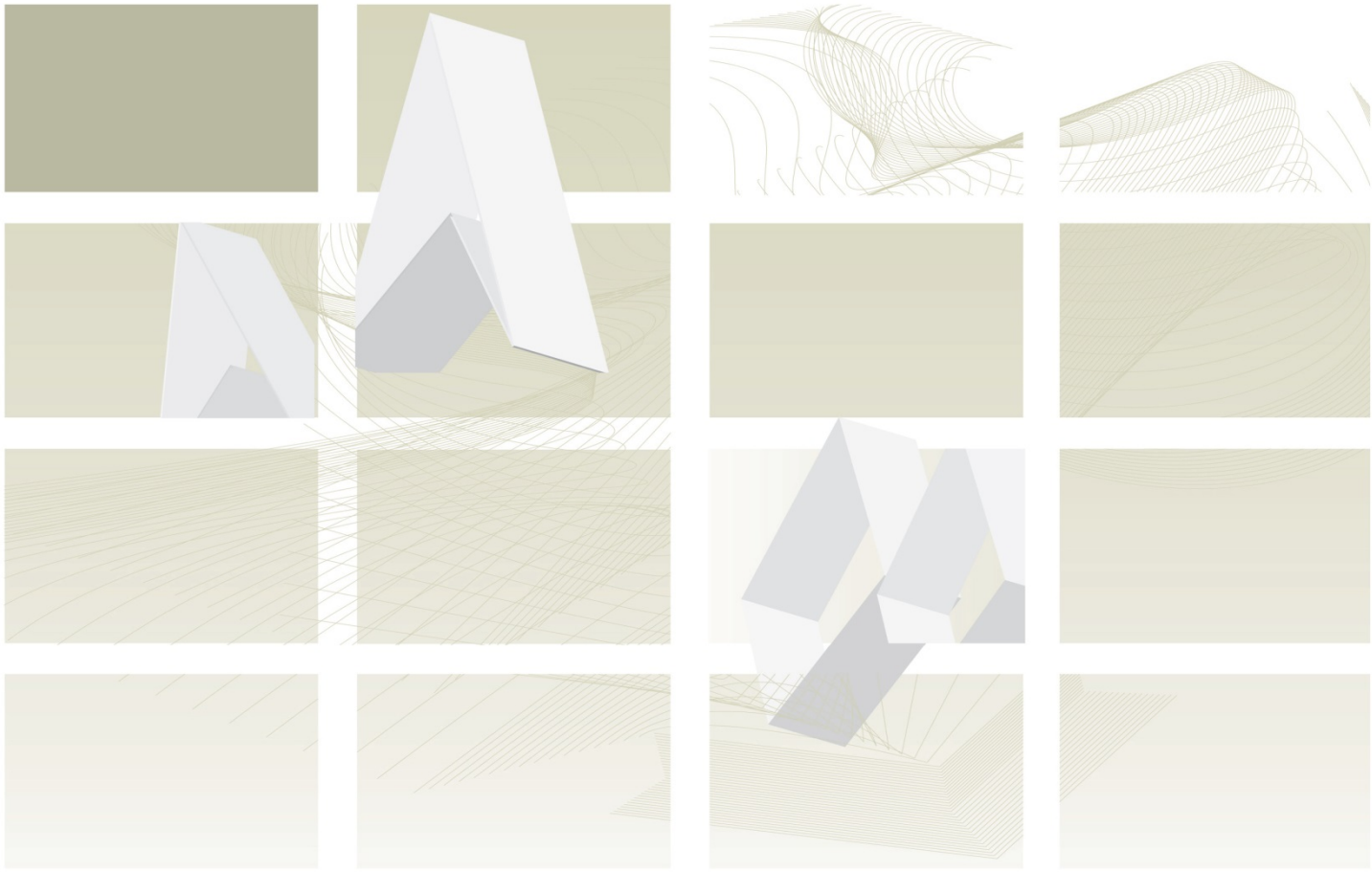
Public Health England

NHS

UK Standards for Microbiology Investigations

Review of users' comments received by
Joint working group for national user manual templates

U 2 National user manual worked example for conjunctivitis



NICE accredited
www.nice.org.uk/accreditation

"NICE has renewed accreditation of the process used by **Public Health England (PHE)** to produce **UK Standards for Microbiology Investigations**. The renewed accreditation is valid until **30 June 2021** and applies to guidance produced using the processes described in **UK standards for microbiology investigations (UKSMIs) Development process, S9365', 2016**. The original accreditation term began in **July 2011.**"

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

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First consultation: 24/10/2016 – 04/11/2016

Version of document consulted on: U b dc+

Proposal for changes

Comment number	1		
Date received	24/10/2016	**Lab name**	Consultant in Public Health
Is the template populated with enough/right kind of information for the examples used?			
The template is confusing. *Acanthamoeba* culture/detection is listed as a first line investigation with a comment to consider in contact lens wearers. However, it is not specifically featured in Appendix 1. This is very confusing and potentially misleading. The document is correct to mention this as a first line investigation for contact lens wearers but this needs to be more obvious in the appendix. Otherwise, there is a danger that the users will just turn to the appendix and miss the point about acanthamoeba. This could be added to the appendix, with a comment about testing for contact lens wearers (represents 13% of the population).			
Do you think that there is too much information in the document?			
No.			
Financial barriers			
No.			
Recommended action	**ACCEPT** The testing in contact lens wearers has been removed from the document.		

Comment number	2		
Date received	28/10/2016	**Lab name**	Microbiology Northern Health and Social Care Trust
Is the template populated with enough/right kind of information for the examples used?			
Think it is.			
Do you think that there is too much information in the document?			
Think we may run the risk of over testing eye swabs given the lack of clinical detail on request forms.			
What advantages does the syndromic approach have over the sample type approach and vice versa?			
Syndromic approach makes one think of other causes of infection more suited to clinical			

service while sample approach more helpful from BMS perspective.
Overall, which approach would be most useful for your users?
Hybrid.
Does seeing a worked example help you know how best to use the User Manual Template?
Yes, the flow charts are helpful as they include PCR testing as well.
Would you prefer to see the syndrome/sample specific information as a separate section within individual UK SMIs (if this initiative is taken forward)?
Think it would be useful. However UKAS inspections expect labs to follow SMIs to the letter so would lead to lots of extra work/administration if syndrome/sample specific information included in SMIs.
Any other comments you wish to make
Not sure what IF and MIF mean in Appendix 1 flow chart?
Health benefits
Potential over testing of eye swabs.

Recommended action	**PARTIAL ACCEPT** Many thanks for the information. The issue of over testing eye swabs will be noted. The full meaning of the acronyms in Appendix 1 flowchart has been updated accordingly.

Comment number	3		
Date received	28/10/2016	**Lab name**	ViaPath King's College Hospital, Medical Microbiology / HCPC clinical scientist/ member of RCPath

Is the template populated with enough/right kind of information for the examples used?
a. In the introduction about the infective conjunctivitis I would add conjunctivitis is also caused by parasites. b. Locating and contacting the laboratory: The 6th point telephone number should be mentioned. c. Investigation of parasites are missed out from the Appendix 1 (national user manual conjunctivitis).
Do you think that there is too much information in the document?
It is the right amount of information.

What advantages does the syndromic approach have over the sample type approach and vice versa?	
Syndromic approach cannot be ignored even if we use the sample type approach. Clinical symptoms help the pathologist medical doctors and clinical scientists to think about other conditions that the ward doctor or GP did not think.	
Overall, which approach would be most useful for your users?	
Both.	
Does seeing a worked example help you know how best to use the User Manual Template?	
Yes, it is a very good example.	
Would you prefer to see the syndrome/sample specific information as a separate section within individual UK SMIs (if this initiative is taken forward)?	
Yes.	
Evidence	
Klotz et al., Fungal and Parasitic Infections of the Eye, Clinical Microbiology Reviews,0893-8512/00/$04.0010 October 2000, p. 662-685	
Financial barriers	
No.	
Health benefits	
No.	
Recommended action	a. **NONE** Many thanks for the information. Information on the parasitic causes of conjunctivitis will be not added in the document. This has been made clearer in the scope of the document. b. **ACCEPT** The issue of mentioning telephone number of key members of staff in the subsection "*Location and contacting the laboratory*" will be added as a change request in the next review for the User Manual template. c. **NONE** Many thanks for the information. Information on the parasitic causes of conjunctivitis will not be added in the document. This has been made clearer to the scope of the document.

Comment number	4		
Date received	28/10/2016	**Lab name**	Keith Shuttleworth and Associates Ltd
Is the template populated with enough/right kind of information for the examples used?			
Yes.			
Do you think that there is too much information in the document?			
I do not believe so.			
What advantages does the syndromic approach have over the sample type approach and vice versa?			
Quick and easy to use.			
Overall, which approach would be most useful for your users?			
Both.			
Does seeing a worked example help you know how best to use the User Manual Template?			
Perhaps to some people.			
Would you prefer to see the syndrome/sample specific information as a separate section within individual UK SMIs (if this initiative is taken forward)?			
Not necessary.			
Any other comments you wish to make			
Thank you.			
Recommended action	**NONE** Many thanks for the information.		

Comment number	5		
Date received	02/11/2016	**Lab name**	University Hospital Limerick
Is the template populated with enough/right kind of information for the examples used?			
Yes.			
Do you think that there is too much information in the document?			
No.			
What advantages does the syndromic approach have over the sample type			

approach and vice versa?	
For clinicians the syndromic approach is good for encouraging appropriate sampling and test requesting so this is an excellent approach for a user manual. Could the syndromic approach increase inappropriate test requests? Appropriate guidelines in relation to HVS specimens etc should be taken into account re. discharge etc. From the laboratory perspective the sample type approach in SMIs is more useful as we use sample type to inform set up on a broad range of media to cover all possible targets for that specimen type- clinical details of syndrome may not be given on some request forms.	
Overall, which approach would be most useful for your users?	
Syndromic.	
Does seeing a worked example help you know how best to use the User Manual Template?	
Yes.	
Would you prefer to see the syndrome/sample specific information as a separate section within individual UK SMIs (if this initiative is taken forward)?	
I would prefer sample specific SMIs for Laboratory processing (this could be broad range eg superficial wounds) with syndrome specific information as a separate section. For Laboratory user manual the syndromic approach is excellent.	
Any other comments you wish to make	
Suggest GC investigation performed on swabs from non-neonates only where requested with supporting clinical information. Gram stain has not been mentioned - is this removed from repertoire?	
Evidence	
GC a rare isolate too expensive and time consuming to cover all eye swabs for GC.	
Recommended action	**ACCEPT** The feedback is very useful for this document. **PARTIAL ACCEPT** With regards to the other comments below "*Suggest GC investigation performed on swabs from non-neonates only where requested with supporting clinical information. Gram stain has not been mentioned - is this removed from repertoire?* ". It was agreed that Gram stain, where indicated eg neonatal sticky eyes should be added and the UK SMI B 2: *Investigation of bacterial eye infections* indicates that a GC plate for neonates should be included. The UK SMI B 28: *Investigation of genital tract and associated specimens* document will be checked to ensure that this information is already provided within it.

Comments received outside of consultation

Comment number	1		
Date received	05/11/2016	**Lab name**	Royal Cornwall Hospitals Trust
Is the template populated with enough/right kind of information for the examples used?			
Good for the examples used.			
Do you think that there is too much information in the document?			
There is too much generic information at the start – would prefer that it was contents page, amendment table and then Introduction/scope of the specific syndrome/test. The acknowledgments, UK SMI: scope and purpose would be better as an Appendix – that is because we access these documents all the time.			
What advantages does the syndromic approach have over the sample type approach and vice versa?			
We think that the syndromic approach is good for requesting clinicians and trainees/explaining things to trainees. The sample type is great for a working diagnostic lab, making sure we cover all the different clinical conditions. However, I personally have used both and appreciate the knowledge and references that are provided.			
Overall, which approach would be most useful for your users?			
For our requesting users, probably syndromic.			
Does seeing a worked example help you know how best to use the User Manual Template?			
Not sure.			
Would you prefer to see the syndrome/sample specific information as a separate section within individual UK SMIs (if this initiative is taken forward)?			
Would need to see an example – one person said yes.			
Any other comments you wish to make			
These SMIs are fantastic for bacteriology, but do not work quite as well for virology. There were a few people who were unsure about who the expected audience is for these SMIs. Microbiology has to provide a user manual and it seems more appropriate to provide information such as location maps just the once, rather than with each SMI.			
Recommended action	**ACCEPT** Thanks for the feedback. The generic information at the start of the document is part of the UK SMI template and cannot currently be removed.		

Comment number	2		
Date received	08/12/2016	**Lab name**	GP Partner
Any other comments you wish to make			
CONJUNCTIVITIS: Generally good. How useful this is will depend on info completed by local lab / CCG. a. Local availability of eye swabs with photos of the different types would definitely be required - they are certainly not standard stock for the majority of GP surgeries. b. I was surprised by the comment in the table that "viral cause in neonates is rare" - this implies that all cases should be swabbed?! - although I agree that it is important to consider chlamydia / gonococcal causes, the labs would be swamped if we sent swabs on all cases of sticky eye in newborns!!! c. I wonder whether it is worth including something about symptomatic treatment with cooled, boiled water for uncomplicated cases?			
Recommended action	a. **PARTIAL ACCEPT** The use of pictures is recommended but it is down to local decision for implementation. b. **NONE** This is not what is implied in the document. c. **NONE** This is outside the remit of this UK SMI document.		

Comment number	3		
Date received	17/12/2016	**Lab name**	College of Ophthalmologists Quality and Safety Group
Any other comments you wish to make			
We appreciate this document is aimed at laboratory and infectious diseases staff not ophthalmologists. However it is important that ophthalmologists do agree with the ophthalmic content of the document for accuracy. Our comments are as follows: a. The introduction and scope could be improved with input from an ophthalmologist. The College Chair of Q&S Group would be happy to edit this for your consideration. Examples in this part of the document where we would consider changes are the mention of parasites and fungi as causes of conjunctivitis - whilst not impossible this is extremely unusual especially in the UK. Another example is the lack of mention of immune mediated conjunctivitis eg in Stevens Johnson syndrome and pemphigoid (there is mention of a "rash" section, but cannot find this, is this available elsewhere?). Allergic conjunctivitis is not well described here. b. It is very important to emphasise even more that testing is really NOT needed in			

most cases partly because there is currently a lot of unnecessary testing in both ophthalmology and primary care setting which is a waste of resources. It would be important to mention that most cases resolve with time whether viral or bacterial even without treatment and so testing is rarely important in management. In addition there is no mention of some of the ocular associations of severe viral (especially adenoviral) conjunctivitis such as scarring and keratitis which need ophthalmic care and treatment usually with steroids. c. In the testing repertoire section, for neonatal conjunctivitis, most ophthalmologists would routinely do HSV testing. In addition, although mention is made that neonates with HSV need urgent paeds referral, actually chlamydia and gonococcal infection usually also require referral due to risk of systemic infection and problems such as pneumonitis.	
Recommended action	a. **ACCEPT** The College of Ophthalmologists Quality and Safety Group has been approached to assist with the rewrite of the introductory section with restriction of the scope to conjunctivitis as intended by the UK SMIs. b. **PARTIAL ACCEPT** The importance of not testing all eye swabs will be discussed in the introductory section with assistance from the College of Ophthalmologists Quality and Safety Group. c. **ACCEPT** This has been updated in the document accordingly as a second line of investigation in neonates.

Comment number	4		
Date received	04/01/2017	**Lab name**	Primary Care Guidance
Any other comments you wish to make			
Introduction – I think this needs to be referenced and have more information on differentiating viral from bacterial. It is not at all clear from the introductory section, when or how swabs should be taken for suspected viral and / or bacterial infection.			
Recommended action	**NONE** Many thanks for the information. The instructions on when or how swabs should be taken for suspected bacterial or viral infections are down to local decision.		

Second consultation: 15/03/2017 – 29/03/2017

Version of document consulted on: U b dh+

Proposal for changes

<table>
<tr><td>Comment number</td><td>1</td><td colspan="2"></td></tr>
<tr><td>Date received</td><td>21/03/2017</td><td>Lab name</td><td>Microbiology Society Technical Advisory Group</td></tr>
<tr><td>Section</td><td colspan="3"></td></tr>
<tr><td colspan="4">Comment</td></tr>
<tr><td colspan="4">General comments:
a. It was discussed that keratitis and Acanthamoeba are not included in this document. If the User manual is aimed only at Conjunctivitis this is correct however would it be worth considering the inclusion of keratitis?
b. It was discussed that it was not really clear as to who the User manuals are aimed at. The document states that the microbiology service provider’s user manual is intended as a general resource for practising healthcare professionals, this document explains clinical details and if this is aimed at GPs and service users does not need to do so? The text needs justifying.
c. The page numbering needs addressing, the last page states Page 4 of 17.
d. Suggestion that a hyperlink could be added to laboratory user manuals to refer users to this document.
e. Suggestion that a hyperlink may be used in ward ordercomms if possible referring to this document.
f. Page 14: It was discussed that the inclusion of a sentence on “uncertainty of measurement” may not be necessary. Members of the group reported that no service users had ever asked for this and by inclusion it may open up a can of worms!</td></tr>
<tr><td>Recommended action</td><td colspan="3">a. NONE
Many thanks for the information. Keratitis and Acanthamoeba are not included in this document as it is outside the scope of this document.
b. NONE
Many thanks for the information. The document clearly states the people for whom the User manuals are aimed at in the background.
c. ACCEPT
This has been amended in the document accordingly.
d. NONE
The hyperlink will not be added to laboratory user manuals as agreed by the User Manual Working Group.</td></tr>
</table>

	e. **NONE** Many thanks for the information. The addition of hyperlink in ward ordercomms is down to local decision. f. **NONE** Many thanks for the information. Uncertainty of measurement is a requirement and will be kept in the document.

Comment number	2		
Date received	22/03/2017	**Lab name**	Keith Shuttleworth and Associates Ltd
Section	Consent, collection and transport of specimens		
Comment			
Instructions for preparation for sample collection (for example, for caregivers, phlebotomists, sample collectors and patients). I presume that instructions include hand hygiene before and after to avoid cross contamination.			
Evidence			
This is only a comment.			
Recommended action	**NONE** The instructions for sample collection are down to local decision in the local hospital laboratories.		

Comment number	3		
Date received	23/03/2017	**Professional body**	The Royal College of Ophthalmologists
Section			
Comment			
Under comments: We appreciate this document is aimed at laboratory and infectious diseases staff not ophthalmologists. However it is important that the ophthalmic content of the document is accurate and fits with accepted clinical practice and understanding which it currently does not in areas. Our comments are as follows: a. The introduction and scope could be significantly improved with input from an ophthalmologist. It currently reads as if not written by someone with ophthalmic expertise. The College Chair of Q&S Group would be happy to edit this for your consideration. Examples in this part of the document where we would consider changes are: a mix up between describing symptoms and describing signs; lack			

of clarity between what is a red eye from primary inflammation of the conjunctiva and what is a red eye due to other ocular inflammations or pathologies; irritant conjunctivitis is not a recognised entity, however toxic is as is chemical injury, and red eye due to a foreign body is not primary inflammation of the conjunctiva; there is no pressing need to test in hyperacute conjunctivitis; Another example is the lack of mention of immune mediated conjunctivitis e.g. in Stevens Johnson syndrome and pemphigoid (there is mention of a rash section, but cannot find this, is this available elsewhere?). Allergic conjunctivitis is not well described here.

b. It is very important to emphasise even more that testing is really NOT needed in most cases partly because there is currently a lot of unnecessary testing in both ophthalmology and primary care setting which is a waste of resources. It would be important to mention that most cases resolve with time whether viral or bacterial even without treatment and so testing is rarely important in management. In addition there is no mention of some of the ocular associations of severe viral (especially adenoviral) conjunctivitis such as scarring and keratitis which need ophthalmic care and treatment usually with steroids.

c. In the testing repertoire section, for neonatal conjunctivitis, most ophthalmologists would routinely do HSV testing. In addition, although mention is made that neonates with HSV need urgent paeds referral, actually chlamydia and gonococcal infection usually also require referral due to risk of systemic infection and problems such as pneumonitis.

d. In testing, acanthamoeba testing is done for microbial keratitis not for conjunctivitis.

e. In practice viral conjunctivitis is much more common than bacterial in adults and I am surprised it is stated the other way around. See evidence.

Evidence

Conjunctivitis A Systematic Review of Diagnosis and Treatment JAMA 2013;310:1721-29.BMJ best practice 2017. http://bestpractice.bmj.com/best-practice/monograph/68/basics/epidemiology.html

I am sure there are many more references to support viral is far more common than bacterial but all ophthalmologists recognise this to be the case.

Financial barriers

There will be barriers if ophthalmologists do not recognise and accept the content as accurate.

Recommended action	a. **ACCEPT** The College of Ophthalmologists Quality and Safety Group has been approached to assist with the rewrite of the introductory section with restriction of the scope to conjunctivitis as intended by the UK SMIs. b. **PARTIAL ACCEPT** The importance of not testing all eye swabs will be discussed in the introductory section with assistance from the College of Ophthalmologists Quality and Safety Group.

	c. **ACCEPT** This has been updated in the document accordingly as a second line of investigation in neonates. d. **ACCEPT** Acanthamoeba testing has been removed from the test repertoire in the document. e. **ACCEPT** The above recommended reference has been added to the document accordingly.

Comment number	4		
Date received	23/03/2017	**Lab name**	Wythenshawe Hospital
Section			
Comment			
A general comment – again, fungi seem to be missing from the conjunctivitis one. It is true that fungi cause more keratitis but telling these two from each other clinically can be very difficult (unless you are an ophthalmologist). Also, I don't think that we have a separate SMI for keratitis. Not that rare (risk groups include contact lens wearers, nature explorers, hikers) and should be covered somewhere. Therefore, I would think it is reasonable to include both main external eye infections into this SMI. Will be a bit of work but not outrageously so. Link to CDC website: https://www.cdc.gov/fungal/diseases/fungal-eye-infections/			
Recommended action	**NONE** Many thanks for the information. Information on the fungal/parasitic causes of conjunctivitis will not be added in the document. This has been made clearer in the scope of the document.		

Respondents indicating they were happy with the contents of the document

Overall number of comments: 3			
Date received	20/03/2017	**Lab name**	Member of the public
Date received	26/03/2017	**Professional body**	RCGP Clinical Advisor
Date received	29/03/2017	**Professional body**	Institute of Biomedical

			Science