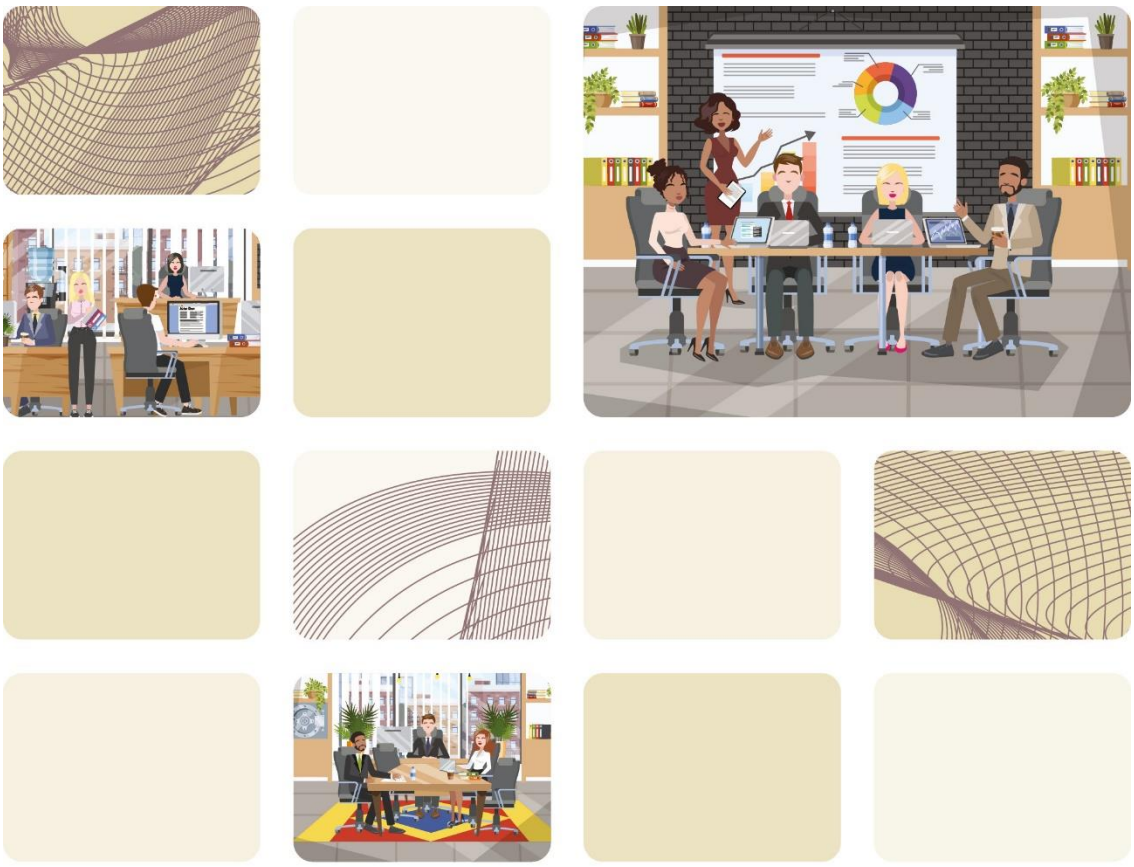
UK Health Security Agency

UK Standards for Microbiology Investigations

Review of users' comments received by Joint working group for syndromic algorithms

S 06 Infectious syndromes affecting the genitourinary tract and reproductive organs



This publication was created by UK Health Security Agency (UKHSA) in partnership with the partner organisations.

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

Consultation: 31/07/2024 – 04/09/2024
Version of document consulted on: S 06 dq+

Definitions

Comment number: 1

Date received: 03/08/2024
Laboratory or organisation name: Leicester Royal Infirmary

Not all neovaginas are derived from penile and scrotal skin. Surgical procedures also exist that create neovaginas from sigmoid colon grafts and tissue also.

Long A, Leroy K, Wong P. Sigmoid Neovagina: A Case Presentation and Pathological Review of Intestinal Transfer. ACG Case Rep J. 2019;6(9):e00220

Birse KD, Kratzer K, Zuend CF, et al. The neovaginal microbiome of transgender women post-gender reassignment surgery. Microbiome. 2020;8(1):61

Recommended action

1. Accept.

Comment number: 2

Date received: 29/08/2024
Laboratory or organisation name: UKHSA STIRL

1. Neovaginas are constructed from intestinal tissue - which has a different microbiome.
2. Neo-penis is more complex than just being constructed from clitoral tissue.
3. MSM superseded by GBMSM

Recommended action

1. Accept.
2. Accept.
3. Accept.

Comment number: 3

Date received: 03/09/2024
Laboratory or organisation name: University Hospitals of Leicester NHS Trust

Page 6 - first paragraph - Line should read ''acceptable *to* their users.

Recommended action

1. Accept.

4.1 Sexually transmitted infections (STIs)

Comment number: 4

Date received: 03/08/2024
Laboratory or organisation name: Leicester Royal Infirmary

1. Page 7 "A pregnant mother with gonorrhoea can infect her child through childbirth"
   Doesn't 'during' sound more appropriate than 'through'? Change 'child' to 'newborn' as well?
2. Include a section on Tinea genitalis here also? There are noted case reports of sexually transmitted dermatophytes resulting in Tinea genitalis especially in the MSM demographic.

   Chromy D, Osmers AM, Bauer WM, et al. Sexually Transmitted Dermatophytes Can Cause Severe Infection Among Men who Have Sex With Men as Tinea Genitalis. Open Forum Infect Dis. 2023;10(11)

   Jabet A, DelliÃ¨re S, Seang S, et al. Sexually Transmitted Trichophyton mentagrophytes Genotype VII Infection among Men Who Have Sex with Men. Emerging Infectious Diseases. 2023;29(7)
3. Trichomoniasis - Is it worth including some sentences on fomite transmission as well?
   Bishop KM. A Resistant Case of Familial Nonsexual Transmission of Trichomonas. Cureus. 2020;12(7):e9246
   Kandamuthan S, Thambi R, Yeshodharan J. Trichomoniasis: Is it always sexually transmitted?. Indian J Sex Transm Dis AIDS. 2014;35(2):166-167
4. "Transmission to neonate can occur at birth and newborn babies can develop eye infections or pneumonia". Change to "Vertical transmission can occur at birth with the risk of eye infections or pneumonia in the neonate"
5. Brucella should be mentioned? It is a valid consideration in endemic areas and has a well known relation to epididymo-orchitis and scrotal related abscesses.

   Al-Tawfiq JA. Brucella epididymo-orchitis: a consideration in endemic area. Int Braz J Urol. 2006;32(3):313-315
   Hamoda TAA, Bahassan O, Almalki AM, et al. Brucellar testicular abscess: The 17th case report and review of literature. Urol Ann. 2023;15(3):340-348.

Recommended action

1. Accept. Changed to suggested text.
2. None. The focus is on common infections. This is also outside the scope.
3. Accept. Sentence added on fomite transmission.
4. Accept. Changed to suggested text.
5. Accept. Sentence added on Brucella.

Comment number: 5

Date received: 08/08/2024
Laboratory or organisation name: Salisbury Microbiology

I feel this section should include reference to Granuloma inguinale caused by Klebsiella granulomatis (formerly known as Calymmatobacterium granulomatis) under genital ulcers section. Albeit rare, I have seen requests for this from our local GUM department over the last 2 years. With the increased migration and climate changes, I think this needs to be a consideration once more common syndromic requesting has been carried out.

Recommended action

1. Accept. *Klebsiella granulomatis* has been included.

Comment number: 6

Date received: 08/08/2024
Laboratory or organisation name: Salisbury Microbiology

Keep awareness of Granuloma inguinale in scope and ensure appropriate testing should this be clinically suspected

Recommended action

1. None. There is mention of *Klebsiella granulomatis* in the text.

Comment number: 7

Date received: 08/08/2024

Laboratory or organisation name: Severn Pathology (collaboration between North Bristol NHS Trust and UKHSA), Infection Science department

Page 7 paragraph 3. N. gonorrhoeae - should be in italics

Recommended action

1. Accept.

Comment number: 8

Date received: 08/08/2024
Laboratory or organisation name: Severn Pathology (collaboration between North Bristol NHS Trust and UKHSA), Infection Science department

Section 4.2 Balanitis and Balanoposthitis. Page 14 - typo - N. gonorrhoea - needs to be N. gonorrhoeae

Recommended action

1. Accept.

Comment number: 9

Date received: 14/08/2024
Laboratory or organisation name: Department of Microbiology, University Hospitals of Leicester NHS Trust

1. As this is a fairly comprehensive clinical syndrome based guideline, we feel it would be useful to add a comment regarding blood-borne virus infections, given the common route of transmission to other infections in the SMI.
   Our suggestion is a simple addition to the first paragraph in the background section stating. 'Although blood-borne virus infection is not covered in this guideline, consideration should always be given to such testing in the context of patients presenting with a sexually-transmitted infection.'
2. Page 7 - line 1 - should be 'increasingly high' rather than 'increasing high'
3. Page 7 - line 3 - should be 'International spread of a ceftriaxone-resistant gonococcal strain...'
4. Page 8 - line 23 - HPV follows human papillomavirus and should therefore be in brackets
5. Page 9 - line 35 - The sentence regarding M.genitalium being associated with C.trachomatis doesn't make sense; M.genitalium is frequently a co-infection with C.trachomatis. It is also a cause of non-gonococcal urethritis and should be treated as such. As the sentence stands, it seems to play this down almost implying M.genitalium doesn't need treating in and of itself.
6. Page 9 - line 40 - 'Sexually acquitted reactive arthritis' should be 'sexually acquired reactive arthritis'.
7. Page 10 - Ureaplasma. The last sentence statues 'Testing is no longer recommended by BASHH'. This is not entirely true, and we would suggest changing to 'Routine testing is no longer recommended by BASHH, but can be considered in certain scenarios under expert guidance'.
8. Page 10 - Mpox. Last line of second paragraph - we didn't feel the sentence regarding confusion with chickenpox rash was helpful here without a line about

distinguishing the two rashes clinically. We feel this therefore needs expanding or removing.
9. Page 11 - Genital ulcers - the second paragraph in this section are very confused, with missing commas, and enterovirus appearing twice in the list.
10. We would also add Klebsiella granulomatis as a cause (Donovanosis) of genital ulcers and consider adding testing with biopsy to the genital ulcer algorithms when other testing is negative.
11. In the third paragraph, some important differentials are missing, suggest: 'Not all genital ulcers are caused by infection. Other causes include sexual injury, chemical burns and trauma, as well as autoimmune disease and malignancy'.

Recommended action

Background section states ‘Although blood-borne virus infection is not covered in this guideline, consideration should always be given to such testing in the context of patients presenting with a sexually-transmitted infection. Please refer to the Guidance for the design of self-sampling packs and associated support for self-sampling processes within Sexually Transmitted Infection and Blood Borne Virus testing’.

1. Accept. Changed to suggested text.
2. Accept. Changed to “In many countries, ciprofloxacin and azithromycin resistance is high and resistance to cefixime and ceftriaxone continue to increase”.
3. Accept. Changed to “International spread of ceftriaxone-resistant gonococcal strains have been reported in Denmark, France, Japan and the United Kingdom”
4. Accept.
5. Accept.
6. Accept.
7. Accept.
8. Accept. Sentence removed.
9. Accept. Paragraph re-worded.
10. Accept. Included Klebsiella granulomatis.
11. Accept.

Comment number: 10

Date received: 28/08/2024
Laboratory or organisation name: Institute of Biomedical Science

Document would benefit of greater detail comparing the normal microbiota of vagina vs neovagina.

Neovagina microbiota is more in line with uncircumcised penises, than cis vaginas
The neovaginal microbiome of transgender women post-gender reassignment surgery | Microbiome | Full Text (biomedcentral.com).
https://microbiomejournal.biomedcentral.com/articles/10.1186/s40168-020-00804-1

Recommended action

1. None. The focus is on the vagina even though there is mention of the neovagina. It is stated in the text that at the time of writing there is not much literature that can be used in the document.

Comment number: 11

Date received: 29/08/2024
Laboratory or organisation name: UKHSA STIRL

Chlamydia

1. *Chlamydia trachomatis,* which is the most common “bacterial” STI.

Gonorrhoea

2. Move paragraph to the start “Gonorrhoea is caused by the Gram-negative diplococcus *Neisseria gonorrhoeae*. Diagnoses are highest in young people aged 15-24 years and in the GBMSM community”.
3. Re-word to “In many countries, ciprofloxacin and azithromycin resistance is high and resistance to cefixime and ceftriaxone continue to increase [1]. International spread of ceftriaxone-resistant gonococcal strains have been reported in Denmark, France, Japan and the United Kingdom. There are increasing numbers of treatment failures being reported from Austria, the United Kingdom and other countries.
4. Refer to Managing incidents of ceftriaxone-resistant Neisseria gonorrhoeae in England.

Recommended action

1. Accept.
2. Accept.
3. Accept.
4. Accept. Rephrased sentence and added the reference.

Comment number: 11

Date received: 03/09/2024
Laboratory or organisation name: University Hospitals of Leicester NHS Trust

1. Page 7 - Gonorrhoea section, 1st bullet point in the comment on 'penile urethral infection', the second line should start with 'Some' rather than 'Same'.
2. Page 8 - in the section on 'Genital warts' there is an unnecessary comma between urethral and meatus.
3. Page 9 - in the section on LGV, there is a typo in the second spelling of genovars.
4. Page 12 - Under 'Non-gonococcal urethritis, 'balano-posthitis' is spelt incorrectly.
5. Also under same section, ureaplasma is identified as a common cause of non-gonococcal urethritis and yet testing is not recommended. It would be useful to qualify this here.

6. Page 12 - Under 'vaginitis', trichomoniasis is mentioned but under the section of non-sexually transmitted disease. Is this meant to reflect that vaginitis is not usually an STI but can be on occasion?
7. Page 14 - is M hominis meant to be at the end of the the list of organisms that cause salpingitis as it is written?

Recommended action

1. Accept.
2. Accept.
3. Accept.
4. Accept.
5. Accept.
6. None. Some infection/disease can be listed as both STI and non STI. The decision was made with our working group where it would fit best.
7. None. For non-gonococcal urethritis, can refer to BASHH guidance as referenced for further information.

Comment number: 12

Date received: 04/09/2024
Laboratory or organisation name: British Association for Sexual Health and HIV (BASHH)

1. Mycosplasma Genitalium: Page 9 - Current wording states that Mgen complications include tubal factor infertility (TFI). A causal link between Mgen and TFI however is currently unproven and this section should be amended accordingly.
2. Ureaplasma: Page 10 - Use of the plural version i.e. ureaplasmas should be adopted, as ureaplasmas encompass both Ureaplasma urealyticum and ureaplasma parvum

Recommended action

1. Accept. Removed TFI.
2. Accept

Comment number: 13

Date received: 04/09/2024
Laboratory or organisation name: British Association for Sexual Health and HIV (BASHH)

The subheadings for these two sections at present don't make sense and are not helpfully set out. They are a mixture of pathogens, syndromes. Neisseria Meningitidis does not warrant mention. Epidiymo-orchitis appears under the STI heading, yet PID appears under the non-STI heading. The current order of organisms puts those of

greater importance towards the end and those of lesser importance at the start

We would recommend the following lay out/subheading and order:

Section 4.1 Sexually transmitted pathogens:

Bacterial

Gonorrhoea
Chlamydia

Syphilis
Trichomonas vaginalis
Mycoplasma genitalium
Lymphogranuloma venereum
Ureaplasmas

Viral
Herpes simplex
Human Papilloma virus
Molluscum contagiosum
Mpox

Other pathogens

Candidiasis (vulvo-vaginal)
Bacterial vaginosis

Section 4.2 STI- and non STI-related Clinical syndromes

Cervicitis
Pelvic Inflammatory disease including salpingitis
Vulvovaginitis
Urethritis
Balanitis and balanoposthi
Epididymo-orchitis
Prostatitis
Proctitis
Genital ulcer disease
Bartholinitis

Section 4.3 Other issues

Complications in pregnancy
IUCDs (not sure why this has been included)

Recommended action

1. Accept. The order has been changed as suggested and agreed at the UK SMI Joint working group on 27.11.2023

4.2 Non Sexually transmitted infections (STIs)

Comment number: 14

Date received: 03/08/2024
Laboratory or organisation name: Leicester Royal Infirmary

1. Bacterial vaginosis:

Include a section for aerobic vaginitis as well?

This is a distinct condition from bacterial vaginosis but similarly involves an altered vaginal microbiome.

Donders GG, Vereecken A, Bosmans E, Dekeersmaecker A, Salembier G, Spitz B. Definition of a type of abnormal vaginal flora that is distinct from bacterial vaginosis: aerobic vaginitis. BJOG. 2002;109(1):34-43

Donders GGG, Bellen G, Grinceviciene S, Ruban K, Vieira-Baptista P. Aerobic vaginitis: no longer a stranger. Res Microbiol. 2017;168(9-10):845-858

2. IUCDs: Mention rare association of respiratory organisms of H.influenzae and S.pneumoniae here as well?

Tanaka K, Mikamo H, Ninomiya M, et al. Microbiology of Bartholin's gland abscess in Japan. J Clin Microbiol. 2005;43(8):4258-4261

Mikamo H, Tamaya T, Tanaka K, Watanabe K. Jpn J Antibiot. 2005;58(4):375-381.

Recommended action

1. Accept.
2. None: We are only focusing on the main organisms. Rare association of respiratory organisms of H.*influenzae and S.pneumoniae* will be mentioned in the relevant syndromic document.

Comment number: 15

Date received: 14/08/2024
Laboratory or organisation name: Department of Microbiology, University Hospitals of Leicester NHS Trust

1. The pelvis inflammatory disease section appears under non-sexually transmitted infections. While as outlined, C.trachomatis and N.gonorrhoeae make up less than 50% of causes, and therefore it is more likely to be non-sexually transmitted (although M.gen contribution not stated), such testing would be performed first. Consider therefore moving this section to the end of Section 4.1
2. There is also a typo in the first sentence of the PID section â€“ PID is a 'term' not 'tern'.
3. Page 15, line 7 (Bacterial vaginosis)- ''relacing'' should be ''replacing''
4. Miscarriage/recurrent miscarriage/intrauterine death; In the final paragraph on page 15, we would suggest adding a caveat to coxsackie virus to say '(in late pregnancy)' as enterovirus transplacental infection is not generally considered to occur earlier in the pregnancy as it can be with the other infections listed.
5. There is inconsistency in the IUCDs section regarding both the phrase of intra-uterine contraceptive device and the acronym, between IUCDs and IUCs.

Recommended action

1. None. The layout of the sections have been discussed and agreed by our working groups.
2. Accept.
3. Accept.
4. Accept.
5. Accept. Changed to IUCs.

Comment number: 16

Date received: 21/08/2024
Laboratory or organisation name: Microbiology Leeds Teaching Hospitals NHS Trust

P13 end VVC section.

I would say that the guidelines referenced (Saxon et al 2020) recommend for recurrent VVC an exam and HVS and that the swab should be processed for culture with identification of the yeast and antifungal sensitivity. Microscopy is only done for acute vaginitis and in fact is rarely done outside of a GUM clinic.

Recommended action

1. Accept.

Comment number: 17

Date received: 22/08/2024
Laboratory or organisation name: Southwest Pathology Services

1. Pelvic Inflammatory Disease - SOP needs to state that HVS or CX swabs should not be sent for the diagnosis of PID
2. SOP should clearly state that examination of IUDs should not be performed in routine IUD changes. It should also state that routine HVS are not required if clinical details indicate IUD change or new IUD.

Recommended action

1. None. Stated to refer to BASHH guidance.
2. None.

Comment number: 18

Date received: 04/09/2024
Laboratory or organisation name: British Association for Sexual Health and HIV (BASHH)

Salpingitis: Page 14 - Reference to the involvement of M.hominis to Salpingitis appears to be incorrect, as it is instead M.genitalium that has a causal link to Salpingitis.

Recommended action

1. Accept. M. hominis removed. Section moved to PID.

5 Medicolegal Cases

Comment number: 19

Date received: 14/08/2024
Laboratory or organisation name: Department of Microbiology, University Hospitals of Leicester NHS Trust

1. Under the tables, there are further points on testing. While syphilis testing is correct later in the document, here it suggests dark field microscopy for T.pallidum. This has by and large been replaced by T.pallidum PCR and you would be hard pushed to find a lab still offering dark field microscopy. It does not appear in the SMI for syphilis testing.
2. In swabbing a child for HSV DNA PCR in a medico-legal context, we would also suggest HSV type specific serology.

3. The last part in 5 regarding anogenital warts is not formatted correctly as its own point.

Recommended action

1. None. This section has been updated. All information removed and users directed to the appropriate guidance documents.

Comment number: 20

Date received: 14/08/2024
Laboratory or organisation name: British Association for Sexual Health and HIV (BASHH) Herpes Simplex Advisory Board Special Interest Group

NAAT for TV is more sensitive than culture or microscopy and is now widely available - you also reference TV NAAT later in section 6 so why not consistency across the document. Most sites with TV NAAT will not be able to offer culture any more

Recommended action

1. Accept.

Comment number: 21

Date received: 22/08/2024
Laboratory or organisation name: UKHSA regional SW (Bristol)

I would omit this section entirely- not an infection syndrome.

Recommended action

1. None. The medicolegal section remains and refers to appropriate guidance.

Comment number: 22

Date received: 22/08/2024
Laboratory or organisation name: Southwest Pathology Services

I am very, very concerned about this section. I believe that the routine clinical microbiology laboratory should play no part in the medico-legal process in patients of suspected sexual abuse. Examination of specimens from such cases MUST be performed by appropriate Home Office Accredited laboratories. The SMI indicates direct plating for the investigation of GC (swabs acceptable if transported immediately) yet many labs offering this service only receive swabs (often with delays between

sampling and receipt). Why try prescribing a process that is poorly controlled, not adhered to properly (at the clinical end) and is prone to mistakes?

Recommended action

1. None. The medicolegal section remains and refers to guidance

Comment number: 23

Date received:03/09/2024
Laboratory or organisation name: University Hospitals of Leicester NHS Trust

In the tables, 'Vulvo-vestibular' has been misspelt in both the prepubertal and postpubertal females sections.

Recommended action

1. Accept.

Comment number: 24

Date received: 04/09/2024
Laboratory or organisation name: British Association for Sexual Health and HIV (BASHH)

1. Page 16 - Suggestion that the positioning of this section is moved down, to sit beneath sections on 'Clinical Presentations' and 'Pre-laboratory processes', which are likely to be more relevant to most users of this guidance.
2. Proofing error in the 'Specimen' column. 'Vulvo-vestiblar' should read 'Vulvo-vestibular'.

Recommended action

1. Accept.
2. Accept.

Algorithm 1: Sexually transmitted infections in persons with a vagina

Comment number: 25

Date received: 03/08/2024
Laboratory or organisation name: Leicester Royal Infirmary

Page 19 and 20 NAAT is written in red text?

Recommended action

1. Accept

2.

Comment number: 26

Date received: 14/08/2024
Laboratory or organisation name: Department of Microbiology, University Hospitals of Leicester NHS Trust

1. The subpoint 'a' mentions TV culture or wet mount where NAAT is not available. We suggest caveating that wet mount is a near patient test. Due to transport delays/storage, both are likely to be less sensitive than NAATs.
2. In the genital ulcer section, we suggest also Chlamydia NAATS as a second line test followed by LGV PCR testing as a less common cause of ulcers.
3. Do the writers of the SMI wish to also include a specific part of the algorithm for asymptomatic testing, or leave this to the text section regarding contacts etc?

Recommended action

1. Accept.
2. Accept.
3. None. In the scope we mention that screening is not included and we focus on symptomatic patients.

Comment number: 27

Date received: 14/08/2024
Laboratory or organisation name: British Association for Sexual Health and HIV (BASHH) Herpes Simplex Advisory Board Special Interest Group

MPOX is included as a primary test but in algorithm 2 (penis) it's included as a secondary test. I would suggest based on UK epidemiology that MPOX should be a secondary test for both groups.
Also you have Chlamydia trachomatis and LGV as secondary tests for penis but not for vagina - this doesn't make sense, they should be secondary tests for both groups as LGV in women is no rarer in the UK than chancroid and probably a bit more common or certainly likely to become more common as we see increases again in LGV in MSM

Recommended action

1. Accept.

Comment number: 28

Date received: 22/08/2024
Laboratory or organisation name: UKHSA regional SW (Bristol)

Algorithm 1. Remove mpox from primary screen and place in secondary. Consider VZV in secondary.

Recommended action

1. Accept.

Comment number: 29

Date received: 04/09/2024
Laboratory or organisation name: British Association for Sexual Health and HIV (BASHH)

Page 20 - Reference to Mycoplasma genitalium NAAT should be removed from the list of secondary tests for Vaginal Discharge and Urethritis in women, as these clinical presentations alone are not a sufficient indication for Mgen testing (whereas they are in men).

Recommended action

1. Accept.

Algorithm 2: Sexually transmitted infections in persons with a penis

Comment number: 30

Date received: 22/08/2024
Laboratory or organisation name: UKHSA regional SW (Bristol)

Algorithm 2. Mpox for secondary, consider VZV.

Recommended action

1. Accept.

Comment number: 31

Date received: 04/09/2024
Laboratory or organisation name: British Association for Sexual Health and HIV (BASHH)

Page 21 - Reference to Mycoplasma genitalium NAAT should be removed from the list of primary tests for clinical presentations for Epididymitis and Orchitis as this is not in line with accepted evidence.

Recommended action

1. Accept.

7.1 Specimen type, collection, and handling

Comment number: 32

Date received: 03/08/2024
Laboratory or organisation name: Leicester Royal Infirmary

Page 25 "...however, assays are emerging"

Could this be reworded to "commercial assays are available"?

Recommended action

1. Accept.

Comment number: 33

Date received: 08/08/2024
Laboratory or organisation name: Severn Pathology (collaboration between North Bristol NHS Trust and UKHSA), Infection Science department

Page 23 - Table 5, in Organism column - typo - Neisseria gonorrhoea - needs to be Neisseria gonorrhoeae

Recommended action

1. Accept

Comment number: 34

Date received: 14/08/2024
Laboratory or organisation name: Department of Microbiology, University Hospitals of Leicester NHS Trust

1. Intrauterine contraceptive device acronym should be IUCD, not ICUD.
2. The formatting looks off for 'Fluids and pus vaginal-rectal specimens'.
3. In the bacterial investigations section of the table, under the NAATS testing for C.trachomatis and N.gonorrhoeae, the first sample type is 'endocervical swab' which is not the best sample, suggest re-order this section to vulvovaginal swab first. It is not clear here as it is in the text that not all these sample types are equally sensitive, especially urine in persons with a vagina.

   For genital reconstructive surgery, are users likely to be familiar with whether mesothelial grafts were used in the construction of the neovagina? Suggest state to send both urine and a swab of the neovagina regardless.

   Under the N.gonorrhoeae culture section, specimen types are given as swabs/ urine. This disagrees with NICE guidance. For culture, urine is not used and nor are vulvovaginal swabs. Should specify endocervical, endourethral (for persons with a penis), rectal, neovaginal or pharyngeal swabs.

Recommended action

1. Accept
2. Accept
3. Accept

Comment number: 35

Date received: 14/08/2024
Laboratory or organisation name: British Association for Sexual Health and HIV (BASHH) Herpes Simplex Advisory Board Special Interest Group

1. LGV NAAT should include ulcer swab as an option
2. GUM clinics have moved to vulvovaginal swabs for CT and NG - we don't swab the os even if pelvic infection is suspected for NAAT as less sensitive. And for MGen there's no need to have a VVS followed by an endocervical swab - VVS is fine
3. for GC culture I think you should state the site as urethral or endocervical swab. We don't culture urine for GC
4. T pallidum - seems risks to say that serology will be positive within 2 weeks of a chancre. Window period can be up to 3 months
5. TV - endocervical swab less sensitive than VVS

Recommended action

1. Accept
2. Accept
3. Accept

4. Accept
5. Accept

Comment number: 36

Date received: 22/08/2024
Laboratory or organisation name: Unidentified

Section 7 table 5 Chlamydia trachomatis / Neisseria gonorrhoea is too vague to be useful. The tests are listed but not prioritised and best test not highlighted in any order. Also the test doesn't link to the type of sample-which could be useful. Can it align to the BASH guidelines which give more information regarding preferred swabs/samples for individual tests?
E.g. https://www.bashh.org/resources/15/chlamydia_2015 .
" Chlamydia Diagnosis
The current standard of care for all cases, including medico-legal cases and extra-genital infections, is NAAT.
Although no test is 100% sensitive or specific, NAATs are known to be more sensitive and specific than EIAs.
Vulvo-vaginal swabs (VVS): A vulvo-vaginal sample is the specimen of choice in women (Level IIa, Grade B).
Endocervical swabs: These have been shown to be less sensitive than VVS and require a speculum examination performed by an HCW. Inadequate specimens reduce the sensitivity of NAATs.
First-catch urine: Variable sensitivities have been reported using first-catch urine (FCU) specimens in women. FCU in men is reported to be as sensitive or more sensitive than urethral sampling (Level IIa, Grade B).
Urethral swabs: Can be taken but may be less acceptable than urine samples for patients.
Extra-genital sampling:
Rectal swabs and pharyngeal swabs: NAATs are the assays of choice for both genital and extra-genital samples, though the sensitivities are variable (Level IIa, Grade B)."

Recommended action

1. None. The BASHH guidance has been referenced.

8.3 Culture media, conditions and organisms

Comment number: 37

Date received: 03/08/2024
Laboratory or organisation name: Leicester Royal Infirmary

Page 29 - Should Listeria be added to the table in association with 'Miscarriage' and Brucella in association with epididymo-orchitis?

Recommended action

1. None. Mentioned in the text.

Comment number: 38

Date received: 13/08/2024
Laboratory or organisation name: Northampton General Hospital - Microbiology

The current SMI (B28i4.6 April 2017) lead to some confusion regarding the appropriate media for a Bartholin's abscess swab culture as the summary table appears to indicate the addition of only a blood agar plate to the standard set despite Section 4.2 outlining associated infections as including "Anaerobes, N. gonorrhoeae, streptococci, Enterobacteriaceae, C. trachomatis, H. influenzae, S. aureus, other Neisseria species and M. hominis".

The revised S06 summary table (Table 6) now does not include Bartholin's abscess as a clinical detail for guidance on appropriate supplementary media, and the description of Bartholin's abscess includes as causative organisms "aerobic and anaerobic organisms including E. coli....N. gonorrhoeae and C. trachomatis."

If appropriate, I would welcome inclusion of Bartholin's abscess as a specific clinical detail into the table for clarity on appropriate plate sets to culture for Bartholin's abscess swabs as e.g. H. influenzae has now not been listed as a (significant) causative organism.

In my own reckoning (for what it's worth as a Trainee BMS) I would think an appropriate plate set in our laboratory would be the routine CUTI/CNA + SAB, with additional FAANEO (with MTZ) and selective GC agar - this would be my interpretation from the SMI, but it would be nice if it was explicitly listed in the summary table.

Many thanks.

Recommended action

1. Accept. Bartholin’s abscess has been added to the table.

9.3 Reporting Culture results

Comment number: 39

Date received: 22/08/2024

Laboratory or organisation name: Southwest Pathology Services

Instructions for reporting significant isolates or no growth but what about when no significant isolates and NOT no growth? Report as No Pathogens Isolated? Report specific target organisms not isolated?

Recommended action

1. Accept.

10 Antimicrobial susceptibility testing

Comment number: 40

Date received: 21/08/2024
Laboratory or organisation name: Microbiology Leeds Teaching Hospitals NHS Trust

1. Candida - add "and other ascomycetous yeasts"
2. There are no breakpoints for nystatin, clotrimazole and miconazole.
   I would be sceptical about recommending these sensitivity tests in an SMI and leave this kind of testing to the Reference lab.
   Also the chances of needing Amphotericin, echinocandins or flucytosine to treat Genito-urinary tract (as opposed to urinary which is not covered here) is extremely low, again I wouldn't include these as "standard" investigations.

Recommended action

1. Accept.
2. None. The table is to aid laboratories to decide the appropriate antibiotic panel. Users should refer to EUCAST and BSAC guidelines.

Comment number: 41

Date received: 22/08/2024
Laboratory or organisation name: Southwest Pathology Services

Whilst I understand the need for a 'National approach' to antimicrobial susceptibility testing protocols and reporting I can't help thinking that you're opening a can of worms with this one. Firstly, UKAS (with their almost black and white approach to assessment) are going to require all labs to stick to this SMI. Secondly, antimicrobial testing is more than often driven by local guidelines, GU clinic requirements and Lead pharmacist directive. Finally (and in consideration of the first point), this SMI is effectively indicating all Candida sp should be identified and fluconazole testing performed (logistical nightmare).

Recommended action

1. None. The table is to aid laboratories to decide the appropriate antibiotic panel. Users should refer to EUCAST and BSAC guidelines.

Comment number: 42

Date received: 27/08/2024
Laboratory or organisation name: British Society of Antimicrobial Chemotherapy (BSAC); Antimicrobial Susceptibility Testing committee

This table shows a list of antimicrobial agents for laboratories to susceptibility test. Breakpoint for existing antimicrobial agents can change annually and breakpoints for new agents added. For this reason, the table should only be added if the document is to be updated annually, alongside the EUCAST breakpoint table updates.

In the table there are a number of considerations, see below:

N. gonorrhoeae: 1. azithromycin can only be interpreted using an ECOFF. 2. There is no breakpoint for ertapenem or gentamicin; in the EUCAST breakpoint tables Insufficient evidence is stated for ertapenem whilst there is a dash (meaning do not test) for gentamicin.

Beta-haemolytic streptococci: There is not breakpoint for linezolid against Streps grp ACFG. An ECOFF exists for group B strps.

Anaerobes: 1. generic EUCAST breakpoints for anaerobes do not exist, they have been divided into the following species with different breakpoints (Bacteroides spp., Prevotella spp., Fusobacterium spp., C. acne & C. perfringens. The breakpoints of metronidazole and other agents are different for each species. 2. Amoxicillin and amoxicillin-clavulanic acid are misspelt in the document.

Listeria monocytogenes: there is no breakpoint for linezolid.

Candida: there are no breakpoints for nystatin, clotrimazole, miconazole or flucytosine.

For the above reasons and to mitigate against outdated information BSAC would advise that the table is removed and replaced with a link to the EUCAST breakpoint table and BSAC webpage for UK advice. This table shows a list of antimicrobial agents for laboratories to susceptibility test. Breakpoint for existing antimicrobial agents can change annually and breakpoints for new agents added. For this reason, the table should only be added if the document is to be updated annually, alongside the EUCAST breakpoint table updates.

In the table there are a number of considerations, see below:

N. gonorrhoeae: 1. azithromycin can only be interpreted using an ECOFF. 2. There is no breakpoint for ertapenem or gentamicin; in the EUCAST breakpoint tables Insufficient evidence is stated for ertapenem whilst there is a dash (meaning do not test) for gentamicin.

Beta-haemolytic streptococci: There is not breakpoint for linezolid against Streps grp ACFG. An ECOFF exists for group B strps.

Anaerobes: 1. generic EUCAST breakpoints for anaerobes do not exist, they have been divided into the following species with different breakpoints (Bacteroides spp., Prevotella spp., Fusobacterium spp., C. acne & C. perfringens. The breakpoints of metronidazole and other agents are different for each species. 2. Amoxicillin and

amoxicillin-clavulanic acid are misspelt in the document.

Listeria monocytogenes: there is no breakpoint for linezolid.

Candida: there are no breakpoints for nystatin, clotrimazolem micronazole or flucytosine.

For the above reasons and to mitigate against outdated information BSAC would advise that the table is removed and replaced with a link to the EUCAST breakpoint table and BSAC webpage for UK advice. BSAC have advised a similar approach in past SMI syndromic documents, where the tables were removed and EUCAST links added.

Recommended action

1. None. The table is to aid laboratories to decide the appropriate antibiotic panel. Users should refer to EUCAST and BSAC guidelines.

Comment number: 43

Date received: 04/09/2024
Laboratory or organisation name: Scottish Bacterial STI Reference Laboratory

1. Testing recommendations for N. gonorrrhoeae are largely in line with current UK guidance (BASHH 2018). However, ertapenem is not included in the clinical guideline and no breakpoints (clinical or epidemiological) are available from EUCAST for interpretation. Ertapenem has been used in small numbers of literature reports. I think usage should be based on expert guidance in specific complicated cases, and testing not recommended in this document until further evidence to guide wider clinical use is available.

Recommended action

1. None. The table is to aid laboratories to decide the appropriate antibiotic panel. Users should refer to EUCAST and BSAC guidelines.

General Comments

Comment number: 44

Date received: 14/08/2024
Laboratory or organisation name: Department of Microbiology, University Hospitals of Leicester NHS Trust

1. Contents list - Hyphen between pre-analytical but not between post analytical is inconsistent
2. Formatting needs fixing on reference 26.

Recommended action

1. Accept
2. Accept

Comment number: 45

Date received: 04/09/2024
Laboratory or organisation name: British Association for Sexual Health and HIV (BASHH)

We would appreciate further clarity on the intended purpose of this document, particularly when thorough and robust BASHH guidelines on these areas already exist. We would be grateful for an opportunity to meet with representatives to discuss this further.

Recommended action

None. BASHH has been contacted and made aware of the development and engaged during national meetings and public consultation.

Health benefits

Respondents were asked: 'Are you aware of any health benefits, side effects and risks that might affect the development of this UK SMI?'.

Comment number: 46

Date received: 02/08/2024
Laboratory or organisation name: NHS Lothian

There is a risk that the protocol over simplifies the investigation of STIs as it is not based on assessment of behaviours and instead is based on anatomy

Recommended action

None. Assessment of behaviours is outside the scope of this document.

Comment number: 47

Date received: 22/08/2024
Laboratory or organisation name: Southwest Pathology Services

Overreporting of fluconazole, candida identification, full implementation of guidelines for medico-legal specimens.

Recommended action

The information has been removed and referred to appropriate guidance.

Respondents indicating they were happy with the contents of the document

Overall number of comments: 3		
14/08/2024	**Organisation name**	IPC lead
03/09/2024	**Organisation name**	Microbiology Society
24/08/2024	**Organisation name**	Royal College of General Practitioners
Financial Barriers		
In my area, NHS Highland, distance to healthcare facilities is a barrier. Even in larger urban areas, such as where I worked previously, some patients are not aware of STI clinics, so attend GPs often requesting empirical treatment straight away.		