

17 March 2011  
Gateway reference 15766

Dear Colleague

### **Diagnostic testing for *Clostridium difficile* infection**

I am writing to remind you of the Department of Health's (DH) current advice to the NHS on testing for *C. difficile* infection (CDI) and also to update you on the programme of work we have commissioned to support improvements in CDI testing.

This seems the appropriate time to do this, as I am aware the introduction of the new CDI Objective from April has raised concerns in some organisations that recently changed their testing algorithms to one more aligned with the current DH and Health Protection Agency (HPA) guidance issued in March 2009.

Separate to this letter, Strategic Health Authorities have been informed by the DH on the suggested process that commissioners and providers should use when approached by an organisation that believes its ability to achieve its CDI Objective has been compromised as a result of recently changing to a more accurate testing algorithm.

Following the publication of evidence in early 2009, showing that the accuracy of currently available testing kits for CDI is sub-optimal, DH sought to ensure it put in place a range of activity and guidance to support improvements in the short, medium and long term. It has done this in two main ways.

#### **Current Department of Health and HPA Guidance**

Firstly, DH and HPA issued updated guidance on testing for CDI. In March 2009, the HPA released: *Questions and answers about the laboratory diagnosis of C. difficile infection*. It gave information about the implications of incorrect results from laboratory tests, and the likelihood that a 2-stage test would be the best approach (i.e. stage 1 sensitive but less specific, and stage 2 more specific for confirmatory purposes), and noted the need for further research.

Also in March 2009, DH's Inspector of Microbiology and Infection Control issued updated guidance advising against relying on single tests for the laboratory detection of CDI, and the need for a local 2-test diagnostic

algorithm to determine the reporting of cases to the mandatory surveillance system. All laboratory diagnostic results should be considered alongside the clinical presentation of the patient's symptoms.

The text that was issued as a "bug-alert" to the NHS, which acknowledged the CEP report, stated:

*"All NHS laboratories should ensure that they review the methods they are using to diagnose C. difficile infection. It is not advisable to rely on toxin detection kits as single tests for the laboratory detection of C. difficile. If such kits are used then these should be one of the better performing assays. Laboratories should consider the use of a confirmatory test for positive results. Test options and further advice is available on the HPA website at <http://www.hpa.org.uk>*

*All laboratory diagnostic results should be considered alongside the clinical presentation of the patient's symptoms."*

Additional Q&As on this issue published by the HPA can be found at:

[www.hpa.org.uk/web/HPAwebFile/HPAweb\\_C/1238055363795](http://www.hpa.org.uk/web/HPAwebFile/HPAweb_C/1238055363795)

Advice to the NHS on what they should be reporting was also published by the HPA and can be found at:

[www.hpa.org.uk/web/HPAweb&HPAwebStandard/HPAweb\\_C/1179746015058](http://www.hpa.org.uk/web/HPAweb&HPAwebStandard/HPAweb_C/1179746015058)

### **DH commissioned programme of work to improve accuracy of testing algorithms for CDI**

Secondly, we introduced a programme of work, in partnership with the HPA on ways to improving CDI testing. Details on this programme of work are shown below:

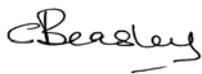
- **Test kit review project to determine the best combination of the currently available test-kits.** This work is being undertaken by Professor Mark Wilcox (Leeds Teaching Hospitals NHS Trust) and colleagues at three other trusts (St Georges Healthcare NHS Trust, University College London Hospitals NHS Foundation Trust and Oxford Radcliffe Hospitals NHS Trust) on behalf of the HPA. It aims to determine optimal testing algorithms using currently available kits. At the same time, the project will determine the best gold standard method for the diagnosis of *C. difficile* infection. This commenced in October 2010 and results are expected in Summer 2011.
- **Develop a new improved rapid cytotoxin testing approach.** Prof. Mark Wilcox has been funded to develop a new testing approach. The project commenced in January 2010 and should produce results during 2011, allowing an assessment of the feasibility of making the test more widely available.

- **Review of current testing approaches and model the likely impact that changing the testing approach would have.** This study included an audit of NHS diagnostic microbiology laboratories, using an electronic questionnaire, to investigate changes in testing (in response to the guidance). The results have been used to model the impact that changes in testing could have on national and local surveillance data. The preliminary findings are currently being reviewed by the DH and will be submitted to a peer-reviewed journal.
- **Ensure the HPA's Data Capture System allows for changes to CDI testing approaches.** The HPA team has amended the advice on its website to make it clear that cases should only be reported to the mandatory surveillance system if they meet the diagnostic algorithm used in the trust. All final CDI positive reports that are issued locally must be reported to the mandatory surveillance system.
- **Meetings with the current test-kit manufacturers.** Individual meetings with all of the manufacturers have now taken place. There seems to be interest from some of the manufacturers to improve on their current kits, but with no specific plans at the moment. Most of the next generation tests are scheduled for release from 2012 onwards.

Together, these projects will enable DH, with advice from our advisory committee and the HPA, to decide if updated evidence-based guidance on CDI should be issued. Therefore, we will review the position in Summer 2011, once the programme of work has been completed and will advise the NHS as soon as possible after this on any recommended changes in practice that should be made.

## **Conclusion**

I hope that this information assures you that we are determined to support the NHS in improving the accuracy and effectiveness of CDI testing through the outputs of the programme of work that we have commissioned.



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