

Assessment

	Judgement	Research evidence	Additional considerations
Problem	<p>Is the problem a priority?</p> <p> <input type="radio"/> No <input type="radio"/> Probably no <input type="radio"/> Probably yes <input checked="" type="radio"/> Yes <input type="radio"/> Varies <input type="radio"/> Don't know </p>	<p>STIs are important because of their magnitude, potential complications and increased risk of HIV. STIs have health, social and economic consequences. The consequences of STIs (such as HSV and syphilis) disproportionately affect women and newborn children. For example, women acquiring primary HSV in the third trimester of pregnancy may result in congenital herpes, leading to neurocognitive problems, developmental delays or death of infants. Congenital syphilis can also cause serious morbidity or death among infants.</p> <p>Presentation of genital ulcer disease is a major challenge for clinicians to distinguish STI-related versus non-STI-related causes. Many individuals keep having sex even in the presence of a genital ulcer. It has been proposed that timely diagnosis of STIs could reduce HIV incidence.</p> <p>High cost of molecular STI testing</p> <p>Molecular based tests enable etiological diagnosis to guide appropriate treatment (such as multiplex PCR test for HSV and syphilis) but are expensive and not available in many settings.</p>	
Test accuracy	<p>How accurate is the test?</p> <p> <input type="radio"/> Very inaccurate <input checked="" type="radio"/> Inaccurate <input type="radio"/> Accurate <input type="radio"/> Very accurate <input type="radio"/> Varies <input type="radio"/> Don't know </p>	<p>We conducted a systematic review (2–4), searching up to September 2019, of the sensitivity and specificity of a syndromic management approach to identify multiple STIs related to anogenital ulcers. In summary, we identified four articles that assessed the diagnostic accuracy of the clinical diagnosis of a pathogen causing genital ulcer disease to detect any STI (Table A6.1), 15 studies for herpes (Table A6.2), 15 studies for syphilis (Table A6.3) and 13 studies for chancroid (Table A6.4). We found no studies on detecting lymphogranuloma venereum.</p> <p>For detecting herpes from a clinical diagnosis of herpes, 15 studies provided 20 estimates for pooling. The pooled sensitivity for detecting herpes using a syndromic management approach is 40.4% (95% CI: 23.0–60.6%), and pooled specificity is 88.0% (95% CI: 75.3–94.6%).</p> <p>For detection of syphilis using clinical diagnosis of syphilis among individuals with genital ulcer disease, 15 studies provided 22 estimates for pooling. The pooled sensitivity for detecting syphilis is 64.4% (95% CI: 44.8–80.2%) and pooled specificity 83.7% (95% CI: 67.0–92.9%).</p> <p>The global distribution, incidence and prevalence of causal agents of genital ulcer disease varies widely by geographical region and population subgroup. This is important, since the positive and negative predictive values depend on the prevalence of pathogens.</p> <p>Other considerations related to the accuracy of tests</p> <p>We found that the accuracy of the syndromic approach depends on clinician skill and experience, clinical setting (STI centre versus primary care) and patient characteristics (membership of subpopulation(s)).</p> <p>The positive and negative predictive values may be worse among non-STI clinic attendees (because of lower prevalence of STIs among "general populations") (24).</p> <p>No difference in causal agents for genital ulcer disease between people living with HIV and those without HIV (12).</p>	

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Desirable effects	<p>How substantial are the desirable anticipated effects of syndromic approach?</p> <p>○ Trivial</p> <p>● Small</p> <p>○ Moderate</p> <p>○ Large</p> <p>○ Varies</p> <p>○ Don't know</p>	<p>Desirable effects and undesirable effects</p> <p>The potential consequences of true positive could include appropriate treatment, cure, side-effects, partner notification, reduced transmission of STIs and HIV, resistance, couple difficulties and costs.</p> <p>The potential consequences of true negative could include alternative diagnoses possible and psychological benefit.</p> <p>The potential consequences of false negative could include cure still possible, persistent symptoms, complications, STI and/or HIV transmission, no counselling and no partner notification.</p> <p>The potential consequences of false positive could include inappropriate treatment, side-effects, antimicrobial resistance, couple difficulties and costs.</p> <p>GRADE summary of findings table for clinical diagnosis and HSV</p> <p>Based on the sensitivity and specificity of clinical diagnosis of STIs, we calculated the number of people appropriately treated (true positive), the number of missed cases (false negative) and the number of people treated unnecessarily or overtreated (false positive).</p>	<p>The Guideline Development Group agreed that the desirable effects of syndromic management (few unnecessarily treated) were small compared with treating all.</p> <p>The Guideline Development Group also agreed that the undesirable effects (number of missed cases) were moderate compared with treating all in particular for syphilis (due to the consequences of transmission).</p> <p>Overtreatment may be acceptable if high morbidity and mortality from undetected cases requires controlling the STI in the population (such as syphilis).</p>																							
	<p>Treatment of people with HSV based on a clinical diagnosis</p> <p>Pooled sensitivity: 0.40 (95% CI: 0.23 to 0.61) Pooled specificity: 0.88 (95% CI: 0.75 to 0.95)</p> <table border="1"> <thead> <tr> <th rowspan="2">Test result</th> <th colspan="2">Number of results per 100 patients tested (95% CI)</th> <th rowspan="2">Number of participants (studies)</th> <th rowspan="2">Certainty of the Evidence (GRADE)</th> </tr> <tr> <th>Prevalence 30% Typically seen in</th> <th>Prevalence 70% Typically seen in</th> </tr> </thead> <tbody> <tr> <td>True positives</td> <td>12 (7 to 18)</td> <td>28 (16 to 42)</td> <td rowspan="2">2667 (15)</td> <td rowspan="2">⊕⊕⊕⊕ High^a</td> </tr> <tr> <td>False negatives</td> <td>18 (12 to 23)</td> <td>42 (28 to 54)</td> </tr> <tr> <td>True negatives</td> <td>62 (53 to 66)</td> <td>26 (23 to 28)</td> <td rowspan="2">2667 (15)</td> <td rowspan="2">⊕⊕⊕⊕ High^a</td> </tr> <tr> <td>False positives</td> <td>8 (4 to 17)</td> <td>4 (2 to 7)</td> </tr> </tbody> </table> <p>CI: Confidence interval</p> <p>Explanations</p> <p>^a Some heterogeneity but confidence intervals not wide.</p>	Test result	Number of results per 100 patients tested (95% CI)		Number of participants (studies)	Certainty of the Evidence (GRADE)	Prevalence 30% Typically seen in	Prevalence 70% Typically seen in	True positives	12 (7 to 18)	28 (16 to 42)	2667 (15)	⊕⊕⊕⊕ High ^a	False negatives	18 (12 to 23)	42 (28 to 54)	True negatives	62 (53 to 66)	26 (23 to 28)	2667 (15)	⊕⊕⊕⊕ High ^a	False positives	8 (4 to 17)	4 (2 to 7)	<p>However, there is still a risk of unnecessary treatment and potential for STI-related stigma due to low specificity of syndromic management.</p> <p>Underdiagnosis of herpes may not be a problem (except for pregnant women) since adequate treatment with antiviral agents may not be easily accessible or too expensive in resource-limited settings.</p>	
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		<p>GRADE summary of findings table for clinical diagnosis and syphilis</p> <p>Treatment of people with syphilis based on a clinical diagnosis</p> <p>Pooled sensitivity: 0.64 (95% CI: 0.45 to 0.80) Pooled specificity: 0.84 (95% CI: 0.67 to 0.93)</p> <table border="1"> <thead> <tr> <th rowspan="2">Test result</th> <th colspan="2">Number of results per 100 patients tested (95% CI)</th> <th rowspan="2">Number of participants (studies)</th> <th rowspan="2">Certainty of the Evidence (GRADE)</th> </tr> <tr> <th>Prevalence 5% Typically seen in</th> <th>Prevalence 10% Typically seen in</th> </tr> </thead> <tbody> <tr> <td>True positives</td> <td>3 (2 to 4)</td> <td>6 (4 to 8)</td> <td rowspan="2">2667 (15)</td> <td rowspan="2">⊕⊕⊕○ Moderate^a</td> </tr> <tr> <td>False negatives</td> <td>2 (1 to 3)</td> <td>4 (2 to 6)</td> </tr> <tr> <td>True negatives</td> <td>80 (64 to 88)</td> <td>75 (60 to 84)</td> <td rowspan="2">2667 (15)</td> <td rowspan="2">⊕⊕⊕○ Moderate^a</td> </tr> <tr> <td>False positives</td> <td>15 (7 to 31)</td> <td>15 (6 to 30)</td> </tr> </tbody> </table> <p>CI: Confidence interval</p> <p>Explanations</p> <p>^a Estimates from studies varied widely, meaning wide confidence intervals and then absolute effects.</p>	Test result	Number of results per 100 patients tested (95% CI)		Number of participants (studies)	Certainty of the Evidence (GRADE)	Prevalence 5% Typically seen in	Prevalence 10% Typically seen in	True positives	3 (2 to 4)	6 (4 to 8)	2667 (15)	⊕⊕⊕○ Moderate ^a	False negatives	2 (1 to 3)	4 (2 to 6)	True negatives	80 (64 to 88)	75 (60 to 84)	2667 (15)	⊕⊕⊕○ Moderate ^a	False positives	15 (7 to 31)	15 (6 to 30)	
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Desirable effects		<p>Prevalence of chancroid</p> <p>Chancroid</p> <p>A: Master B: Low income C: Middle income D: High income</p>	<p>There is a potential for the loss of confidence in the health system if genital ulcer disease is inappropriately managed.</p> <p>There is a lower likelihood of antimicrobial resistance with syphilis and HSV.</p>
Undesirable effects	<p>How substantial are the undesirable anticipated effects?</p> <p><input type="radio"/> Large</p> <p><input checked="" type="radio"/> Moderate</p> <p><input type="radio"/> Small</p> <p><input type="radio"/> Trivial</p> <p><input type="radio"/> Varies</p> <p><input type="radio"/> Don't know</p>	<p>Same-day treatment</p> <p>Prompt treatment (within 72 hours after genital lesions appear) of HSV with antiviral agents can reduce genital viral shedding and the duration of ulcers by 1–4 days (25–27).</p> <p>Considerations for the certainty of the evidence of accuracy</p> <p>Reference laboratory tests are not always equivalent in studies included in the meta-analysis.</p> <p>Clinical diagnosis can be highly variable between and within countries and settings since it depends on the skill of the clinician: previous experience, knowledge of risk factors and the prevalence of the pathogen (13).</p>	
Certainty of the evidence of test accuracy	<p>What is the overall certainty of the evidence of test accuracy?</p> <p><input type="radio"/> Very low</p> <p><input type="radio"/> Low</p> <p><input checked="" type="radio"/> Moderate</p> <p><input type="radio"/> High</p> <p><input type="radio"/> No included studies</p>	<p>Global distribution and the incidence and prevalence of causal agents of genital ulcer disease vary widely by geographical region and population subgroup. This is important as the positive and negative predictive values depend on the prevalence of the pathogens.</p> <p>Studies relying on HSV and syphilis serology as the reference may overestimate positivity since they may not distinguish current infection (as the cause of the genital ulcer disease) or past treated infection.</p> <p>Untested pathogens could be a cause of anogenital ulceration, although they are less common, such as <i>C. trachomatis</i> lymphogranuloma venereum, <i>Haemophilus ducreyi</i> and <i>Candida glabrata</i>.</p> <p>All studies were convenience samples, and none had a truly random sample, so generalizing the results is difficult. Most were recruited from sexual health clinics, biasing the sample. Similarly, since the studies were cross-sectional, we were unable to assess temporal association between symptoms and STIs.</p>	
Certainty of the evidence of the effects of management	<p>What is the overall certainty of the evidence of effects of the management that is guided by the test results?</p> <p><input type="radio"/> Very low</p> <p><input type="radio"/> Low</p> <p><input checked="" type="radio"/> Moderate</p> <p><input type="radio"/> High</p> <p><input type="radio"/> No included studies</p>	<p>The evidence for management was based on current WHO recommendations for treating women with pelvic inflammatory disease.</p>	

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Certainty of effects	<p>What is the overall certainty of the evidence of effects of the test?</p> <p> <input type="radio"/> Very low <input type="radio"/> Low <input checked="" type="radio"/> Moderate <input type="radio"/> High <input type="radio"/> No included studies </p>		
Values	<p>Is there important uncertainty about or variability in how much people value the main outcomes?</p> <p> <input type="radio"/> Important uncertainty or variability <input type="radio"/> Possibly important uncertainty or variability <input checked="" type="radio"/> Probably no important uncertainty or variability <input type="radio"/> No important uncertainty or variability </p>	The Guideline Development Group placed greater value on not missing cases than on unnecessary treatment.	
Balance of effects	<p>Does the balance between desirable and undesirable effects favour the intervention or the comparison?</p> <p> <input checked="" type="radio"/> Favours the comparison <input type="radio"/> Probably favours the comparison <input type="radio"/> Does not favour either the intervention or the comparison <input type="radio"/> Probably favours the intervention <input type="radio"/> Favours the intervention <input type="radio"/> Varies <input type="radio"/> Don't know </p>	Treating all was favoured since there were no missed cases in people presenting with ulcers, and there was little value placed on unnecessarily treating people.	

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Resources required	<p>How large are the resource requirements (costs)?</p> <ul style="list-style-type: none"> <input type="radio"/> Large costs <input type="radio"/> Moderate costs <input checked="" type="radio"/> Negligible costs and savings <input type="radio"/> Moderate savings <input type="radio"/> Large savings <input type="radio"/> Varies <input type="radio"/> Don't know 	<p>Need for better training for nurses working in primary health care settings in Botswana (28).</p> <p>Etiological diagnosis requires training, infrastructure, time and money.</p>																																								
Certainty of evidence of required resources	<p>What is the certainty of the evidence of resource requirements (costs)?</p> <ul style="list-style-type: none"> <input type="radio"/> Very low <input type="radio"/> Low <input type="radio"/> Moderate <input type="radio"/> High <input checked="" type="radio"/> No included studies 	<p>Korenromp (29) reported the unit cost of treatment.</p> <table border="1"> <thead> <tr> <th>STI or syndrome</th> <th>Treatment dose per day</th> <th>Drugs, per dose</th> <th>Treatment duration (days)</th> <th>Drugs per treatment</th> <th>Drugs + service delivery</th> </tr> </thead> <tbody> <tr> <td>Herpes</td> <td>Acyclovir 400 mg</td> <td>3</td> <td>7</td> <td>US\$ 0.04</td> <td>US\$ 11.05</td> </tr> <tr> <td>Syphilis</td> <td>Benzathine PCN 2.4 M</td> <td>1</td> <td>1</td> <td>US\$ 0.44</td> <td>US\$ 11.65</td> </tr> <tr> <td>Chancroid</td> <td>Azithromycin 500 mg</td> <td>2</td> <td>1</td> <td>US\$ 0.38</td> <td>US\$ 10.95</td> </tr> </tbody> </table> <table border="1"> <thead> <tr> <th>STI</th> <th>Test</th> <th>Cost</th> <th>Service delivery</th> <th>Total</th> </tr> </thead> <tbody> <tr> <td>Syphilis, herpes, chancroid</td> <td>mPCR</td> <td>??</td> <td>??</td> <td></td> </tr> <tr> <td>Syphilis</td> <td>Rapid test</td> <td>US\$ 0.50</td> <td>US\$ 3.00</td> <td>US\$ 3.50</td> </tr> </tbody> </table>	STI or syndrome	Treatment dose per day	Drugs, per dose	Treatment duration (days)	Drugs per treatment	Drugs + service delivery	Herpes	Acyclovir 400 mg	3	7	US\$ 0.04	US\$ 11.05	Syphilis	Benzathine PCN 2.4 M	1	1	US\$ 0.44	US\$ 11.65	Chancroid	Azithromycin 500 mg	2	1	US\$ 0.38	US\$ 10.95	STI	Test	Cost	Service delivery	Total	Syphilis, herpes, chancroid	mPCR	??	??		Syphilis	Rapid test	US\$ 0.50	US\$ 3.00	US\$ 3.50	
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Cost-effectiveness	<p>Does the cost-effectiveness of the intervention favour the intervention or the comparison?</p> <ul style="list-style-type: none"> <input checked="" type="radio"/> Favours the comparison <input type="radio"/> Probably favours the comparison <input type="radio"/> Does not favour either the intervention or the comparison <input type="radio"/> Probably favours the intervention <input type="radio"/> Favours the intervention <input type="radio"/> Varies <input type="radio"/> No included studies 	<p>Overall, the Guideline Development Group agreed that, although there are few differences between the costs of treating all, not treating and syndromic management, the costs of more cases missed with syndromic management made treating all the more cost-effective.</p> <p>Adams et al. (30) examined the cost-effectiveness of syndromic management (including genital ulcer disease) in pharmacies in Lima, Peru. They reported an overall cost saving of US\$ 1.51 per adequately managed case, from a societal perspective.</p> <p>The mean cost per syphilis treated for syndromic management of genital ulcer disease cases in China was US\$ 13.54 in 2003 (6).</p> <p>Cost-effectiveness analysis in Cambodia: cost per genital ulcer disease case = US\$ 43.21 (USD, 2002) for men from the general population, US\$ 43.56 for women from the general population and US\$ 44.05 for female sex workers.</p> <p>US\$ 10.15 per syndrome treated in the United Republic of Tanzania (in 1993) – no disaggregated data for genital ulcer disease (31).</p> <p>The average cost per STI treated in a primary care setting in the Central African Republic (including 7% with genital ulcer disease) was US\$ 3.90 (in 1993) (32).</p> <p>China, Taiwan: US\$ 14.30 (in 2005) for the cost of correctly treating syphilis using a syndromic approach versus US\$ 21.58 for an etiological approach (33). The authors conclude that, in Taiwan, China, syndromic management was more cost-effective than etiological diagnosis in terms of cost per person with STI treated (health-care provider perspective).</p>																																								

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Cost-effectiveness		<p>A modelling study to evaluate the incremental cost-effectiveness ratio of the WHO 2003 genital ulcer disease algorithm versus the 1994 genital ulcer disease algorithm reports that the incremental cost-effectiveness ratio for treating HSV-2 ranged from US\$ 0.50 to US\$ 8.50 depending on the prevalence of genital ulcer disease causes (<i>Haemophilus ducreyi</i>, true positive, HSV-2) (34).</p> <p>Syndromic management is likely to be cost-saving in rural South Africa, considering its potential impact on reducing HIV incidence (35).</p> <p>In Côte d'Ivoire, the mean drug cost per cure = US\$ 4.50 (in 1994) and mean direct cost per cure = US\$ 4.90 (36).</p>	
Equity	<p>What would be the impact on health equity?</p> <p><input type="radio"/> Reduced</p> <p><input type="radio"/> Probably reduced</p> <p><input checked="" type="radio"/> Probably no impact</p> <p><input type="radio"/> Probably increased</p> <p><input type="radio"/> Increased</p> <p><input type="radio"/> Varies</p> <p><input type="radio"/> Don't know</p>	<p>The cost of antiviral agents might be prohibitive for some people or in some settings. The cost of STI management – including consultation, drugs and tests – might also be prohibitively high for some subpopulations.</p> <p>Partner notification processes in resource-limited settings are poorly described and largely non-existent.</p>	<p>Diagnostic test for ulcers (such as M-PCR) are costly, technically sophisticated, time-consuming and thus rarely affordable, available or accessible in resource-limited settings.</p> <p>If a diagnostic is used, the patient might need to return to discuss the results.</p>
Acceptability	<p>Is the intervention acceptable to key stakeholders?</p> <p><input type="radio"/> No</p> <p><input type="radio"/> Probably no</p> <p><input checked="" type="radio"/> Probably yes</p> <p><input type="radio"/> Yes</p> <p><input type="radio"/> Varies</p> <p><input type="radio"/> Don't know</p>	<p>Clinicians</p> <p>Pharmacy and clinicians offered syndromic management in Peru – community randomized controlled trial (37).</p> <p>More than 90% of 100 clinicians from Pakistan were willing to attend educational sessions and follow the national STI treatment protocols (38).</p> <p>Concerns about how general practitioners treat people with genital ulcer disease in Namibia (39).</p> <p>Difficulties in providing syndromic STI management noted among health-care providers (doctors and midwives) in Karachi (40).</p> <p>Patients</p> <p>83% of patients in the United Republic of Tanzania reported satisfaction with STI services using syndromic management (41).</p> <p>For algorithms that required follow-up (such as that in Rwanda) (42), 50% failed to return for follow-up.</p>	<p>May be difficulties from health-care providers in communicating or discussing sensitive issues related to sex.</p> <p>Symptomatic patients may not disclose their symptoms for a variety of reasons (fear of stigma, lack of access, etc...)</p> <p>Immediate relief of symptoms may be preferred rather than waiting for test results</p>

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Feasibility	<p>Is the intervention feasible to implement?</p> <p><input type="radio"/> No</p> <p><input type="radio"/> Probably no</p> <p><input checked="" type="radio"/> Probably yes</p> <p><input type="radio"/> Yes</p> <p><input type="radio"/> Varies</p> <p><input type="radio"/> Don't know</p>	<p>Etiological diagnosis requires skilled personnel and sophisticated equipment and is expensive and time-consuming.</p> <p>Successful use of syndromic management</p> <p>Syndromic management for genital ulcer disease has been implemented in many resource-limited settings with variable success: Ethiopia (43,44), Kenya (24,45), Malawi (46,47), Peru (23), United Republic of Tanzania (48), Peru (49), India (50–53), United Republic of Tanzania (41), Zambia (22), Namibia (39), China (6), Malawi (54), Zimbabwe (55), Karachi (40), South Africa (25,56–59), Bangladesh (53), Burkina Faso (54), Brazil (60), Central African Republic (32), Rwanda (42), Côte d'Ivoire (36), Swaziland (61), Gambia (62) and Mozambique (63).</p> <p>Standardized simulated patients visited pharmacies in the United Republic of Tanzania but found challenges for pharmacies to adequately manage genital ulcer disease syndromes (48). Pharmacy staff in Gambia were willing to offer syndromic management, but none of the simulated patients with genital ulcer disease would be treated appropriately (64).</p> <p>Rural clinics in South Africa – only 9% were correctly managed using a syndromic management approach (no disaggregated data for genital ulcer disease) (65).</p> <p>A survey of 43 doctors working in South Africa found that 23% had correct knowledge about managing genital ulcer disease (66).</p> <p>Only 9% of patients in South Africa received comprehensive syndromic management (67).</p> <p>None of the 50 general practitioners interviewed in Namibia could manage genital ulcer disease properly according to the syndromic management guidelines (39).</p> <p>Interviews with health-care workers from 240 health-care facilities in six countries in western Africa found suboptimal STI management, with effective treatment given to only 14% of the patients (68).</p> <p>Community pharmacies see many potential STIs, but none of the 85 head pharmacists from South Africa correctly identified the treatment for genital ulcers (69).</p> <p>Nurses in Rwanda could deliver STI syndromic management in country towns (42).</p> <p>Syndromic management protocol followed for 70% of genital ulcer disease cases presenting to Male Health Clinic in India (52).</p> <p>Interviews with 120 GPs and 244 occupational health nurses working in the private sector in South Africa in 1997 (59): 14% of GPs reported effective treatment for genital ulcer disease.</p> <p>Training</p> <p>A mixed-methods study of 250 clinicians in Ethiopia, including the use of mystery patients, found that only 13% were trained in the syndromic management of STIs (70), highlighting the need for training and supervision.</p> <p>Sixteen nurses from primary health centres in Nigeria were trained to manage STIs using a syndromic approach, demonstrating its acceptability and feasibility (62).</p> <p>Doctors and paramedics in India were successfully trained for syndromic case management (71).</p> <p>Surveillance of STIs</p> <p>Change in the causes of genital ulcer disease over time in Malawi (1992–1999) (52).</p>	<p>Syndromic management often provided at primary care level (including pharmacies) in low- and middle-income countries without clinical examination.</p> <p>A syndromic algorithm may be preferable to nothing, enabling health-care providers to make a diagnosis rapidly without special skills or sophisticated laboratory investigations.</p> <p>If syndromic management is to be scaled up, it is essential that adequate training and supervision is provided.</p> <p>Ongoing need for regular updating of syndromic management protocols in accordance with changing trends of STIs.</p> <p>Need ongoing evaluation of the quality of the services offering syndromic management, such as adherence to the algorithms.</p> <p>Intermittent etiological diagnosis to track changes in the underlying epidemiology of STIs causing the syndromes and thus whether the antibiotics prescribed need to be changed.</p>