NHS
East and North Hertfordshire
Clinical Commissioning Group

Review of *Clostridium difficile* Control Measures at East & North Hertfordshire NHS Trust - 12th February 2014.

This report is a summary of a review of *Clostridium difficile* (*C. difficile)* control measures at East & North Hertfordshire NHS Trust performed on 12th February 2014. The review was carried at the request of the Trust and NHS East and North Hertfordshire Clinical Commissioning Group, in response to concerns raised by a whistleblower in a letter to Sir Bruce Keogh, Medical Director NHS England. The review was undertaken jointly by Dr Nicholas Brown, Consultant Microbiologist, Cambridge University Hospitals NHS Foundation Trust and Fiona Simpson, Head of Infection Prevention and Control, NHS East and North Hertfordshire Clinical Commissioning Group.

The overall conclusion of this review was that we are satisfied that the Trust is compliant with current guidelines for *C. difficile* management and were reassured that the Trust takes this issue very seriously. However, we recognise that there is a potential conflict in the initial assessment of patients between, on one hand, avoiding inappropriate sample testing and, on the other, staff perception that the Trust does not want samples to be taken. We think that this could be improved by the way in which the Trust's policies are documented and communicated.

Dr Brown and Fiona Simpson met with the whistleblower to clarify the concerns of the whistleblower and to ensure the terms of reference for the review addressed the issues raised. The key points raised by the whistleblower at this meeting were that perceived delays in the testing of stool samples for *C. difficile* toxin potentially resulted in delays in diagnosis and a risk that cases of *C. difficile* infection could be missed. There was a perception by some staff that processes put in place for the management of *C. difficile* testing were driven by a need to reduce the number of cases reported by the Trust. It was the view of the whistleblower that these concerns were not having a clinical impact on patient care.

The agreed terms of reference for our visit were:
- to ensure the Trust's *C difficile* policy is consistent with Department of Health guidance;
- to determine whether-or-not there are appropriate recording, monitoring and reporting of *C difficile* cases;
- to determine whether the criteria for testing for *C difficile* have been applied appropriately.

The relevant guidance includes: Advisory Committee on Antimicrobial Resistance and Healthcare Associated Infection *(ARHAI) Updated Guidance on the Diagnosis and Reporting of Clostridium difficile* (March 2012) and DH/HPA guidance *Clostridium difficile infection: How to deal with the Problem* (January 2009).

The above guidance states:
- If a patient has diarrhoea (Bristol Stool Chart types 5-7) that is not clearly attributable to an underlying condition (e.g. inflammatory colitis, overflow) or therapy (e.g. laxatives, enteral feeding) then it is necessary to determine if this is due to *C. difficile*. The stool sample must take on the shape of the container…before it is sent to the laboratory for testing. If in doubt, please seek advice, for example, from your microbiologist, Director of Infection Prevention and Control or your Infection Prevention and Control Team.

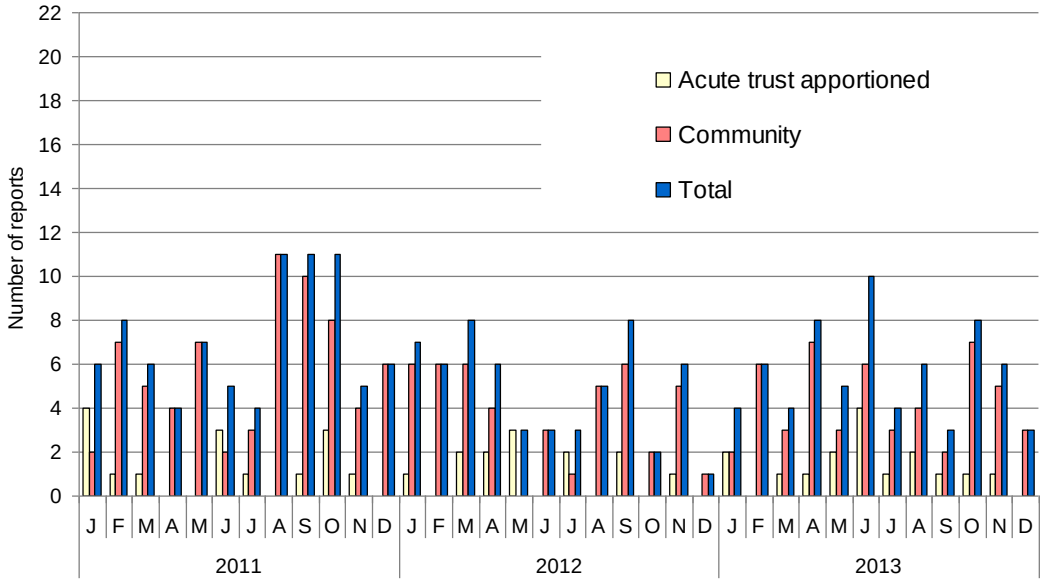
- All diarrhoeal samples from hospital patients aged >2 years and, as a minimum, all diarrhoeal samples from those aged >65 years in the community where clinically indicated should be tested.

The overall Trust performance for *C. difficile* is good. The infection control annual report for 2012/13 and the monthly Board performance reports document how the annual number of reported cases has fallen from very high absolute numbers to the low teens (see below). We were told that the 2013/14 total to date was 14 cases.

Year	**04/05**	**05/06**	**06/07**	**07/08**	**08/09**	**09/10**	**10/11**	**11/12**	**12/13**
Total	474	487	594	457	108	81	56	12	13
Ceiling	n/a	n/a	n/a	414	183	90	63	65	14

At the time of last comparison in July 2013, the rate of *C difficile* infection in the Trust (at approx 0.07 cases per 1,000 occupied bed days) was the lowest in the East of England (mean 0.15: range 0.07-0.27 cases per 1,000 occupied bed days). This rate is just outside the 95% confidence limit as a low outlier.

Figure: *C difficile* toxin-positive test results at East & North Herts NHS Trust 2011-2013



Therefore, it seems appropriate that the main focus of this review was on the initial assessment of patients and the decision on whether-or-not to take a stool sample and test it for *C. difficile* toxin. Given the low number of *C difficile* cases, we wanted to establish that all cases of *C difficile* were being diagnosed, that patients were not developing severe infection as a result of delayed diagnosis, and there was no evidence that patients with a diarrhoeal illness were mismanaged on the wards.

During the visit to the Trust on 12 February 2014, we had the chance to discuss *C difficile* control measures with Angela Thompson, Dr Awad El Kariem, Helen O'Conner, Dr Kandil, Dr Ahmad, Martin Strickland and Vishal Sookhoo. We also visited four wards at Lister Hospital and talked to the ward managers, junior nursing staff and trainee medical staff.

The Trust's protocol for review of patients before testing for *C difficile* toxin was discussed at length. The protocol emphasises that the process for patients in the community and within 72

hours of admission differs from that in hospital in-patients. After 72 hours of admission, the key difference is that the Trust protocol states that the patient should be reviewed by the infection control team and that stool samples should not be taken until after this has happened. Before 72 hours, staff are encouraged to take a stool sample to test for *C difficile* immediately.

The difference in testing protocol can be justified by the wording of the national guidance, although it is also easy to see how staff might perceive that it has been established to prevent hospital cases from being diagnosed. Cases identified before 72 hours of admission are attributed to the community whereas cases after this time point are attributed to the Trust, even if the patient has symptoms before then. Therefore, it makes sense to ensure that patients with symptoms at or soon after admission are diagnosed quickly. It is also important that stool specimens are taken from patients who have symptoms of loose stools on or shortly after admission to diagnose any intestinal bacterial and viral infections acquired prior to admission, in order to facilitate appropriate treatment and initiate measures to prevent cross infection.

The review of hospital in-patients before testing for *C difficile* is consistent with national guidance, as it is important not to test patients with a clear alternative reason to have diarrhoea. Carriage of *C difficile* in the gut is common enough that positive toxin tests will be obtained if patients without true *C difficile* infection are tested. These toxin-positive patients are counted as cases for the purposes of mandatory reporting and attributed to the Trust according to current reporting instructions. They appear as 'own goals' from the point-of-view of the Trust's *C difficile* trajectory.

Samples are also reviewed before testing for *C difficile* toxin upon receipt in the laboratory. Samples that do not take the shape of the specimen container (i.e. are not 'diarrhoeal' samples) are rejected. Likewise, samples from the community are rejected if the patient is under 65 years of age, unless the test is specifically requested by the sender.

The monthly Trust Board infection control reports contain information on the number of samples that have been rejected by either the infection control team or the laboratory. Therefore the review process is reported openly. This has been the case since its implementation. The table below is an example from the report for December 2013.

C.diff Specimen Testing (All Specimens Received Including Community)
Criteria for testing DH (2008) Bristol Stool Chart types 6-7

Samples	Total 12-13	Jan-13	Feb-13	Mar-13	Apr-13	May-13	Jun-13	Jul-13	Aug-13	Sep-13	Oct-13	Nov-13	Dec-13	YTD
No. of Specimens for CDT to lab	1483	173		161	152	174	152	146	148	152	156	162	124	1388
No. Tested	1191	117	103	108	110	97	108	113	123	122	126	97	94	988
No. Not tested for lab reasons	248	29	25	9	20	21	11	10	7	12	13	48	9	162
No. Not tested as advised by the ICT	223	27	16	38	22	51	35	22	18	18	17	16	21	221
% of Specimen's tested	80.3%	67.6%	#DIV/0!	78.6%	72.4%	65.7%	69.7%	77.8%	82.6%	80.3%	80.8%	59.8%	75.8%	72.33%

Stools samples from GPs from <65 yrs are no longer tested for *C diff*, unless explicitly requested by the GP.

Thus, in the calendar year 2013, between 16 and 51 samples (mean 25) were rejected by the infection control team each month. Overall, just over 70% samples sent to the laboratory are tested for *C difficile* toxin, but it is not clear from the table how many of these samples are from the community and how many are from hospital in-patients. It would be useful to know what proportion of in-patient samples and particularly those in-patient samples taken 72 hours after admission, are rejected to gain greater assurance of the process. We recommend that these data are presented.

We were reassured that there is active surveillance for adverse patient outcomes associated with *C difficile*. In particular, there is no evidence of excess morbidity or mortality (as

evidenced by death certification), admissions to ICU or requirement for emergency colectomy.

A very positive feature of the infection control team review of patients is the proactive approach to identify any patient with diarrhoeal symptoms in the Trust. This was evident when we visited a selection of wards at the Lister Hospital. Staff showed us the daily checklist used by ward managers to identify any patient with diarrhoea, to ensure that these patients are isolated in a side room, and that the infection control team are notified. Patients are reviewed by the infection control team on a daily basis while they have symptoms. If no obvious cause for the diarrhoea is evident, the infection control team escalate the case to one of the consultant microbiologists to assess and decide if testing for *C difficile* should be performed.

We were told that records of the assessment of patients are kept in several places. There is a record in the patient's own medical records. The infection control team keep a record and there is also a record in WinPath, the pathology system used by the Trust and accessed by the microbiologists. One way of improving the perception of the *C difficile* testing process would be to make this assessment process more accessible to all Trust staff and, in particular, the consultant responsible for the care of the patient. The obvious place for on-going documentation of any testing or treatment decision is the main patient medical record.

We were also told of some concern about potential for delayed diagnosis of *C difficile* infection. The requirement for a review of a patient with diarrhoea by a consultant microbiologist before a sample can be taken for testing for *C difficile* toxin has potential to delay the ultimate receipt of a positive result. Although there is no evidence of patient harm as a result of this potential delay, we think that this remains a risk.

We were shown an audit of patients at the Lister Hospital presented by Dr S Khan in January 2012 and including patients who had *C difficile* toxin tests rejected during September-November 2011. This audit included a small number of patients (20) and noted that a lack of documentation made review of the decision not to test difficult. We would suggest that it would be useful to repeat this audit and report the outcome of the patients assessed as not fulfilling the criteria for *C difficile* toxin testing. Such an audit could also identify if any patients have a delayed diagnosis and hence delayed initiation of appropriate treatment.

The Trust gains assurance on compliance with the Trust's C. difficile policy through the audit of the patient pathway incorporated in the root cause analysis tool used to carry out case reviews on all patients with *C. difficile* positive results. During the visit to the ward areas staff were very aware of the need to isolate patients with diarrhoea without delay and the need to escalate this when delays in isolating patients occurred. However the Trust was not able to provide documentation at the time of the visit of their internal assurance that the requirement to isolate patients within 2 hours as outlined in the ARHAI *Updated Guidance on the Diagnosis and Reporting of Clostridium difficile* (March 2012) was being complied with. We recommend that the trust reviews how it can demonstrate compliance with the national guidance to isolate patients with diarrhoea within 2 hours.

The following recommendations are given as a result of the visit:

- Documentation of the reasons for a decision not to carry out *C difficile* testing on a patient should be readily available to all relevant staff involved in the care of a patient. This includes documentation in the main patient medical record.
- The Trust should consider how messages for staff in relation to the rationale for differences in approach to testing before and after 72 hours from admission can be delivered and also incorporated into policies.

- The Trust should consider processes for providing assurance that the national requirement to isolate patients with diarrhoea within 2 hours is complied with.
- The audit of patients who had had C. difficile testing declined should be repeated, with identification of outcomes for patients assessed as not fulfilling the criteria for *C difficile* testing, including any delays in diagnosis or treatment.
- Data showing what proportion of samples rejected for C. difficile testing are community samples, samples taken from inpatients in the first 72 hours of admission and samples taken from patients more than 72 hours after admission should be presented.

The efforts of all staff involved in the preparation for this visit and on the day of the visit are acknowledged and we request that our appreciation is passed on to all staff involved.

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