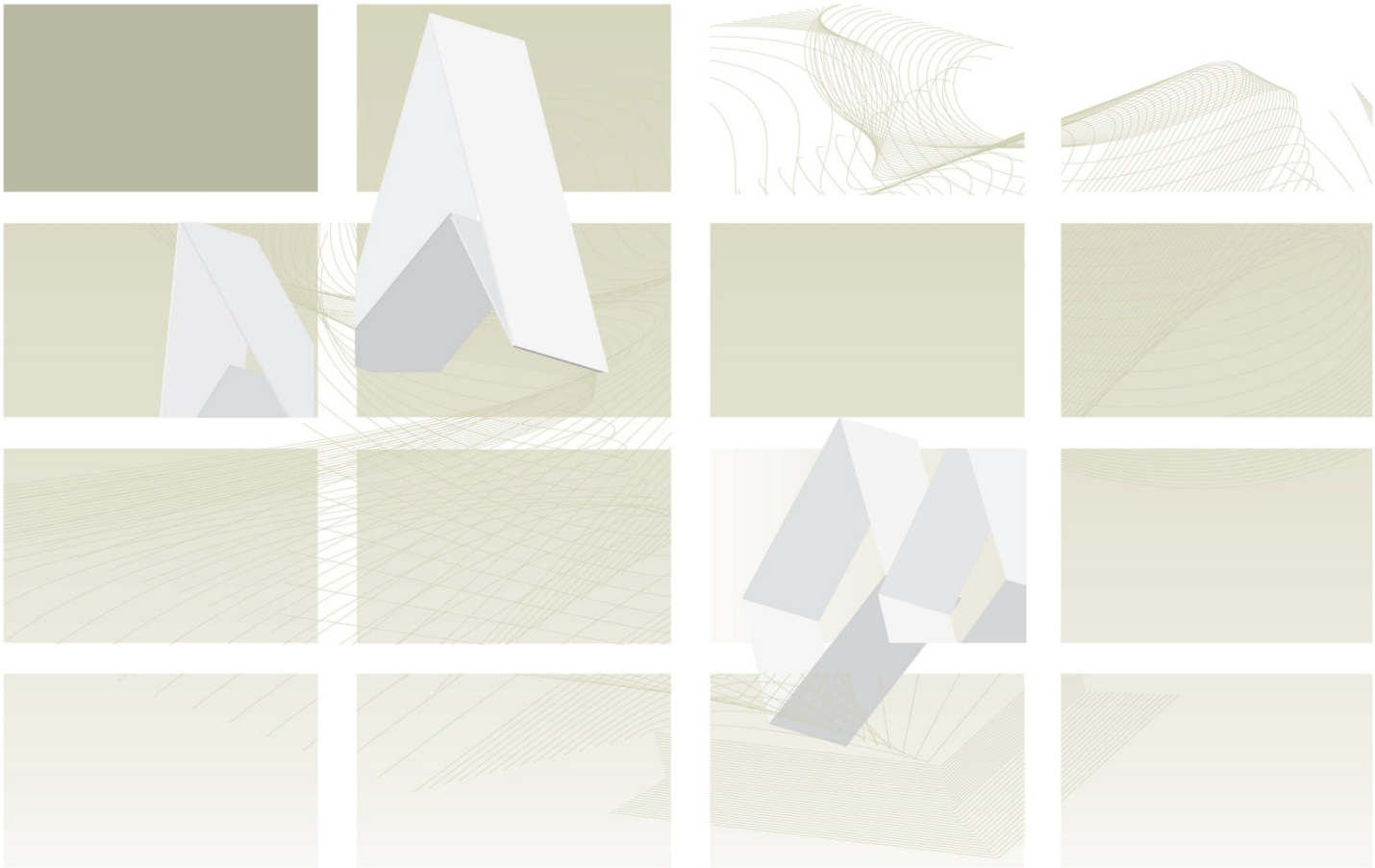
Public Health England

NHS

UK Standards for Microbiology Investigations

Review of Users' Comments received by
Joint Working Group for Syndromic Algorithms

S 6 Sexually Transmitted Infections



NICE accredited
www.nice.org.uk/accreditation

Recommendations are listed as ACCEPT/ PARTIAL ACCEPT/DEFER/ NONE or PENDING

PROPOSAL FOR CHANGES

Comment Number	1		
Date Received	09/08/2011	**Lab Name**	Royal Gwent Hospital
Section	Various		
Comment			

a. Page 8

"Pharyngeal swabbing for gonorrhoea" - Would this be useful as another footnote to the algorithm?

b. Footnotes Page 10

Add tenesmus to footnote b.

c. Replace "If the presenting complaint is lymphadenopathy of the groin only, the first recommended tests are syphilis and Lymphogranuloma venereum (LGV)" with footnote “If the presenting complaint is lymphadenopathy of the groin only, the first recommended tests are syphilis and Lymphogranuloma venereum (LGV)”.

d. Footnote d probably not needed, in view of footnote n (but footnote n would then have to be added for male as indicated also if footnote d to be removed).

e. Footnote j needs clarification.

f. Footnote o needs a reference.

g. Footnote r "Herpes simplex type specific serology may be useful in detecting the stage of newly diagnosed lesions (primary or non-primary)" - is there evidence for this – UHW Virologists usually advise against.

h. Footnote t "Culture of *Chlamydia trachomatis* may be required in some clinical settings" - Such as? No longer required for medicolegal, provided confirmed by more than 1 molecular platform?

i. Footnote x add example of travel.

j. Algorithm - Add ulcers/vesicles.

k. Algorithm - Add ulcer swabs/vesicles fluids. Is anyone culturing *Treponema pallidum* routinely? hazardous.

l. Algorithm - under lumps add *Treponema pallidum* and LGV with footnotes s and t.

m. Algorithm - rectal swabs. Is NAAT licensed for rectal specimens. Our Chlamydia amplification test was not licensed.

n. Should the secondary test under HVS be primary testing?

Recommended Action	a. **ACCEPT** The document will be amended. b. **ACCEPT** The document will be updated along with a supporting reference.

	c. **ACCEPT** The information will be added to the footnote. d. **NONE** It is the view of the Working Group that it gives greater clarity as it is. e. **ACCEPT** The footnote will be reworded for clarity. f. **ACCEPT** g. **ACCEPT** References will be inserted to support the statement. h. **ACCEPT** The footnote will be reworded for clarity. i. **ACCEPT** j. **ACCEPT** k. **ACCEPT** The document will be updated. l. **ACCEPT** m. **ACCEPT** Local validation is required. A footnote will be added and referenced to the BASHH guidelines. n. **NONE** It is the view of the Working Group that it is acceptable as a secondary test.

Comment Number	2		
Date Received	09/08/2011	**Lab Name**	BASHH
Section	Various		
Comment			
a. Where do these fit into the BASHH guidelines and who is this algorithm aimed at. GUM clinicians are unlikely to use this as they would go to their extensive guidelines already produced and regularly updated. b. The BASHH guidelines need to be referenced and the algorithm checked against them http://www.bashh.org/guidelines. c. It is suggested that the LGV typing is specifically mentioned in the proctitis pathway as it is felt that it is too important to be left just to a footnote (in case it isn't read). A reference to the HPA policy on testing symptomatic patients who are CT positive could be added. d. There have been a number of comments around pharyngeal testing for MSM.			

While this is a symptomatic flowchart testing of the pharynx seems an omission. There is a wider issue about screening of asymptomatic MSM and some women at the rectum and the pharynx and current thoughts on this is that all MSM and some women should have rectal and pharyngeal swabs regardless of symptom presence or history. Have you considered adapting this algorithm to include asymptomatic screening or having an additional one? If the flow chart is only for symptomatics then it should be included in the title and more prominent in the document. e. For symptomatic individuals culture should be a must for Neisseria gonorrhoeae in line with the new BASHH guideline, in order to obtain isolates for susceptibility testing in view of emerging treatment failure. NAATs should be additional for symptomatics and not an alternative. f. *Haemophilus ducreyi* and *Klebsiella granulomatis* are rare in this country and *H. ducreyi* declining worldwide – you may want to consider putting these in a footnote to simplify the algorithm. g. *Trichomonas vaginalis* should be with *N. gonorrhoeae* and *C. trachomatis* under HVS/cervical swab as it is a primary sexually transmitted pathogen and not sexually associated as is bacterial vaginosis and *Candida* species.	
Recommended Action	a. **NONE** The syndromic algorithm will act as the interface between the microbiology laboratory and clinical users and will reference the BASHH guidelines as the primary resource. b. **ACCEPT** c. **ACCEPT** A link to the HPA laboratory policy will be added to the footnote. d. **NONE** The remit was set by the UK Standards for Microbiology Investigations Steering Committee for a STI syndromic algorithm for symptomatic patients only. It is stated in the scope that the management of asymptomatic individuals is not covered in the document. e. **ACCEPT** The footnote will be amended to make it clear that culture is required on NAATs positive samples with an additional reference to the BASHH guidelines. f. **ACCEPT** *Klebsiella granulomatis* and *Haemophilus ducreyi* will be removed from the algorithm and put into a footnote. g. **NONE** Secondary testing is described under the scope of document as: “If the primary testing set does not identify a causative pathogen, secondary testing should

	be performed if clinical and/or epidemiological features support such testing. Laboratories may wish to undertake second line tests either after, or at the same time as, the primary testing set according to the clinical and local epidemiological setting and laboratory operational capabilities.”

Comment Number	3		
Date Received	05/08/2011	**Lab Name**	Dundee
Section	Various		
Comment			
Format issues: a. The use of dashed lines does not work well. The legend, with small boxes that explain the colour coding, comes out differently to the large boxes they are seeking to explain, at least on my PC/hardcopy. I suggest that if possible we use concentric rectangles. So PCR and/or microscopy would be a magenta rectangle around an orange rectangle. If concentric rectangles are not possible how about using a fill colour for one option, so that PCR could be a yellow fill with no border and PCR and/or microscopy would be an orange border with a yellow fill. b. The colours of clinical diagnosis, microscopy and their combination are too similar for me; a bright yellow might work better for clinical diagnosis. c. *T. pallidum* under ulcers: this appears to advocate PCR and/or microscopy, but this dashed box type has been left off the legend. d. The font is too small, particularly on the superscripts in the boxes. **Clinical issues:** e. PCR or culture would be better as PCR and/or culture for GC. f. I think that Lumps as defined is too broad, lymphadenopathy would bring in other pathogens that are more common in sexually active people eg EBV and CMV. I suggest re-defining as warts and papules. g. It may be worth changing Blood Serum to just Blood as some labs have standardised their serology and blood PCR to plasma. h. Footnote M: It seems likely that the average man with a sore urethra would prefer urine sampling to swabbing. Perhaps change this to “perform equally well and choice of sample can be guided by patient preference.” i. Sometimes the footnotes refer to PCR sometimes to NAAT, suggest a footnote to the PCR legend indicating as the BBC says that “other NAATs are available”.			
Recommended Action	a. **ACCEPT** A fill colour is reserved for the minimum testing algorithms. Concentric rectangle is an option but we will make the legend bigger and use a different colour to denote clinical diagnosis in the first instance.		

	b. **ACCEPT** A bolder colour will be used for clinical diagnosis. c. **ACCEPT** The legend will be corrected. d. **ACCEPT** The size of the superscript will be increased. e. **ACCEPT** The document will be amended. f. **NONE** EBV and CMV are not common presenting complaints of patients with STIs. g. **ACCEPT** The document will be amended. h. **ACCEPT** The footnote will be amended. i. **ACCEPT** PCR will be replaced by NAATs.

Comment Number	4		
Date Received	03/08/2011	**Lab Name**	Lead BMS Clinical Microbiology
Section			
Comment			
Just to check we have read, happy with the document and have no comments - we do not feedback if no comments is this correct?			
Recommended Action	**NONE** The Working Group wishes to thank you for your response. We welcome all feedback including those that have no comment to make but have read the document and are happy with the content.		

Comment Number	5		
Date Received	03/08/2011	**Lab Name**	Ipswich Hospital NHS Trust
Section	Flowchart		
Comment			
Replace "PCR" with "NAAT".			
Recommended Action	**ACCEPT** The flowchart will be amended.		

Comment Number	6		
Date Received	18/07/2011	**Lab Name**	Launch Diagnostics Limited
Section	Sexually transmitted infections - footnotes		
Comment			
In addition to PCR tests, rapid antigen tests are available for *Trichomonas vaginalis* which have increased sensitivity compared to culture. Footnote 'v' states PCR tests are available could this be extended to include rapid antigen tests.			
Recommended Action	**ACCEPT** The footnote will be extended.		

Comment Number	7		
Date Received	13/07/2011	**Lab Name**	Glasgow Royal Infirmary
Section	Flowchart		
Comment			
Should there be a footnote with regards investigations on vaginal discharge to note that the algorithm pertains to the investigation of vaginal discharge in the context of suspicion of STI? Essentially the primary care guidelines from FFPRHC, RCGP, HPA and CDC advise treating vaginal discharge empirically as either thrush or bacterial vaginosis unless one or more of the following:- <25 years old, new partner, >1 partner in 12 months (any one of these three constitutes 'high risk'), symptoms of upper reproductive tract infection (eg abnormal vaginal bleeding,			

dyspareunia, abdominal pain), atypical symptoms or signs, vaginitis without discharge, pregnancy, post-partum, pre- and post-termination of pregnancy, pre- and post-operative gynaecological surgery, 3 weeks post-IUD insertion, recurrent infections, failed treatment, medical conditions including diabetes mellitus. If any of these exist they advise endocervical swabs for GC and CT NAAT, and a high vaginal swab.

Recommended Action	**ACCEPT** The footnote will be amended and cross referenced to the HPA primary care guidance.

Comment Number	8		
Date Received	13/06/2011	**Lab Name**	Public Health Wales Microbiology Rhyl
Section	Various		
Comment			
a. There are two things that concern me about the algorithm. First is the context in which it is used. Use of the algorithm by a true GUM clinic is fine but I would have concerns over a GP surgery or what used to be a Family Planning type service being presented with the algorithm – I think there would be a great tendency to over investigate. b. The other point is the box labelled dysuria. I appreciate it has the qualifying statement about excluding a UTI first, but given that the comment has to be found elsewhere in the document I am concerned that clinical staff in primary care settings may be inappropriately encouraged to do GC and Chlamydia screening on any case of dysuria.			
Recommended Action	a. **NONE** The algorithm represents a good standard of practice and is consistent with BASHH guidelines. Clinical judgement will avoid the tendency to over investigate. b. **ACCEPT** The HPA primary care guidelines on UTI will be added to the footnote.		

Comment Number	9		
Date Received	09/06/2011	**Lab Name**	Ha-Emek Medical Center Afula 18101 Israel
Section	Various		
Comment			
I was wondering why the genital Mycoplasmas were left out from the algorithm and the text of the draft. They are known to be the cause of NGU and should be treated clinical presentation pending. There would be the following to consider: 1. *Mycoplasma genitalium* (in the recent ECCMID meeting there was a presentation entitled "….*Mycoplasma genitalium*: the new Chlamydia trachomatis?...") 2. *Mycoplasma hominis* and 3. *Ureaplsama urealyticum* (more implication in PID but nonetheless)			
Recommended Action	**NONE** See additional footnote which states that "Ureaplasma and Mycoplasma are not covered in this algorithm due to the lack of clinical significance in PID and vaginal discharge". This statement will be referenced.		

Comment Number	10		
Date Received	07/06/2011	**Lab Name**	Royal Infirmary of Edinburgh
Section	S 6 Sexually Transmitted Infections (draft)		
Comment			
a. I note that HIV is not covered in detail. I can understand why this is, as it deserves separate detailed guidance. However I think that should be more explicitly stated, and I think the paragraph on page 8 that mentions HIV should be expanded to make it more comprehensive. I suggest [new bits in capitals] "Individuals who are at increased risk of any STI, or those with a diagnosed STI are at risk of multiple STIs. Therefore a screening approach SHOULD be undertaken to account for possible asymptomatic, subclinical, or past unrecognised infections ESPECIALLY HIV, AND SYPHILIS, BUT ALSO HEPATITIS B AND OTHER INFECTIONS IN SELECTED CASES WITH ADDITIONAL RISK FACTORS.." b. Secondary testing ideas need to be couched as optional. Page 7: "Secondary tests may be performed either after the primary testing set has been completed without identifying a causative pathogen.." could be taken to mean they must be			

done in primary tests are negative. That would be a significant change in practice with greatly increased numbers of tests for *H du*reyi and *K granulomatosis*. I think it would be better to say "Secondary tests may be performed after the primary testing set has been completed without identifying a causative pathogen IF CLINICAL AND EPIDEMIOLOGICAL FEATURES ARE JUDGED TO SUPPORT SUCH SECONDARY TESTING. IN SOME CASES SECONDARY TESTS MAY BE DONE IN PARRALEL WITH PRIMARY TESTS IF LOCAL TECHNOLGY ALLOWS AND CLINICAL/EPIDEMIOLOGICAL FEATURES SUGGEST. [wording could be improved but I think you will get the idea] c. Page 11 "Ureaplasma and Mycoplasma are not covered in this algorithm due to the low incidence in PID and vaginal discharge" I believe these organisms are very common, including in people with PID, discharge etc but they are not worth looking for because of lack of association with clinical problems and lack of treatment of known efficacy. So I would re-word that to say "Ureaplasma and Mycoplasma are not covered in this algorithm due LACK OF CLINICAL SIGNIFICANCE in PID and vaginal discharge" I can find evidence to support this view if you don't already have it.	
Recommended Action	a. **ACCEPT** The information will be covered in the footnote and in scope, with a reference to BASHH guidelines. b. **ACCEPT** The scope will be amended. c. **ACCEPT** The footnote will be amended with an additional reference to support the statement.

Comment Number	11		
Date Received	06/06/2011	**Lab Name**	Luton & Dunstable Hospital
Section	Various		
Comment			
In the algorithm female urine sample doesn't lead anywhere?			
Recommended Action	**ACCEPT** The algorithm will be amended.		