Reviewer's report

Title: The role of a sequencing-based clinical intestinal screening test in patients at high-risk for Clostridium difficile and other pathogens: A case report

Version: 0 Date: 30 Sep 2018

Reviewer: Tammey Naab

Reviewer's report:

1. Do you believe the case report is authentic?

Yes

2. Do you have any ethical concerns? Please consider if local Institutional Review Board approval or ethical approval was obtained (if appropriate) and if the patient (or their parent or guardian in the case of children under 18) gave written, informed consent to publish this case and any accompanying images. A statement to this effect should appear in the manuscript. I assume that the patient gave written consent for the possible publication of this manuscript.

Objectivity is nonexistent since this case report was authored by employees of the product being recommended. I do have serious concerns about the possibility that a patient with a virulent strain such as NAP could die before treatment is started. In no way should the product being described be considered as a screening product for Clostridium difficile because many far cheaper tests with much faster TATs are available. I see no mention of the incidence of C. difficile in IBS by category. I recommend that a literature be performed and the incidence of C. diff and toxin positive C. diff in IBS of all types be made. In one study of 89 patients with IBS, C. diff incidence was <10% but 4 of 5 cases were toxin positive and occurred in patients with IBS-constipation. You failed to describe the methodology of uBiome testing (? targeted sequencing using 16S rRNA). What is the sensitivity, specificity, precision and NPV of your test for C. difficile? What is the cost of uBiome? A comparison of cost and TAT should be made between conventional C. diff testing (GDH, EIA toxin, PCR toxin/NAP id). A patient could die with fulminant C. diff colitis before they received treatment if your test was used. That is a significant concern.

3. Does the Introduction explain the relevance of the case to the medical literature?

Yes in the authors' estimations

4. Does the article report the following information? Where information is missing, please specify.
a. The relevant patient information, including:
   - De-identified demographic information (age, gender, ethnicity)
   - Main symptoms of the patient
   - Medical, family and psychosocial history
   - Relevant past interventions and their outcomes

b. The relevant physical examination findings

c. Important dates and times in this case (if appropriate, organized as a timeline via a figure or table); if specific dates could lead to patient identification, consider including time relevant to initial presentation, i.e. initial presentation at T = 0, follow up at T = 1 month.

d. Diagnostic assessments, including:
   - Diagnostic methods
   - Challenges (e.g., financial, language/cultural)
   - Reasoning and prognostic characteristics (e.g., staging), where applicable

e. Types and mechanism of intervention

f. A summary of the clinical course of all follow-up visits

Comments:

5. Is the interpretation (discussion and conclusion) well balanced and supported by the case presented?

Comments:

6. Is the anonymity of the patient protected? Please consider any identifying information in images such as facial features or nametags, whether the patient is named etc. If not, please detail below.

Yes/No
7. Is the Abstract representative of the case presented?

Comments:

8. Does the case represent a useful contribution to the medical literature?

Comments:

9. Additional comments for the author(s)?

Level of interest
Please indicate how interesting you found the manuscript:

An article of importance in its field

Quality of written English
Please indicate the quality of language in the manuscript:

Acceptable

Declaration of competing interests
Please complete a declaration of competing interests, considering the following questions:

1. Have you in the past five years received reimbursements, fees, funding, or salary from an organisation that may in any way gain or lose financially from the publication of this manuscript, either now or in the future?

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No