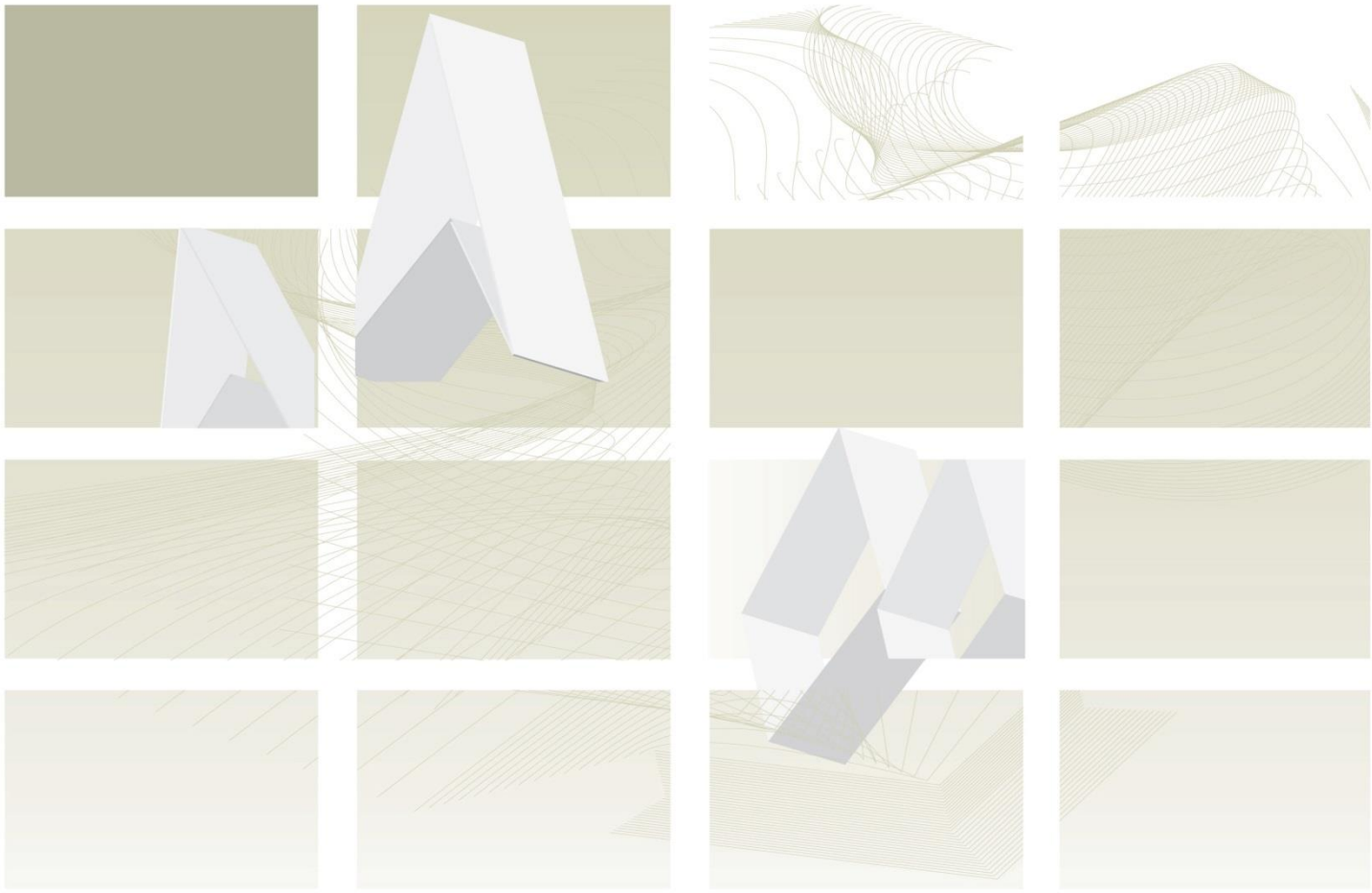
UK Standards for Microbiology Investigations

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

S 7 Gastroenteritis



"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.**"

This publication was created by Public Health England (PHE) in partnership with the NHS.
Recommendations are listed as ACCEPT/ PARTIAL ACCEPT/DEFER/ NONE or PENDING

Consultation: 11/11/2019 – 25/11/2019

Version of document consulted on: S 7dzp+

Proposal for changes

Comment number	1		
Date received	11/11/2019	**Lab name/Professional body**	NHS Lothian
Comment			
1. The testing methodology for sensitivity testing on page 31 and 32 has some flaws. a) Naladixic acid is no longer recommended by EUCAST version 9.0 for testing ciprofloxacin resistance in Salmonella. Perfloxacin should be tested instead. b) I would add cotrimoxazole to both Salmonella and shigella as a supplementary testing agent. c) In patients with appropriate history you might want to screen Salmonella and Shigella for ESBLs and carbapenemases. d) Campylobacter EUCAST suggest test erythromycin and report as clarithromycin. e) There are no trimethoprim break points for campylobacter in EUCAST. Meropenem and gentamicin can be tested using CLSI as additional drugs for campylobacter bacteraemia. 2. I think the document misses out a group of patients with bloody diarrhoea admitted to hospital with query infection/ query Ulcerative colitis. These patients would benefit from rapid PCR testing as we have noticed patients getting unnecessary colonoscopies, CT scans and steroid treatment because conventional culture is too slow. 3. There is another group of patients not included in this algorithm. It may be worth while mentioning atypical presentations of Sexually transmitted infections in MSM where Chlamydia trachomatis including LGV and Neisseria gonorrhoeae can present as colitis. 4. It may also be worth mentioning that parasites such as Entamobea histolytica, Giardia and Cryptosporidum can be sexually transmitted in this group. We have noticed sexual transmission of MDR Shigella in this group. 5. I am sure the virologists might want to mention more pathogens. Perhaps the way forward is to note that men who have sex with men may present with a wide range of STDS as well as classical pathogens as the cause of diarrhoea and that testing for Entamoeba histolytica should be considered as a supplementary test in this group.			
A new syndromic template has been developed for this document, please give any suggestions or amendments to the layout.			
No suggestions.			
Should Cryptosporidium and Giardia be included in the primary testing?			

Yes.	
Financial barriers	
This is a relatively high volume sample type. There will be resource barriers to introducing routine testing for Giardia.	
Health benefits	
Are you aware of any interested parties we should consider consulting with on the development of this document?	
The usual consultation should suffice.	
Recommended action	1. a-e Accept, amendments have been made to the antimicrobial susceptibility testing and reporting table to reflect updated EUCAST guidance on antimicrobial resistance. 2. Accept: The sentence: “Patients with bloody diarrhoea and a suspected ulcerative colitis would benefit from rapid PCR testing” was added under Acute bloody diarrhoea. 3. Accept: The sentence: “Atypical presentations of Sexually transmitted infections in MSM where Chlamydia trachomatis including LGV and Neisseria gonorrhoeae can present as colitis” was added 4. NONE: transmission of *E. histolytica, Giardia* species and *Cryptosporidium* species in MSM is covered in Appendix 1 5. NONE: transmission of *E. histolytica, Giardia* species and *Cryptosporidium* species in MSM is covered in Appendix 1

Comment number	2		
Date received	11/11/2019	**Lab name/Professional body**	member of public
Comment			
Clinical presentations of gastrointestinal infections 1. Section on Vomiting at the bottom of page 7 seems to contradict section on vomiting with diarrhoea at top of page 8 with respect to Staph aureus toxin symptoms.			
A new syndromic template has been developed for this document, please give any suggestions or amendments to the layout.			
Not completed.			
Should Cryptosporidium and Giardia be included in the primary testing?			
Not completed.			

Financial barriers	
Not completed.	
Health benefits	
Not completed.	
Are you aware of any interested parties we should consider consulting with on the development of this document?	
Not completed.	
Recommended action	1. ACCEPT: section has been reworded for clarity

Comment number	3		
Date received	12/11/2019	**Lab name/Professional body**	Microbiology laboratory, Derriford hospital, Plymouth
Comment			
Laboratory processes (analytical phase) Section 7.5.2 molecular assays 1. Current paragraph suggests lab users are responsible for validation of kits. Suggest reword to: Manufacturers produce assays with gene targets which may not necessarily cover the gene targets in emerging strains and so laboratories should ensure that kits have been validated prior to routine use.			
A new syndromic template has been developed for this document, please give any suggestions or amendments to the layout.			
New layout is helpful and has more information available for technical staff.			
Should Cryptosporidium and Giardia be included in the primary testing?			
No.			
Financial barriers			
No.			
Health benefits			
No.			
Are you aware of any interested parties we should consider consulting with on the development of this document?			
No.			

Recommended action	1. ACCEPT: section has been reworded for clarity

Comment number	4		
Date received	13/11/2019	**Lab name/Professional body**	Envirovet/University of Helsinki
Comment			
Clinical presentations of gastrointestinal infections 1. For acute watery diarrhea, page 7: Please consider adding pathogens like yersinia (enterocolitica), EHEC (may be non-bloody, especially in adults), listeria (often with fever), sapovirus (see Jalava et al, 2018), C. perfringens (may come with a diarrhea toxigenic, we had a recent, yet unpublished outbreak, with some longer incubation periods and length of symptoms as well as toxigenic and nontoxigenic strains as suspect causative agents). 2. Vomiting with diarrhea, page 8: Please include norovirus, as the ratio vomiting:diarrhea is very age specific. Children often have exclusively vomiting, while the elderly may have prolonged, predominantly diarrhea 3. Acute diarrhea with or without vomiting: Incubation period with norovirus may be down to 6 hours according to literature. Additionally, my/our experience with around 400 clusters and 7 major viral outbreaks during 2014-2018, was that the lower limit was down to 4 hours. 4. Norovirus may occur in outbreaks outside seasonal increase. We had a major recreational water borne outbreak during hot summer months, please see Polkowska et al., 2018. 5. hospital settings: note listeria clusters 6. 6.3.: overseas travel (also others), include dates, water exposure (define what is meant by this), suspect food intake, cases in the same household within one week/one month prior to the case Jalava K., Kauppinen A., Al-Hello H., Rasanen S. An outbreak of norovirus infection caused by ice cubes and a leaking air ventilation valve, Epidemiology and Infection, 2018 Dec 3:1-6. doi: 10.1017/S095026881800314X. Polkowska A., Räsänen S., Bojang M., Lyytikäinen O., Nuorti P., Jalava K. An outbreak of Norovirus infections associated with recreational lake water in Western Finland, 2014. Epidemiology and Infection 2018 Apr; 146(5):544-550. doi: 10.1017/S0950268818000328. Epub 2018 Feb 26.		
A new syndromic template has been developed for this document, please give any suggestions or amendments to the layout.			
No comments.			
Should Cryptosporidium and Giardia be included in the primary testing?			
Not within my expertise (in the UK).			
Financial barriers			

No.	
Health benefits	
No.	
Are you aware of any interested parties we should consider consulting with on the development of this document?	
No.	
Recommended action	1. NONE: these additional pathogens are covered in Appendix 1 2. ACCEPT: norovirus has been included in the list 3. PARTIAL ACCEPT: The section indicated has not been amended, but the norovirus entry under Appendix 1 has been amended to reflect shorter incubation times 4. NONE: this is covered in Appendix 1 5. PARTIAL ACCEPT: The section indicated has not been amended, but the *Listeria* entry under Appendix 1 has been amended to note *Listeria* clusters 6. PARTIAL ACCEPT: list of details to include on referral forms has been amended

Comment number	5		
Date received	14/11/2019	**Lab name/Professional body**	Microbiology, James Cook University Hospital
Comment			
Appendix 1. Please define Enterohaemorrhagic E.coli (EHEC).From recent literature searches the organism description appears vague, although the definition in the terminology is appropriate i.e E.coli that causes haemorrhagic colitis, haemolytic uraemic syndrome. In order to be classed as EHEC the organism should harbour stx1 or stx2 and eae or aggR genes. Therefore organisms with stx genes without eae or aggR are less likely to be haemorrhagic thus defined as Shiga-Toxin E.coli (STEC).The typical O157 that has caused previous outbreaks is usually stx2 and eae positive. The German outbreak of 2011 was stx2 and aggR positive. As such; Enteropathogenic E.coli or Enteroaggregative E.coli on acquisition of Shiga-Toxin genes become Enterohaemorrhagic E.coli.I personally have found no evidence in the literature that describes outbreaks involving haemolytic uraemic syndrome caused by STEC without adhesion or invasion mechanics, eae (Enterocyte Attachment Effacement/Intimin), aggR (Aggregative transcription Regulator/Aggregative Adherence Fimbriae/Dispersin)). And perhaps to a lesser			

extent if Enteroinvasive E.coli has yet acquired stx genes, if/when it does, it too will become Enterohaemorrhagic by definition.
A new syndromic template has been developed for this document, please give any suggestions or amendments to the layout.
Not completed.
Should Cryptosporidium and Giardia be included in the primary testing?
Not completed.
Financial barriers
No
Health benefits
If EHEC is defined by stx production combined with an adherence mechanism the clinical picture may be more severe than with STEC that lack these genes.
Are you aware of any interested parties we should consider consulting with on the development of this document?
No

Recommended action	1. PARTIAL ACCEPT: a note on common molecular targets has been added

Comment number	6		
Date received	18/11/2019	**Lab name/Professional body**	South Tyneside and Sunderland NHS Trust

Comment

Clinical presentations of gastrointestinal infections

1. Page 9 refers to testing all samples for C. difficile infection in a hospital setting. The guidance quoted in reference 6 does not recommend testing patients under the age of 2 years, due to high expected colonisation rates.
2. Flowchart for Investigation of faecal specimens for additional bacterial pathogens:

   The flowchart refers to use of CCEY agar for C. difficile culture. In practice, chromogenic media is now most commonly used.

A new syndromic template has been developed for this document, please give any suggestions or amendments to the layout.
Not completed.
Should Cryptosporidium and Giardia be included in the primary testing?
Yes.

Financial barriers	
No.	
Health benefits	
No.	
Are you aware of any interested parties we should consider consulting with on the development of this document?	
No.	
Recommended action	1. ACCEPT: a note has been added to cover this recommendation 2. NONE: *C. difficile* has now been removed from this flowchart. Users should refer to UK SMI B 10

Comment number	7		
Date received	19/11/2019	**Lab name/Professional body**	Member of the public
Comment			
I am happy with the document, no further comment.			
A new syndromic template has been developed for this document, please give any suggestions or amendments to the layout.			
Not completed.			
Should Cryptosporidium and Giardia be included in the primary testing?			
Not completed.			
Financial barriers			
No.			
Health benefits			
Yes.			
Are you aware of any interested parties we should consider consulting with on the development of this document?			
No.			
Recommended action	NONE		

Comment number	8	

Date received	19/11/2019	**Lab name/Professional body**	Gateshead NHS Foundation Trust
Comment			
I am happy with the document, no further comment.			
A new syndromic template has been developed for this document, please give any suggestions or amendments to the layout.			
Very good syndromic template proved in the SMI and easy to follow			
Should Cryptosporidium and Giardia be included in the primary testing?			
Yes 100% - the increased numbers identified by our laboratory covering 3 hospital sites suggests, alongside and the identification of these parasites in samples that would not ordinarily have been tested, adds value to Public Health monitoring of outbreaks and/or potential outbreaks.			
Financial barriers			
No.			
Health benefits			
No.			
Are you aware of any interested parties we should consider consulting with on the development of this document?			
No.			
Recommended action	NONE		

Comment number	9		
Date received	20/11/2019	**Lab name/Professional body**	Virology, Hull University Teaching Hospitals
Comment			
Clinical presentations of gastrointestinal infections 1. In section 5.1.2a, mention is made of gastroenteritis caused by CMV, HSV and VZV in immunocompromised patients. Although CMV colitis is important, gastroenteritis caused by HSV or VZV is not, to my knowledge, widely described in the absence of other typical symptoms, and is likely to be rare. These infections are outside the stated scope of the document (excludes... ...infections not transmitted through the enteric route p5); they are not present in the algorithms; and faecal testing is not generally performed or recommended, even for CMV. I would therefore recommend the omission of this paragraph.			

A new syndromic template has been developed for this document, please give any suggestions or amendments to the layout.
Not completed.
Should Cryptosporidium and Giardia be included in the primary testing?
Not completed.
Financial barriers
Not completed.
Health benefits
Not completed.
Are you aware of any interested parties we should consider consulting with on the development of this document?
Not completed.

Recommended action	1. ACCEPT: HSV and VZV have now been removed from the list of viruses in this section

Comment number	10		
Date received	22/11/2019	**Lab name/Professional body**	PHE
Comment			

General comments

1. Really nice document, just because it is so lengthy, the section headings need to be really clear.
2. Page 6: The clinical presentation can feature in particular epidemiological settings community or hospital BOTH as sporadic or outbreak.
3. Page 7: Food-borne outbreaks estimated to cause 3million deaths per year: This does not have a reference. Also, would it not make sense to also indicate disease burden of water borne too?
4. Page 7: In acute bloody diarrhoea it states diarrhoea (passing of liquid or watery stools). I think this should also be stated in the Acute watery diarrhoea: “Acute watery diarrhoea: This is defined as diarrhoea (passing of liquid or watery stools)”
5. Page 8: at the top under vomiting with diarrhoea: is it possible to indicate that sending vomit is not helpful?
6. Page 9: Acute vomiting with or without diarrhoea. It is not clear what specimen you expect them to send, maybe clarify that stool is appropriate.
7. Page 9: This UK SMI recommends inclusion of Giardia and Cryptosporidium species in the primary test set: I think this should be higher up, along with the primary test set, it seems a bit odd at the end.

8. Page 12: Where >72hr, it does not explain that this is >72 hour in hospital, not that this is the length of exposure.
9. Page 13: Note: Vomit swab or actual vomit.
10. Page 13: If OCP needed: three specimens should be sent at least two days apart as OCP are shed intermittently26. What does this mean in reality? Each sample should be 48 hours after the previous, thus over 5 days? How do you send 3 specimens two days apart, unless stipulating that each is 2 days after the previous one?
11. Page 15: For parasites, routine testing for Cryptosporidium and Giardia species is recommended nationally
12. Page 16: 'Standard; paragraph – this is not sample preparation, this is sample processing, should it be in 7.1.2? Not sure of the difference between 7.1.1 and 7.1.2 – can they be put in the same section? Also, this is essentially repeated on page 18 – is this repetition necessary?
13. Page 16: No indication about when to do the wet- preps for motile trophozoites – should they be done on 'all submitted specimens from symptomatic individuals' like the Cryptosporidium slide?
14. Page 19: 7.1.5 – this is very confusing, why are we talking about spreading an inoculum, after explaining how to make the slides in the pages before. This seems very random.
15. Page 19-20. Are the bullet points at the top of page 20 'pre-treatment and dilution for bacteria'? To me, it seems that this is saying how to process a sample onto a plate, yet it falls under pre-treatment. Maybe it needs another heading of 'processing' or something.
16. Page 22: 7.2.4: you often cannot use a sterile pipette (pastette) if the sample does not suck up, it should be sterile pipette or swab
17. Page 23: The table indicates that all diarrhoeal specimens have an MTSB, yet in the words, this is only supposed to be for children<5 and samples with visible blood.
18. Page 24: inclusion of Tris-buffered 1% peptone, yet on page 26 this should only occur when advised by a senior microbiologist. – maybe make this clear on page 24.
19. Page 26: Food poisoning: This should take place when advised by HPU or EHO, or sent to PHE lab.
20. Page 27: Advice regarding which antibiotics might be appropriate to test – refer to page 31.
21. Page 32: 8.3.1 'Refer to table' – appendix 1

A new syndromic template has been developed for this document, please give any suggestions or amendments to the layout.

Potentially clearer demarcation between sections? Maybe start the lab section on a fresh page.

Should Cryptosporidium and Giardia be included in the primary testing? Â

Yes, although it needs to be clear that this is only if BS5-7.

Financial barriers	
Yes, costs of implementing giardia screening to all samples. Uncertainty about when to test for Rotavirus as most children are vaccinated - is it still cost effective to include it in the test?	
Health benefits	
Potential confusion/ lab concern for doing giardia on all samples. Potential confusion about whether wet preps should be done on all samples.	
Are you aware of any interested parties we should consider consulting with on the development of this document?	
None that are not already included.	
Recommended action	1. ACCEPT: headings within the document have been reviewed, and some amendments made 2. ACCEPT: Sentence reworded for clarity 3. PARTIAL ACCEPT: sentence removed 4. PARTIAL ACCEPT: diarrhoea is defined under section 4.2, redundant information in the definitions of acute bloody diarrhoea and acute watery diarrhoea has been removed from section 5 5. NONE: specimen is defined under section 6.1 6. NONE: specimen is defined under section 6.1 7. ACCEPT: placement of *Giardia* species and *Cryptosporidium* species has been amended in the flowchart 8. NONE: this information is given in section 5.1 in the subsection headed “Gastroenteritis in hospital setting (in-patients)” 9. NONE; it was the view of the working group that ‘actual vomit’ as a sample type was not required 10. NONE: the wording used is as per the applicable PHE guidance referenced in the document 11. ACCEPT: the wording pertaining to routine testing for *Cryptosporidium* species and *Giardia* species has been amended for clarity 12. NONE: the document will refer to UK SMI B 31 to cover this 13. NONE: the document will refer to UK SMI B 31 to cover this 14. ACCEPT: section 7.1.5 to be removed 15. NONE; it was the view of the working group that the section was clear and follows the standard template

	16. ACCEPT: sterile swab has been added to the sentence 17. ACCEPT: text has been reworded for clarity 18. ACCEPT: information has been moved into a new row to aid clarity 19. PARTIAL ACCEPT: “where advised by senior microbiologist” wording added 20. ACCEPT: a sentence referring to the antimicrobial susceptibility testing table has been added 21. ACCEPT: a sentence referring to the table in Appendix 1 has been added

Comment number	11		
Date received	22/11/2019	**Lab name/Professional body**	University Hospitals of Leicester NHS Trust
Comment			

Background

1. 4.1 states, Gastroenteritis is the inflammation of the lining of the stomach and the small intestine... I'm not sure that this definition is helpful - microbiological investigations will be prompted by diarrhoea - but if it is to be retained in the SMI it should include large bowel since this is the body part most involved in gastroenteritis.
2. 4.2 The Note in 4.2, Frequently passed formed stools are not considered to be diarrhoea as advocated by the Bristol Stool Form Scale is unclear. Do you mean to say that formed stools (types 1-4 on the Bristol Stool Form Scale) should not be considered to be diarhoea?
3. 4.2 Is there a reason for describing the mechanisms whereby microbes can cause diarrhoea? If so, this should include the full range of mechanisms (e.g. toxin production in the large bowel), not just an arbitrary two.
4. 4.4 The requirement, under the Health Protection (Notification) Regulations 2010, for laboratories to report notifiable organisms should be included in this section.

Clinical presentations of gastrointestinal infections

5. Persistent diarrhoea This section mixes up persistent and chronic diarrhoea. I suggest that this section should be re-written as follows: Persistent diarrhoea: This is diarrhoea of greater than 14 days but less than 30 days duration. It should be noted that viruses (e.g. norovirus) and bacteria (Salmonella, Shigella and Campylobacter species) can be the cause of persistent diarrhoea in patients who are immunocompromised. Chronic diarrhoea last longer than 30 days and is a major clinical feature in AIDS and a cause of morbidity and mortality. Organisms implicated are predominantly parasites - Giardia, Cryptosporidium, Cyclospora and Microsporidia species.

Clinical presentations of gastrointestinal infections

6. 5.1Primary testing. There is an inconsistency between this section and later (p 9 and the flow charts 5.1.1 and 5.1.2) around testing for norovirus. This section indicates that routine procedures will normally include testing for norovirus, while p9 states that norovirus testing is not recommended as frontline testing in sporadic cases.
7. 5.1.1does not include norovirus for sporadic community cases while 5.1.2 includes norovirus testing for sporadic cases less than 72 hours. I presume this means less than 72 hours of admission, in which case the microbial cause is likely to be the same as the sporadic community cases in 5.1.1. Universal testing for norovirus would be a change in practice for many labs but I can see the argument for it. Please clarify the position of the SMI on this.
8. Given that Giardia infection is readily treatable, I suggest that this pathogen should be tested for routinely - many labs already do this. Additionally, testing for cryptosporidium should also be routine, given the public health impact of an outbreak.
9. The flow charts 5.1.1 and 5.1.2 make no reference to age of patient. This is relevant to C difficile testing. The sporadic cases arm in 5.1.1 includes C difficile as a second line test. This approach would delay diagnosis of a potentially lethal but treatable condition. C difficile testing should be a primary test in all cases. The additional investigations following clinical details includes tests (crypto, giardia) that are included as primary tests (although the earlier passage suggests these are optional). Please clarify.

General comments

10. Please be aware that the Royal College of Pathologists has set up a joint working party with the British Society of Gastroenterology to draw up guidelines for the diagnosis and management of E histolytica infection. This follows a number of cases where patients were misdiagnosed with and treated for inflammatory bowel disease (IBD) instead of E histolytica infection, leading to unnecessary colectomies. The incubation period for E histolytica can be as long as months or even years (See https://www.gov.uk/government/publications/amoebiasis-public-health-operational-guidelines). The working party is still considering evidence but early indications are that negative microscopy is not adequate to rule out E histolytica infection and that the gold standard diagnostic method of acute infection is PCR of faeces. Travel to an endemic area increases the risk of infection but this may be months or years in the past. Additionally, we have seen cases of transmission within the UK so a negative travel history does not exclude amoebiasis. Given the difficulty in distinguishing clinically between IBD and amoebiasis, I anticipate that the working party may conclude that ALL patients in whom IBD is considered (bloody diarrhoea, initial diagnosis of IBD and subsequent flares) should be investigated for E histolytica infection and that this should be by PCR. The SMI group may wish to consider this in this consultation.

A new syndromic template has been developed for this document, please give any suggestions or amendments to the layout.

Not completed.

Should Cryptosporidium and Giardia be included in the primary testing? Â

Yes, already routine is my lab.	
Financial barriers	
The cost of molecular testing will be an inevitable financial challenge but the benefits of rapid, sensitive results will be worth the price in my opinion.	
Health benefits	
Not completed.	
Are you aware of any interested parties we should consider consulting with on the development of this document?	
British Society of Gastroenterology.	
Recommended action	1. ACCEPT: reworded to include the large intestine also 2. ACCEPT: reworded for clarity 3. PARTIAL ACCEPT: “such as, but not limited to” wording added. Toxin production in the large intestine now included 4. ACCEPT: reference to the Health Protection (Notification) Regulations 2010 has been added 5. ACCEPT: section has been restructured for clarity 6. NONE: routine procedures for outbreaks in the community setting, and cases of sporadic and outbreak cases in the hospital setting include norovirus in frontline testing; this information included in the algorithms correlates with the information in section 5.1 7. ACCEPT: indications for norovirus testing have been clarified in the document 8. ACCEPT: *Giardia* and *Cryptosporidium* species testing has been included in the primary test set 9. NONE: A detailed testing algorithm for *C. difficile* is not included within the document. A note clarifying this has been added to the scope. Users should refer to UK SMI B 10 10. ACCEPT: additional information on *E. histolytica* testing has been added to the document

Comment number	12		
Date received	24/11/2019	**Lab name/Professional body**	MSTAG
Comment			
General Comments:			

1. CE marking should be removed in favour of IVDR compliant.
2. For a syndromic SMI it was thought that there were too little diagrams and too much text.
3. Page 6_5 Clinical Presentations_Acute watery diarrhoeae_does not mention Adenovirus and should.
4. Page 7_5 Clinical Presentations_Vomiting_Vomiting with Diarrhoeae – should read “this type of vomiting occurs alongside diarrhoea at the same time”
5. Page 8_5.1 Algorithms in the Community and Hospital settings_2. Gastroenteritis in hospital setting (inpatients) a) Sporadic cases <48hrs– discusses the immunocompromised but does not mention Adenovirus, Sapovirus or Astrovirus. They are mentioned later on in the SMI and the document therefore appears inconsistent.
6. Page 9_5.1 Algorithms in the Community and Hospital settings_2. Gastroenteritis in hospital setting (inpatients) a) Sporadic cases >48 hrs– states that the UK SMI endorses the ‘3 day’ rule however what the SMI actually says is “if you do it” and it does not advocate. The MSTAG disagreed and thought that this was a misinterpretation of the SMI as there have been outbreaks detected in care homes and not hospitals because of the 3 day rule.
7. The next paragraph states laboratories considering applying the 3 day rule have to apply risk assessments, consideration should be given to dropping this.
8. Page 10_Gastroenteritis algorithm - Misses out Aeromonas and Plesiomonas and other viruses such as Astrovirus, Sapovirus, Hepatitis A and E.
9. Page 16_Safety considerations the first paragraph is poorly worded and talks about diagnostic work that could contain HG3 organisms then suggests that all work is performed under CL3 conditions wcChich is contradictory.
10. In the next paragraph on the same page, it was thought that this should say that “laboratory staff who may handle S.typhi should be offered vaccination for typhoid” rather than “should be vaccinated”.
11. Page 17_Parasitology – The detail in this section is too detailed and should just say to refer to SMI 31.
12. Page 19_Perianal swab for Enterobius vermicularis – it was not thought that this should in in an SMI for gastroenteritis and that it was doubtful that concentration methods should be included as ? a cause of gastroenteritis.
13. Page 20_Specific technical limitations ?should include Uncertainty of Measurement, this is not a quantity measured value and “misappropriation of the statistical tool”
14. The method does not mention the use of a tea strainer for the Ridley method.
15. Page 22_8.2.2 Sample Preparation – the second bullet point details samples may be diluted 1:4 however there is no reference and this should be referenced.
16. The last bullet point beginning “Automated and semi-automated…” states that All automated systems must be validated prior to use, this should read that “all automated systems should be used in accordance with manufacturers instruction and veritifed for use.

17. Page 24/5_Chromogenic media – should mention Aeromonas chromogenic media 18. Page 25_8.2.4 Investigation table mentions Plesiomonas and but not Aeromonas 19. Page 30_8.2.5.1 Minimum level of identification in the laboratory – It should be noted that NEQAS deducts points for not speciating Aeromonas 20. Page 32_8.3 Other diagnostic tests_LFA_Last line “validated prior to use” should read “verified prior to use” 21. Page 32_8.3 molecular tests are under “other diagnostic tests”, as most labs now use molecular this should be altered. 22. Page 33_8.3.3 UoM note “may result in very major errors” is bad grammar and should be reworded 23. Page 36 STEC should say the gene not the serotype 24. Page 38 Appendix 1 This now includes Adenovirus and Sapovirus but is missing Aeromonas and Plesiomonas 25. The table is difficult to use as it is not in alphabetical order 26. Listeria is mentioned in the table but is not mentioned elsewhere in the SMI. 27. Page 43 The heading is half way down the page due to track changes and requires amendment 28. Page 48 reference 29 references ACDP however this is not the latest reference to the document and should be updated	
A new syndromic template has been developed for this document, please give any suggestions or amendments to the layout.	
Not completed.	
Should Cryptosporidium and Giardia be included in the primary testing?	
Not completed.	
Financial barriers	
Not completed.	
Health benefits	
Not completed.	
Are you aware of any interested parties we should consider consulting with on the development of this document?	
Not completed.	
Recommended action	1. NONE 2. PARTIAL ACCEPT: some duplicated information has been removed 3. ACCEPT: adenovirus has been added

	4. PARTIAL ACCEPT: this sentence has been reworded for clarity 5. ACCEPT: adenovirus, sapovirus and astrovirus have been added 6. ACCEPT: reference to the three-day rule has been amended for clarity 7. NONE, working group estimates that note should be kept 8. NONE: this information is included elsewhere in the document (Appendix 1) 9. NONE; it was the view of the working group that the section was clear an no amendment was required 10. ACCEPT: sentence has been reworded in line with the Green Book 11. ACCEPT: some of the information which has been replicated from UK SMI B 31 has been removed, and a reference to that document provided instead 12. PARTIAL ACCEPT: concentration techniques have been removed from this UK SMI 13. NONE: uncertainty of measurement is covered in section 2: Scientific information 14. NONE: this section has been removed 15. ACCEPT: reference has been added 16. ACCEPT: validation has been replaced with verification 17. NONE: no clear references to the use of Aeromonas chromogenic agar 18. NONE: *Plesiomonas* and *Aeromonas* have been removed from the table 19. NONE; it was the view of the working group that no amendment was required 20. ACCEPT: “validated” has been replaced with “verified” 21. ACCEPT: molecular tests have been moved into a separate subsection 22. ACCEPT: the sentence has been reworded for clarity 23. ACCEPT: the sentence has been reworded for clarity 24. NONE: *Aeromonas* and *Plesiomonas* are covered in a footnote following Appendix 1 25. ACCEPT: the respective subsections of the table have been placed in alphabetical order 26. NONE; it was the view of the working group that no amendment was required

	27. ACCEPT: formatting of headings has been reviewed and issues resolved 28. ACCEPT: reference has been updated

Comment number	13		
Date received	24/11/2019	**Lab name/Professional body**	Gastrointestinal Bacteria Reference Unit
Comment			

1. Page 5. “Not all community cases of acute diarrhoea and vomiting require laboratory investigation as many are self-limiting”. Should it be noted that laboratory investigations for GI infections contribute to surveillance and are not just about treatment?
2. Page 6. The clinical presentations can feature in particular epidemiological settings: community or hospital as sporadic cases or outbreaks.
   Is the punctuation correct in this sentence? Not sure what you mean by epidemiological setting?
3. Page 7. Why define food and waterborne outbreaks in more detail but not those caused by person to person contact, animal contact or exposure to a contaminated environment?
4. Page 7. Shigatoxigenic Escherichia coli (STEC) including O157
   Correct format is Shiga toxin-producing Escherichia coli (STEC) including serogroup O157.
5. Page 8. STEC can present atypically and may be negative using culture methods, and so such specimens/isolates should be referred following the National Reference Laboratory guidelines.
   Needs to be re-phrased. Suggest the following “The tradition culture media used for the detection of STEC O157 is not selective for the STEC serotypes other than serotype O157. When STEC is suspected as the aetiological agent, especially is the patient has haemolytic uraemic syndrome (HUS), faecal specimens should be referred following the National Reference Laboratory guidelines.”
6. Page 8. The text under sporadic cases isn’t clear.
7. Pages 11-12. Figures 5.1.1. and 5.1.2. are good, very clear and comprehensive.
8. Page 13. 6.1 Specimen Type

   When collecting a faecal specimen pre-administration of antibiotics is not possible, either because the patient is constipated or there is not time to wait before treatment is given, we recommend taking a rectal swab. Faecal is preferable but it’s better to take a specimen as early in the care pathway, as close to onset of symptoms as possible and pre-administration of antibiotics.
   Reference:
   https://www.thelancet.com/journals/langas/article/PIIS2468-1253(17)30214-5/fulltext?rss=yes
   https://www.thelancet.com/action/showPdf?pii=S2468-1253%2817%2930214-5
9. Page 15. For parasites, routine testing for Cryptosporidium and Giardia species recommended nationally, subject to local consideration.This sentence isn’t clear.

10. Page 19. Many laboratories utilise molecular techniques for the detection of gastrointestinal pathogens for primary testing however culture techniques described here should be used to detect the pathogens outside the molecular panels in use locally. I'm not clear what your trying to say here.
11. Page 19. Culture is important for typing in cases of increased incidence, in outbreak situations and for surveillance of drug resistance
    Needs to be re-phrased. Suggest the following "Culture is required for typing GI bacterial pathogens. Typing is essential for monitoring trends and identifying emerging threats, outbreak detection and investigation, and for surveillance of drug resistance and highly pathogenic sub-types."
12. Page 20. In section 7.2.3. there's not mention of Shigella species. Has there been any studies on whether XLD or DCA is more suitable for the isolation of Shigella species? I was always told when training that the lab I worked used DCA because it was better for Shigella.
13. Page 22. faecal samples from appropriate cases from whom STEC O157 has not been isolated should be submitted to a reference laboratory for detection of shiga toxin producing E. coli of serogroups other than O157 (non-O157 STEC). Suggest "faecal samples from cases of suspected STEC, especially those with HUS from whom STEC O157 has not been isolated should be referred to a reference laboratory for the detection of non-O157 STEC."
14. Page 2.2 Chromogenic media. There are many different chromogenic agars available and some are recommended for the detection of specific pathogens, for example **CHROMagar™ STEC for STEC.**
15. Page 27. Minimum level of identification in the laboratory Table Suggest "For V. cholerae, to consider whether O1, O139 or non-O1,non-O139"
16. Page 27. Section 7.3. I think maybe this section needs looking at. It seems contradictory to say EIA "…have been found to be useful in the detection of several enteric bacteria, viruses…" and then later on say "… EIA are still being used by some laboratories for detecting viruses despite their inadequate sensitivity".
    Maybe inadequate is too strong – if the test is inadequate – we shouldn't be recommending it's used at all. Maybe just needs re-phrasing.
    Also re – "There are several commercially available assays on the market however these may vary in sensitivity and so laboratories should follow manufacturers' instructions when using these."
    The second part of this sentence doesn't really follow the first.
17. Page 27. It has been used successfully in the direct detection of bacteria, viruses and parasites such as Giardia and Cryptosporidium species from clinical specimens (faeces) which is usually confirmed using a quantitative test method. Are you recommending the results from this type of assay should be confirmed using a quantitative test? I think you need to clarify. Do you mean quantitative test?
18. Page 28 They are highly accurate for viruses, Salmonella, Campylobacter, STEC (including O157), Giardia species and Cryptosporidium species and Shigella species
19. Page 28. Due to the high sensitivity of molecular methods the detection of recognised pathogens may not be diagnostic of acute or ongoing infection. I'm not

sure what you mean here. Why wouldn't a validated PCR be diagnostic in this context?

20. Page 28. Results obtained by molecular testing must be interpreted with caution and clinico-pathological correlation is frequently required. This statement is true and applicable for all tests used in the laboratory – why do you only state in the PCR section?
21. Page 28. If there is a strong clinical suspicion but GI multiplex PCR screening is negative, consider culture-based methods or enrichment for PCR. Strong clinical suspicion of what? What do you mean by enrichment for PCR?
22. Page 30. Table

    I would recommend sending Vibrio and Yersinia for speciation and typing.
    Vibrio species Culture Refer for speciation and typing
    Yersinia species Culture Refer for speciation and typing
    I'm not sure why you have Emteroaggregative E. coli (EAEC) in this table and not the other DECs. I think iot might be a hang-over form the Olympic PCR SOP protocols as EAEC was included in the multiplex PCR but it's not a target in the commercial assays currently used by local labs so I would delete.
23. Page 35. Table S. dysentriae infection can be complicated by haemolytic uraemic syndrome which is seen more commonly in children. Only S. dysenteriae serotype 1 has the potential to cause HUS, and it's extremely rare – I've been working on HUS for 30 years and I don't remember there being any cases. We haven't seen a case of Dys 1 for over 12 years so I'm not sure if it's necessary to add this comment. But if you really think it's important then suggest amended text below. "Historically, S. dysenteriae serotype 1 infection was very rarely associated haemolytic uraemic syndrome."
24. Page 35. Asymptomatic infection can occur with all Shigella species. Suggest delete – not sure why you highlight this for Shigella and not the other GI pathogens. It's a bit of can of worms…for lots of reasons. Also, some would say you can't have "Asymptomatic *infection*" because part of the definition of infection is that there is a reaction in the host.
25. Page 36. Table. Remove reference to enterohaemorrhagic E. coli (EHEC) – just use Shiga toxin-producing E. coli (STEC). Shiga has a capital 'S' as it's a person's name and Shiga toxin is two words not one word.

    The incubation period is commonly 3-4 days but can be 2-8 days.
    I think you should re-order the sentences for emphasis – I think it's essential to highlight that STEC can cause a fatal condition.
    Suggest "STEC has the potential to cause haemorrhagic colitis and haemolytic uraemic syndrome (HUS), which can be fatal. Blood is not always present in faeces in STEC infections."
26. Page 40 Table: In the table in the row above V. cholerae you state Vibrio species excluding V. cholerae and V. parahaemolyticus but you then describe both in the Clinical presentations and mode of transmission boxes.
27. Cholera. Symptoms vary from mild and (***some text missing here?***) accompanied by abdominal cramps and vomiting to explosive diarrhoea - passage of a profuse watery diarrhoea with mucus, but no blood, giving a 'rice water' appearance. Fluid loss and dehydration are severe complications that can lead to shock and death if untreated. Suggest "Cholera. Symptoms vary from diarrhoea accompanied by abdominal cramps and vomiting to explosive, and/or profuse watery diarrhoea

with mucus, but no blood, giving a ‘rice water' appearance. Infection can cause severe fluid loss and dehydration leading to shock and death if untreated.”

28. I don’t think including information on seasonality is relevant for Vibrios in the UK as I think they only test at the frontline lab if the patient has travelled and so the season varies depending on the destination.

General comments

29. As already noted I’m concerned about the recommendation not to culture Campylobacter species. Over the next 12 months we will be discussing options for ramping up our surveillance of Campylobacter species and I’m concern the outcome might be at odds with recommendations not to culture. However, I appreciate the strategy is currently unclear so I can’t push you on it.
30. Do you think you need to expand a little about the PCR target for Shigella also detecting enteroinvasive E. coli? If you think it’s covered – that’s fine.
31. I really like that you have stated that all Shigella should be referred to the reference lab for typing.
32. I wonder if it would be good to emphasise that submitting isolates to the reference lab for surveillance not only enables to monitor trends in GI disease but also monitor AMR in GI pathogens. I’ve attached a draft of a recent paper to illustrate my point.

A new syndromic template has been developed for this document, please give any suggestions or amendments to the layout.

Not completed.

Should Cryptosporidium and Giardia be included in the primary testing?

Not completed.

Financial barriers

Not completed.

Health benefits

Not completed.

Are you aware of any interested parties we should consider consulting with on the development of this document?

Not completed.

Recommended action	1. NONE: Surveillance is covered elsewhere in the document 2. ACCEPT: sentence has been reworded for clarity 3. NONE: it was the view of the working group that the section was clear and no amendment was required 4. ACCEPT: nomenclature for STEC has been made consistent throughout the document 5. ACCEPT: sentence has been rephrased

	6. ACCEPT: sentences have been restructured to improve flow 7. NONE: the working group thank you for the comment 8. ACCEPT: reference to rectal swab has been added 9. ACCEPT: sentence has been reworded for clarity 10. ACCEPT: sentence has been reworded for clarity 11. NONE: comment pertains to an earlier version of the document, which has since been amended 12. NONE: it was the view of the working group that XLD usage was common and no amendment was required 13. ACCEPT: sentence has been included 14. ACCEPT: the chromogenic media section mentions STEC 15. ACCEPT: note on O1, O139 for *V. cholerae* has been added 16. ACCEPT: section has been reworded, removing “inadequate” 17. ACCEPT: quantitative has been replaced with qualitative 18. ACCEPT: *Shigella* species has been added to the list 19. ACCEPT: sentence has been reworded 20. PARTIAL ACCEPT: the preceding sentence has been reworded for clarity 21. ACCEPT: sentence has been reworded 22. ACCEPT: refer for typing has been added for *Vibrio* and *Yersinia* species; EAEC has been removed from the table 23. PARTIAL ACCEPT: sentence has been reworded to emphasise that this complication is rare 24. ACCEPT: Note on asymptomatic infection has been removed 25. ACCEPT: reference to EHEC has been removed from this table row 26. NONE: described elsewhere in the document 27. ACCEPT: sentence has been reworded 28. PARTIAL ACCEPT: sentence has been amended to indicate prevalence in endemic areas during warmer months 29. PARTIAL ACCEPT: “culture if treatment is indicated” has been added 30. NONE: this is addressed under 7.3.2

	31. NONE 32. NONE: more surveillance data is out of scope of this UK SMI

Comment number	14		
Date received	25/11/2019	**Lab name/Professional body**	PHE MRL/LSHTM DPL
Comment			
Pre-laboratory processes (pre-analytical phase) 1. Under section 6.2: three specimens should be sent at least two days apart as OCP are shed intermittently. The ref cited does not evidence this timeframe. Our lab recommends collecting three consecutive faecal samples to capture intermittent shedding of parasites, rather than stating a time limit between samples.			
A new syndromic template has been developed for this document, please give any suggestions or amendments to the layout.			
N/A			
Should Cryptosporidium and Giardia be included in the primary testing?			
Yes.			
Financial barriers			
N/A			
Health benefits			
N/A			
Are you aware of any interested parties we should consider consulting with on the development of this document?			
N/A			
Recommended action	1. NONE: the wording used is as per the applicable PHE guidance referenced in the document		

Comment number	15		
Date received	25/11/2019	**Lab name/Professional body**	Public Health Wales
Comment			
Scope of document 1. Line 14 regarding C. diff testing. The current statement does not make sense given that c.diff is part several routine screens and is referenced throughout the			

document. Suggested alternative; 'This document does not cover a detailed testing algorithm for C. difficile. Due to the varying algorithms used in the UK. Please refer to...

Clinical presentations of gastrointestinal infections

2. Please refer to algorithm 5.1.2. For acute vomiting without diarrhoea, what sample is the SMI proposing to test? Formed stool is not normally accepted for virology testing.
3. More clarity is needed for patient selection criteria with particular reference to age and immunosuppression in relation to testing for viruses. Consideration should be made to testing all children under the age of 5 years for viruses.
4. Under outbreak investigations the routine screen includes norovirus and C. diff, both are mentioned again in healthcare/institution acquired infections. Other viruses are not mentioned for the immunosuppressed yet are included in the sporadic cases for the immunosuppressed. Suggest that for the immunosuppressed with diarrhoea a full screen is performed to include viruses regardless of setting.
5. Refer to algorithm 5.1.1 and main text on gastroenteritis in the community.The criteria for secondary testing is unclear for sporadic cases, for example, when should C.difficile testing be done? Under sporadic cases (text) it notes that C.diff is an important cause of community diarrhoea.Should there be further additional investigation criteria therefore relating to other C. diff risk factor for example antibiotic use and healthcare exposure?
6. In acute diarrhoea in the community with or without vomiting (outbreak text) there is testing for C. perfringens the flowchart implies this is only tested for short incubation periods where vomiting predominates. As such the algorithm and text seem to contradict each other.

Laboratory processes (analytical phase)

7. Section 7.5 (NAATs) paragraph two the statemtn that PCR has greater sensitivity and specificity over culture and EIA for a variety of pathogens. Are we happy this statement is true in all cases? for example some recent publications suggest that there are limitations with NAAT detection of salmonella. Should there be specific indications for doing enrichment culture? for example clearance samples, small children and the immunocompromised? Hapuarachchi CT1, Jeffery KJM1, Bowler ICJW1. Stool PCR may not be a substitute for enrichment culture for the detection of salmonella. J Med Microbiol. 2019 Mar;68(3):395-397. doi: 10.1099/jmm.0.000923. Epub 2019 Jan 21.Moreover for enteric fever the guidance on clearance and contact screens does not endorse PCR.

Post-laboratory processes (post-analytical phase)

8. Please refer to table 8.2.2. The titles are confusing, would suggest rewording for the second column title in the table we would propose: 'Agents to be tested with primary test panel (recommended agents to be reported are in bold depending on clinical presentation)'For the 3rd column would propose: 'Other agents suitable for treatment of this organism and have clinical breakpoints (Supplementary testing)'Furthermore, although elsewhere in the document the user is referred to EUCAST guidance the choice of agents listed does not always seem to take that guidance into account. Specifically for Salmonella species nalidixic acid should be removed and for ciprofloxacin it should be specified that pefloxacin should be

used to screen for resistance or an MIC method used. Under supplementary testing for Campylobacter, there is no breakpoint for trimethoprim this is incompatible with EUCAST guidance. Finally, would suggest given the recent problems with ESBL producing Salmonella and Shigella that under supplementary testing it would be useful to add meropenem and for the primary test panel there should be a choice between cefpodoxime or ceftriaxone and ceftazidime.	
A new syndromic template has been developed for this document, please give any suggestions or amendments to the layout.	
The template is okay, some of the flowcharts are difficult to follow.	
Should Cryptosporidium and Giardia be included in the primary testing?	
Yes.	
Financial barriers	
Not completed.	
Health benefits	
Standardised testing can only be a benefit for patients.	
Are you aware of any interested parties we should consider consulting with on the development of this document?	
Not completed.	
Recommended action	1. ACCEPT: the scope of the document has been reworded to clarify that users should refer to UK SMI B 10 for information on *C. difficile* testing 2. ACCEPT: sentence added to section 6.2 3. NONE: out of scope of this UK SMI 4. NONE: *C. difficile* testing in this instance is considered primary testing, but not included in the routine screen. For clarity, “refer to B 10” has been added to instances of *C. difficile* in the algorithm 5. PARTIAL ACCEPT: users should refer to UK SMI B 10 for further information on *C. difficile* testing, the scope of the document has been amended to clarify this 6. ACCEPT: the distinction between predominantly vomiting and predominantly diarrhoea has been removed from the algorithm 7. ACCEPT: Paragraph amended to reflect comment content 8. PARTIAL ACCEPT: amendments made to the table to reflect updated EUCAST guidance on antimicrobial resistance

Comment number	16		
Date received	25/11/2019	**Lab name/Professional body**	Institute of Biomedical Science
Comment			
Flowchart for Investigation of faecal specimens for routine bacterial pathogens Sporadic Cases - This may look confusing - under what conditions (routine screen positive/or negative, do these get done). Also - unclear if this is done for immunocompetent/immunocompromised/acute diarrhoea, or all of the above. Outbreaks - this may look confusing - under what conditions (routine screen positive/or negative, do these get done). Also - unclear if this is done for predominantly vomiting, predominantly diarrhoeae, or all of the above.			
A new syndromic template has been developed for this document, please give any suggestions or amendments to the layout.			
The template is unclear about work to be performed after the routine screening. Following the lines of the flowchart, differentiation between clinical presentation and patient group gets lost.			
Should Cryptosporidium and Giardia be included in the primary testing?			
These should not be included in primary screening unless there is an abstract suspicion that these are a cause or relevant clinical detail is provided.			
Financial barriers			
None aware of.			
Health benefits			
No.			
Are you aware of any interested parties we should consider consulting with on the development of this document?			
Not completed.			
Recommended action	PARTIAL ACCEPT: flowcharts have been revised		

Comment number	18		
Date received	25/11/2019	**Lab name/Professional body**	British Society of Gastroenterology
Comment			
Pre-laboratory processes (pre-analytical phase) My only comment is that under section 6.3 if the laboratory is in the same trust as the patient is being seen in then do we have to put all these items in the request form			

actively, repeating data entry from the original notes? All notes will be electronic very shortly and risk factors drugs travel and exposure should all be recorded in these notes and should be available to anyone in the lab. Repeated manual entry of patient data should be avoided everywhere in the nhs.
A new syndromic template has been developed for this document, please give any suggestions or amendments to the layout.
Not completed.
Should Cryptosporidium and Giardia be included in the primary testing?
Not completed.
Financial barriers
Not completed.
Health benefits
Not completed.
Are you aware of any interested parties we should consider consulting with on the development of this document?
Not completed.

Recommended action	NONE: out of scope of this UK SMI

Comment number	19		
Date received	25/11/2019	**Lab name/Professional body**	NSS Reference Laboratory Operational Group

Comment
General comments 1) Where referral of isolates to national reference laboratories is mentioned, then acknowledgement should be made that the Devolved Administrations have some of their own services.eg Page 8 section 5.1 “STEC can present atypically and may be negative using culture methods, and so such specimens/isolates should be referred following the National Reference Laboratory guidelines.” The reference for this advice provides a reference for referral criteria for PHE only – this could lead to confusion. 2) In the guidance there is some inconsistency in the recommendations for Giardia testing, we suggest that similar testing criteria should apply to Giardia and Cryptosporidium and we support the broadening of the criteria for Giardia testing. Examples of inconsistencies: a. Figure 5.1.1. Has Giardia as part of the routine screen for sporadic cases with persistent diarrhoea, but not if the patient is already in hospital when is isn’t part of the routine screen.

b. In the text for acute watery diarrhoea (page 7) doesn't mention Giardia, but is only included under persistent diarrhoea (>14 days), which doesn't really align with the figure 5.1.1. 3) The wording on Page 27, Section 7.2.5 "Antimicrobial susceptibility testing" could be strengthened by adding the advice that AST testing for individual patient management should be carried out by the diagnostic laboratory that identified the infection so as to ensure timely sensitivities results are provided.
A new syndromic template has been developed for this document, please give any suggestions or amendments to the layout.
Not completed.
Should Cryptosporidium and Giardia be included in the primary testing?
Yes.
Financial barriers
None additional.
Health benefits
No.
Are you aware of any interested parties we should consider consulting with on the development of this document?
No.

Recommended action	1. ACCEPT: additional reference added 2. ACCEPT: testing for Giardia spp. And Cryptosporidium spp. is now included within routine screen in the flowchart 3. NONE: it was the view of the working group that the UK SMIs could not make the recommendation unless there was significant evidence of clinical impact

Comments received outside of consultation

Comment number	1		
Date received	28/11/2019	**Lab name/Professional body**	Public Health England
Comment			
a. I have looked at the molecular section and noted that section 8.5 "DNA detected", "DNA not detected" is stated, this should be changed to "DNA/RNA" or "nucleic acid" Not all targets will be DNA. b. It is advised to replace all mention of "PCR" in the NAATs sections to "molecular testing". PCR refers to a specific technique and not all commercial assays are based on PCR.			

c. For test commercial test selection, CE marking should be stated and mandatory as per new regulations for IVD	
A new syndromic template has been developed for this document, please give any suggestions or amendments to the layout.	
Not completed.	
Should Cryptosporidium and Giardia be included in the primary testing?	
Not completed.	
Financial barriers	
Not completed.	
Health benefits	
Not completed.	
Are you aware of any interested parties we should consider consulting with on the development of this document?	
Not completed.	
Recommended action	1. ACCEPT: nucleic acid (DNA or RNA) detected/not detected wording has been adopted 2. PARTIAL ACCEPT: “NAATs (including PCR) wording to be used” 3. NONE: it was the view of the working group that this information was not necessary in this document