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

- 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
Urethral Discharge

Patient complains of urethral discharge or dysuria

Take history and examine Milk urethra if necessary

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?

No

Use appropriate flow chart

Yes

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

Source WHO, 2003
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

Yes

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

Use appropriate flow chart

Source WHO, 1995
Département santé et recherche génésiques

Genital ulcers

Patient complains of genital sore or ulcer

Examine

Ulcer present?

Yes

• Treat for syphilis and chancroid
  • Educate and Counsel etc.
  • Advise to return in 7 days

No

Vesicular or recurrent lesion(s) present?

Yes

• Management of herpes
  • Educate
  • Counsel if needed
  • Promote/provide condoms

No

• 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?

Yes

TREAT FOR HSV2.
TREAT FOR SYPHILIS IF INDICATED¹

No

Sore or ulcer present?

No

TREAT FOR SYPHILIS AND CHANCROID.
TREAT FOR HSV2²

Yes

Sore or ulcer present?

Yes

• 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

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

Refer

Ulcer(s) improving?

No

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

Continue treatment for a further 7 days

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

Ulcer(s) healed?

Yes

TREAT FOR SYPHILIS AND CHANCROID.
TREAT FOR HSV2²

¹Indications for syphilis 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

*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

- HSV2: 59%
- T. Pallidum: 2%
- H. ducreyi: 1%
- No organism identified: 39%

Source: M. Rahman, ISSTDR, Ottawa 2003
**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

- Ulcer found on genitals
  - No: Other STD?
  - Yes: Treat
  - No: Educate

- Treat for syphilis and chancroid
- Review in 7 days

- Other STD?
  - Yes: Treat
  - No: Other STD?

- Ulcer healed

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensitivity</td>
<td>33%</td>
</tr>
<tr>
<td>Specificity</td>
<td>45%</td>
</tr>
<tr>
<td>Over treatment rate</td>
<td>99%</td>
</tr>
<tr>
<td>Infections missed</td>
<td>67%</td>
</tr>
<tr>
<td>Cost per infection Tx.</td>
<td>$88.0</td>
</tr>
</tbody>
</table>

Source: M. Rahman, ISSTDR, Ottawa 2003
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

No

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
Patient complains of vaginal discharge (vaginal itching)

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

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

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 tenderness or partner symptomatic or specific risk factors positive?

Yes

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

No

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

Mucopus from cervix?

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

Trichomonas?

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

Candida?

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

No discharge?

Cervical motion tenderness present?

Educate Counsel if needed
Promote/provide condoms

Use flow chart for low abdominal pain

Source: WHO, 1995
Patient complains of vaginal discharge (vaginal itching)

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

Yes

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

No

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

*Risk score = any 2 of:
- age <21
- single
- >1 partner in last 3/12
- new partner in last 3/12

Source WHO, 1995
Patient complains of vaginal discharge, vulval itching or burning

Take history and examine
Assess risk¹

Abnormal vaginal discharge or vulval erythema?

Yes

Lower abdominal tenderness?

Yes

Use flowchart for lower abdominal pain

No

Use flowchart for additional treatment

Any other genital disease?

Yes

Use appropriate flowchart for additional treatment

No

High GC/CT prevalence setting² or risk assessment positive?

Yes

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

Yes

TREAT FOR BACTERIAL VAGINOSIS AND TRICHOMONAS VAGINALIS

No

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

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

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 risk¹
Perform wet mount microscopy of vaginal specimen for TV and yeast cells (optional)

Lower abdominal tenderness or cervical motion tenderness present?

Cervical mucopus or erosions or High GC/CT prevalence setting² or risk assessment positive?

TREAT FOR BACTERIAL VAGINOSIS AND TRICHOMONAS VAGINALIS

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

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

Source WHO, 2003
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

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 setting2 or risk assessment positive?

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

No

Perform wet mount/Gram stain microscopy of vaginal specimen

Motile trichomonads
TREAT FOR TRICHOMONAS VAGINALIS

Clue cells seen plus pH>4.5 or KOH positive?
TREAT FOR BACTERIAL VAGINOSIS

Budding yeasts or pseudohyphae seen
TREAT FOR CANDIDA ALBICANS

No abnormal findings

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

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
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


- 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
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
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

Evaluate programme and interventions

Train and supervise

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
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