

The Impact of Introducing a Two-Step Algorithm for Laboratory Diagnosis of *C. difficile* Infection

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Jonathan Swindells, Richard Anderson and Beryl Oppenheim
Department of Microbiology, SWBH NHS Trust, Birmingham, UK

beryl.oppenheim@swbh.nhs.uk
+44(0)121 507 4078

Introduction

In April 2009 our laboratory introduced a new two-step testing algorithm for *C. difficile* infection (CDI): initially, all liquid stool samples are screened for *C. difficile* antigen and toxins using the *C. DIFF QUIK CHEK COMPLETE™* (Techlab) test. All antigen-positive samples then undergo polymerase chain reaction (PCR) using the Xpert™ *C. difficile* (Cepheid) platform to detect toxin B gene.

No changes to infection control and CDI treatment policies or practices were implemented around this time.

We present our CDI surveillance data in an attempt to evaluate the clinical and epidemiological impact of the new testing strategy.

Methods

Patients whose samples produced a positive antigen result plus at least one of a positive toxin or PCR result were defined as CDI cases and entered into our surveillance database.

Using a retrospective rolling 30-day period, the total numbers of CDI cases, hospital acquired cases (those diagnosed more than 48h after admission) and significant deaths (patients who died within 30 days of CDI diagnosis) were calculated on a daily basis.

The ratio of these two figures was then determined to produce a rolling 30-day case fatality ratio.

Finally, Kaplan-Meier survival curves for the quarters following introduction of the new testing algorithm were compared to those of previous quarters.

Figure 1. 30-day rolling numbers of cases of *C. difficile* infection and 30-day mortality before and after introduction of two-step testing (represented by the line)

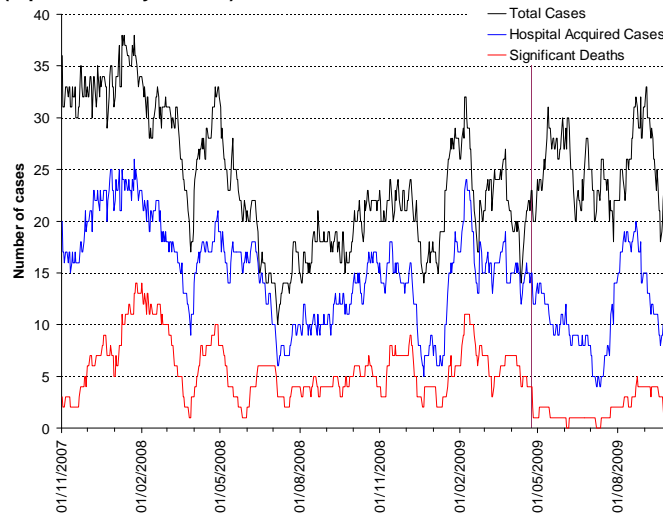


Figure 2. 30-day rolling proportion of significant deaths amongst patients diagnosed with *C. difficile* infection. The line indicates the date of introduction of the two-step testing algorithm.

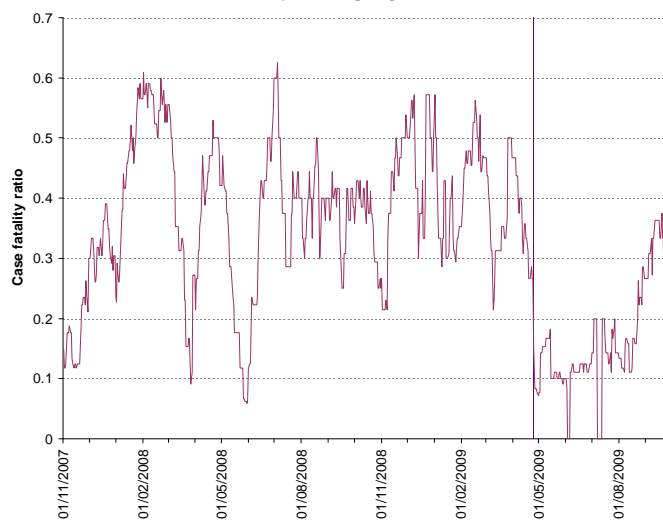
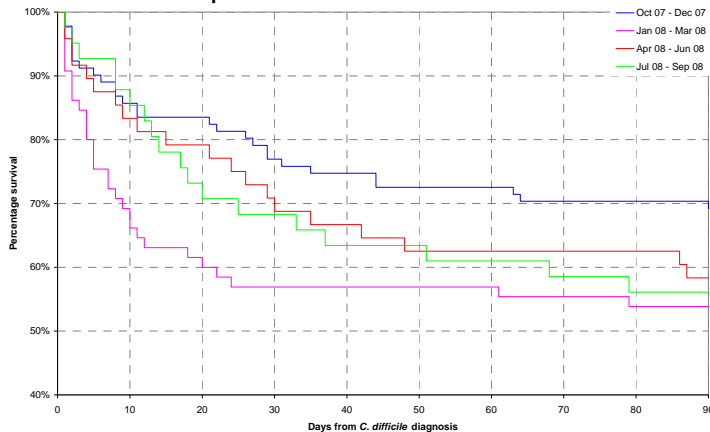
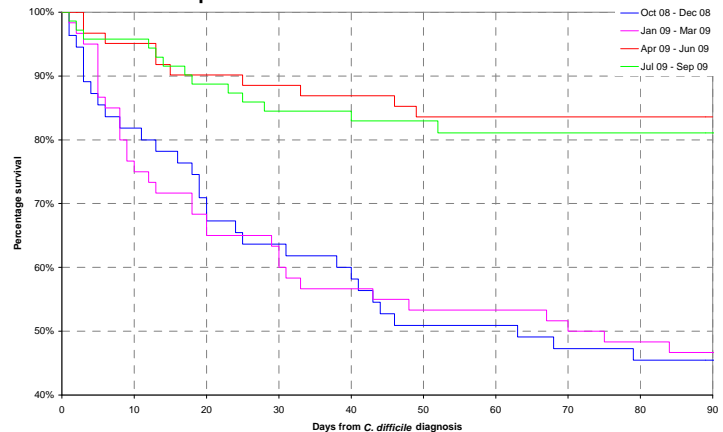


Figure 3. Quarterly Kaplan-Meier survival curves following diagnosis of *C. difficile* infection. The two-step testing algorithm was introduced in April 2009.

A. October 2007 – September 2008



B. October 2008 – September 2009



Results

Although there was no dramatic change in the overall numbers of CDI diagnoses following introduction of the new testing algorithm, many more of these cases were diagnosed within 48 hours of admission and the number of cases diagnosed later into the admission fell steadily (figure 1).

Additionally, for hospital acquired cases there was a sustained reduction in the rolling number of deaths within 30 days of CDI diagnosis and the case fatality ratio also fell dramatically following introduction of the new algorithm (figure 2).

The Kaplan-Meier analysis showed that, compared to previous quarters, survival rates were greatest at every time point after CDI diagnosis following introduction of the two-step testing algorithm (figure 3).

Conclusions

- Our surveillance data suggest that introduction of the new testing algorithm has allowed us to diagnose patients with CDI earlier into their admission than was possible previously.
- Furthermore, it appears that 30-day mortality following CDI diagnosis has fallen dramatically in the absence of a clear alternative explanation.
- Whilst an increase in false positive results and detection of *C. difficile* carriage could partially account for our observations, these would not explain the selective reduction in hospital acquired cases, nor the decrease in the actual numbers of deaths within 30-days of diagnosis.