Reviewer's report

Title: Indeterminate tcdB using a Clostridium difficile PCR assay: a retrospective cohort study

Version: 3 Date: 13 June 2013

Reviewer: Maja Rupnik

Reviewer's report:

Abstract – 'For 5 months after implementation of Xpert® in our laboratory…' - For me difficult to understand. Is it possible to change into 'Samples with indeterminate Xpert® result were collected for 5 months and retested by Xpert®…'

Abstract – replace 'toxin genotyping' by 'detection of toxin genes'

Abstract – 'At least one-third of these results are associated with culture confirmation.' – this could also mean that one third was culture negative… change to 'associated with positive CD culture'

Background, first paragraph – as requested before, I would still like to see at least one of the recent reviews on Molecular diagnostics in C. difficile to be included.

Xpert shows result for three targets – tcdB, tcdC and binary toxin; describe positivity/negativity of other two targets in the IND samples.

Pg 6 – 'To meet this case definition, patients required passage of three or more unformed stools in less than 24 hours that was not due to an alternate cause.' – does the SHEA case definition also includes positive C. difficile test? If so, specify. Otherwise use everywhere CLINICAL CASE DEFINITION.

Namely on page 9 authors state 'Thirty-nine of 48 patients (81%) with indeterminate results met the CDI case definition…' – this, as currently described on page 6 – does not necessarily mean 39 patients were positive for C. difficile while retested. It would be better to say 'met the clinical criteria' and not 'met the CDI case definition'

Level of interest: An article whose findings are important to those with closely related research interests

Quality of written English: Acceptable

Statistical review: Yes, but I do not feel adequately qualified to assess the statistics.

Declaration of competing interests:
I declare that I have no competing interests