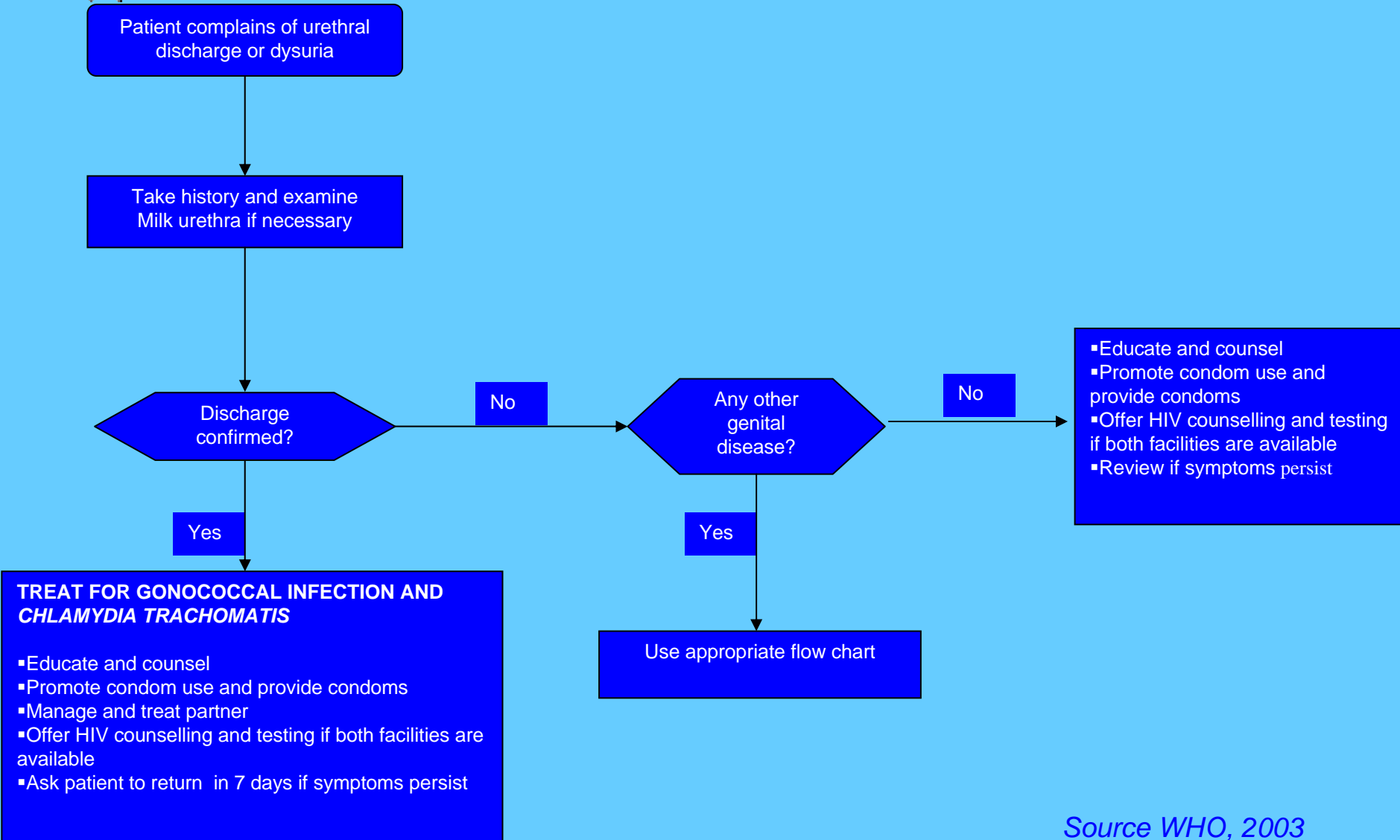 treat the main organisms responsible for causing the syndrome

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

Urethral Discharge

Patient complains of urethral discharge or dysuria

↓

Take history and examine
Milk urethra if necessary

↓

Discharge confirmed? — 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
- Review if symptoms persist

Discharge confirmed? — Yes ↓

TREAT FOR GONOCOCCAL INFECTION AND
CHLAMYDIA TRACHOMATIS

- Educate and counsel
- Promote condom use and provide condoms
- Manage and treat partner
- Offer HIV counselling and testing if both facilities are available
- Ask patient to return in 7 days if symptoms persist

Any other genital disease? — Yes ↓

Use appropriate flow chart

Source WHO, 2003

Urethral discharge (with microscope)

Patient complains of urethral discharge (dysuria)

↓

Examine: milk urethra if necessary

↓

Discharge confirmed? — No → **Ulcer(s) present?** — No →
- Educate
- Counsel if needed
- Promote/provide condoms

Discharge confirmed? ↓ Yes

Ulcer(s) present? ↓ Yes → Use appropriate flow chart

Microscopy

↓

Intracellular diplococci present?

↓ Yes

- **Treat for gonorrhoea and Chlamydia**
- Educate, Counsel etc.
- Return if necessary

↓ No

- **Treat for chlamydia only**
- Educate, counsel etc.
- Return if necessary

Source WHO, 1995

Genital ulcers

Patient complains of genital sore or ulcer

↓

Examine

↓

Ulcer present? —No→ Vesicular or recurrent lesion(s) present? —No→ - Educate
- Counsel if needed
- Promote/provide condoms

Yes

- **Treat for syphilis <u>and</u> chancroid**
- Educate and Counsel etc.
- Advise to return in 7 days

Yes

- **Management of herpes**
- Educate
- Counsel if needed
- Promote/provide condoms

Source WHO, 1995

Genital Ulcer
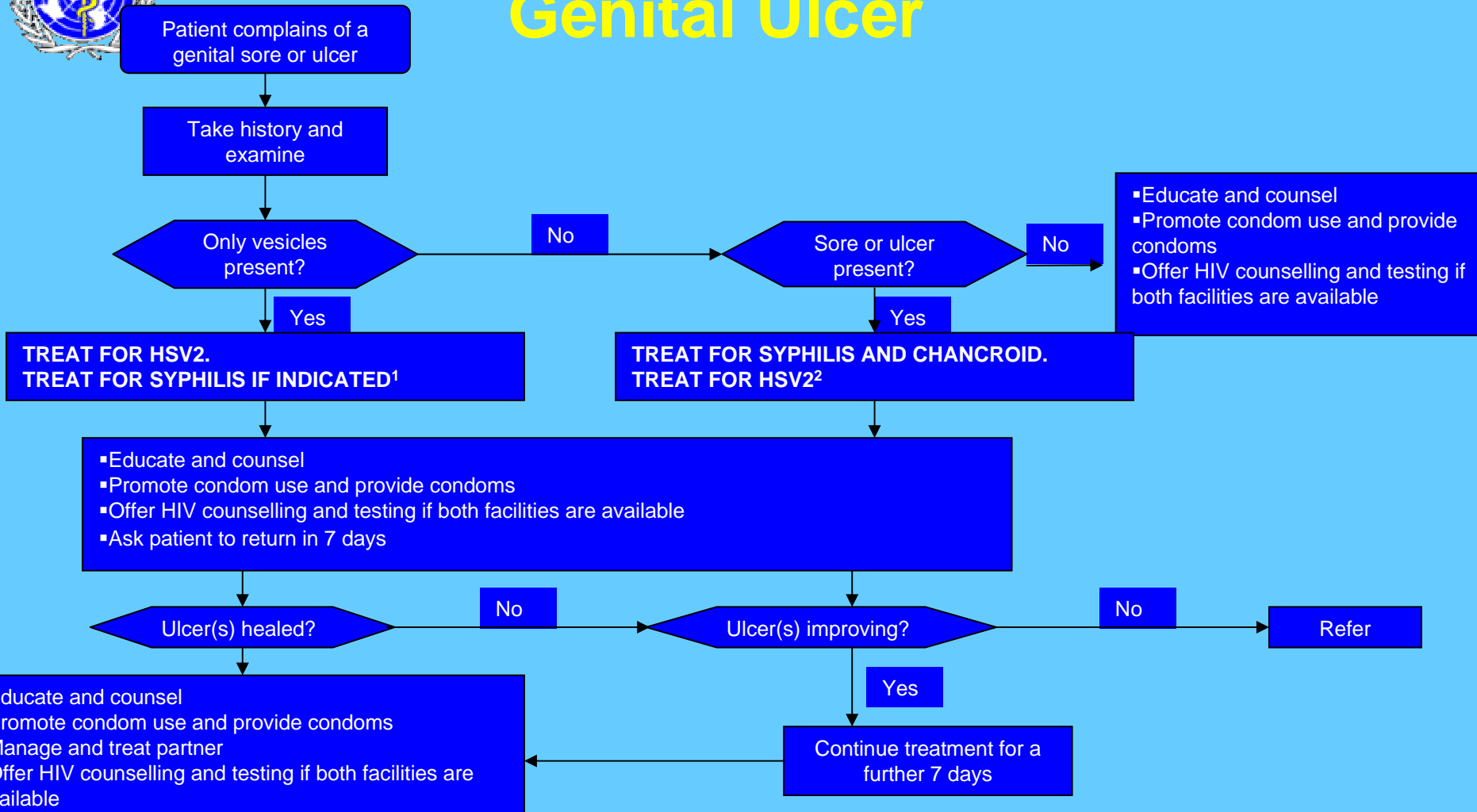
Patient complains of a genital sore or ulcer

↓

Take history and examine

↓

Only vesicles present? — No → **Sore or ulcer present?** — No →
- Educate and counsel
- Promote condom use and provide condoms
- Offer HIV counselling and testing if both facilities are available

Only vesicles present? — Yes ↓

**TREAT FOR HSV2.
TREAT FOR SYPHILIS IF INDICATED[1]**

Sore or ulcer present? — Yes ↓

**TREAT FOR SYPHILIS AND CHANCROID.
TREAT FOR HSV2[2]**

↓

- Educate and counsel
- Promote condom use and provide condoms
- Offer HIV counselling and testing if both facilities are available
- Ask patient to return in 7 days

↓

Ulcer(s) healed? — No → **Ulcer(s) improving?** — No → Refer

Ulcer(s) improving? — Yes ↓

Continue treatment for a further 7 days

Ulcer(s) healed? — ↓

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

[1] indications for syphillis treatment
- RPR positive; and
- No recent syphilis treatment
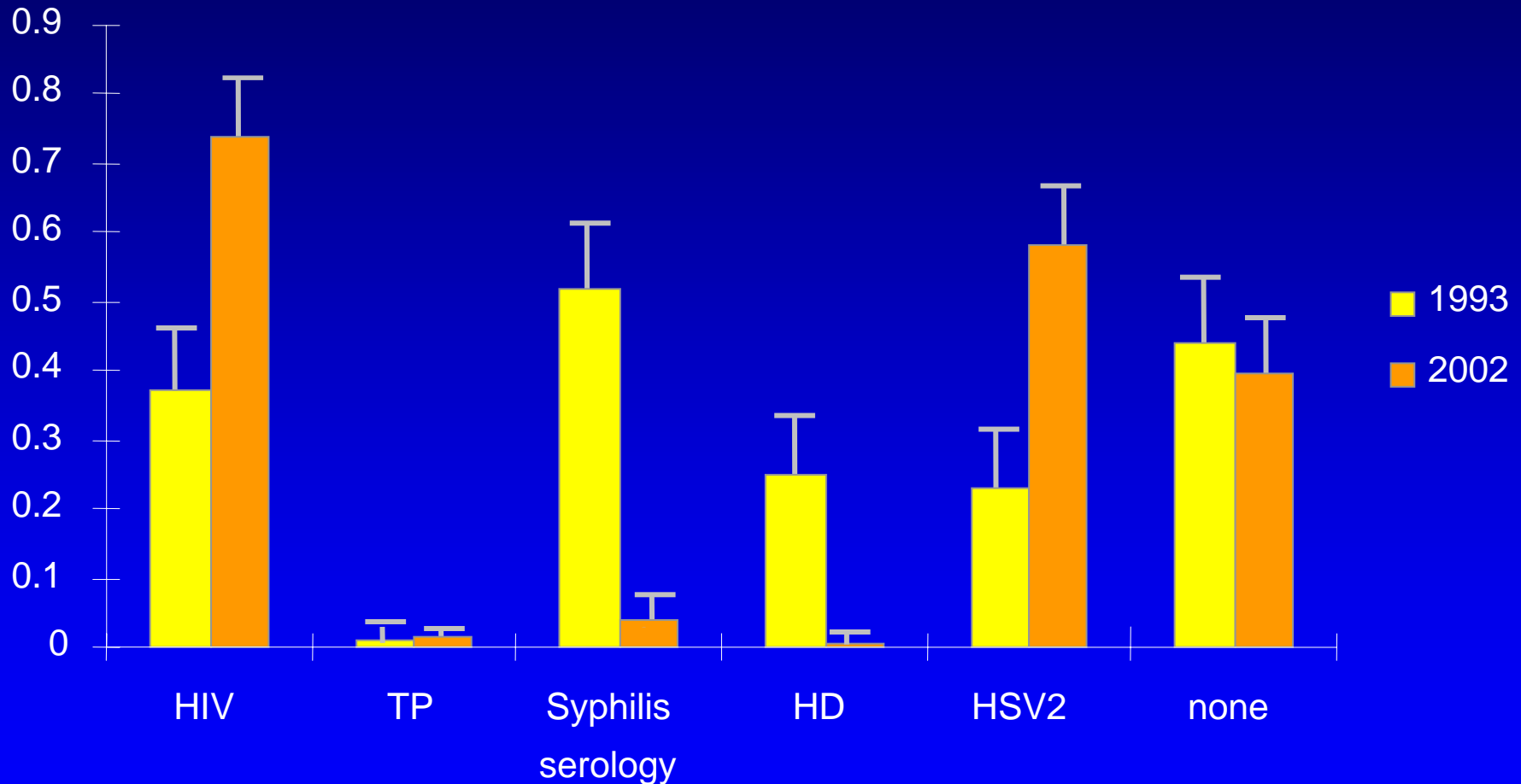[2] Treat for HSV2 where prevalence is 30% or higher, or adapt to local conditions

Source WHO, 2003
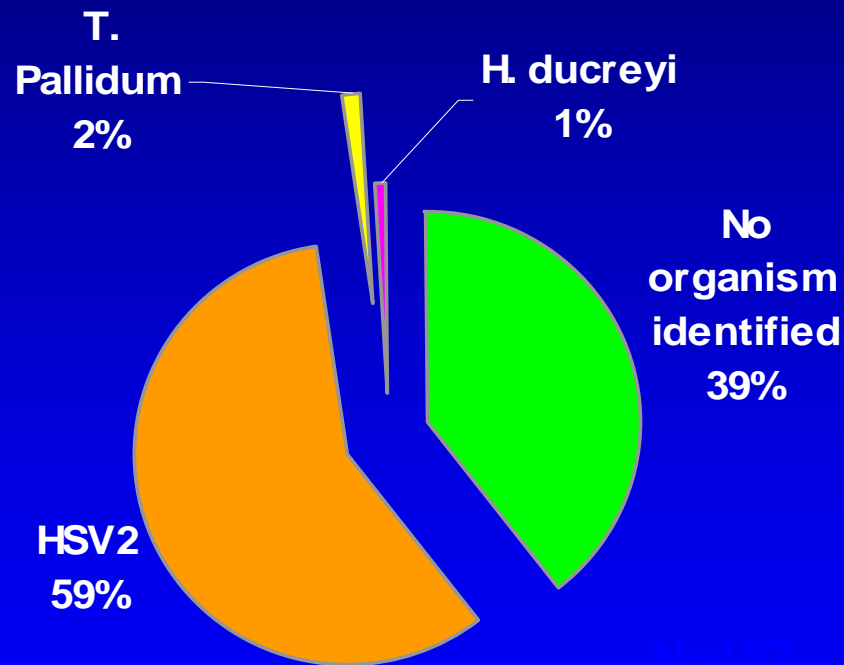
**Botswana
Changes in the aetiology of GUD
1993 - 2002**

Source: M. Rahman, ISSTDR, Ottawa 2003
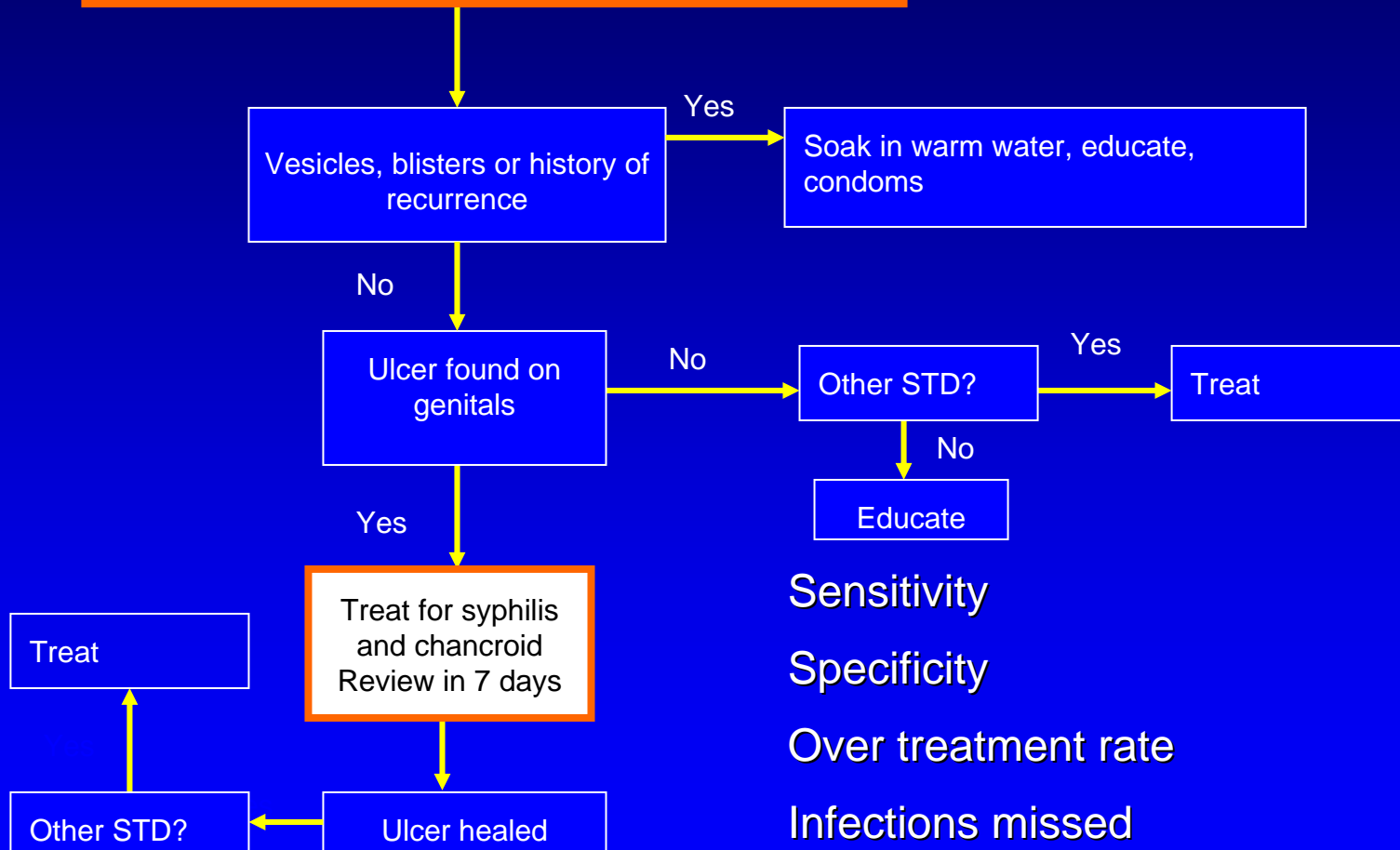
Botswana
Aetiology of genital ulcer disease 2002

T. Pallidum 2%

H. ducreyi 1%

No organism identified 39%

HSV 2 59%

N=187

Current genital ulcer algorithm in Botswana

Complaint sores/ulcer on genitals

Vesicles, blisters or history of recurrence

— Yes → Soak in warm water, educate, condoms

— No →

Ulcer found on genitals

— No → Other STD?

— Yes → Treat

— No → Educate

— Yes →

Treat for syphilis and chancroid Review in 7 days

→ Ulcer healed → Other STD? → Treat

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

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

Source: M. Rahman, ISSTDR, Ottawa 2003

Vaginal discharge (with speculum only)

Patient complains of vaginal discharge (vaginal itching)

↓

Lower abdominal tenderness or partner symptomatic or specific risk factors positive? — **No** →

Yes

↓

Treat for cervical infection plus vaginal infection according to speculum examination findings → Speculum and bimanual vaginal exam

↓

- Mucopus from cervix?
- Profuse vaginal discharge?
- Curd-like vaginal discharge?
- No discharge?
- Cervical motion tenderness present?

↓

- **Treat for cervical infections**
- Educate, Counsel
- Return if necessary

- **Treat for trichomonas and bacterial vaginosis**
- 4 C's
- Return if necessary

- **Treat for candida**
- Educate/counsel
- Return if necessary

- Educate
- Counsel if needed
- Promote/provide condoms

- Use flow chart for **lower abdominal pain**

Source WHO, 1995

Vaginal discharge (with speculum and microscope)

Patient complains of vaginal discharge
(vaginal itching)

Lower abdominal tendernessn or partner symptomatic or specific risk factors positive?

No

Yes

Treat for cervical infection plus vaginal infection according to speculum exam findings

Speculum + bimanual vaginal examinations + wet mount/gram stain microscopy of vaginal specimen

Mucopus from cervix?

Trichomonas?

Candida?

No discharge?

Cervical motion tenderness present?

•**Treat for cervical infections**
•Educate, Counsel
•Return if necessary

•**Treat for trichomonas and bacterial vaginosis**
•4 C's
•Return if necessary

•Treat for candida
• Educate/counsel
• Return if necessary

Educate
Counsel if needed
Promote/provide condoms

Use flow chart for **lower abdominal pain**

Source WHO,1995

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

Source WHO, 1995

Vaginal discharge

Patient complains of vaginal discharge, vulval itching or burning

↓

Take history and examine Assess risk[1]

↓

Abnormal vaginal discharge or vulval eryrthema? → 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 ↓ (from Abnormal vaginal discharge)

Any other genital disease? → Yes → Use appropriate flowchart for additional treatment

Lower abdominal tenderness? → No → **High GC/CT prevalence setting[2] or risk assessment positive?** → No → **TREAT FOR BACTERIAL VAGINOSIS AND *TRICHOMONAS VAGINALIS***

Yes ↓ (Lower abdominal tenderness)

Use flowchart for lower abdominal pain

High GC/CT prevalence setting[2] or risk assessment positive? → Yes → **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*

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

DÉPART... NÉSIQUES

Source WHO, 2003

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[1]
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[2] or
risk assessment positive? → **No** → **TREAT FOR BACTERIAL VAGINOSIS AND *TRICHOMONAS VAGINALIS***

Source WHO, 2003

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**

Yes

TREAT FOR *CANDIDA ALBICANS*

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

[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 & microscope

Patient complains of vaginal discharge, vulval itching or burning

↓

Take history and examine patient (external, speculum and bimanual)
Assess risk[1]

↓

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[2] or risk assessment positive? — No →

↓ Yes

TREAT FOR GONOCOCCAL INFECTION AND *CHLAMYDIA TRACHOMATIS*
plus
vaginal infection according to speculum and microscope examination findings

↓

Perform wet mount/Gram stain microscopy of vaginal specimen

| Motile trichomonads | Clue cells seen plus pH>4.5 or KOH positive? | Budding yeasts or pseudohyphae seen | No abnormal findings |

| **TREAT FOR *TRICHOMONAS VAGINALIS*** | **TREAT FOR BACTERIAL VAGINOSIS** | **TREAT FOR *CANDIDA ALBICANS*** | |

Educate and counsel • Promote condom use and provide condoms • Manage and treat partner • Offer HIV counselling and testing if both facilities are available • Ask patient to return if necessary

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

SANTÉ ET RECHERCHE GÉNÉSIQUE *Source WHO, 2003*

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