

# Clinical impact of a near-patient assay capable of discriminating between viral or bacterial lower respiratory tract infection in ambulatory adult patients: a pilot study.

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## BACKGROUND

- Confidently distinguishing viral from bacterial infections without confirmatory microbiology in acute care is a diagnostic challenge.
- The MeMed BV<sup>®</sup> assay is an FDA approved *in vitro* diagnostic that measures serum levels of three host-released biomarkers (CRP, TRAIL, IP-10) in 15 minutes and integrates this information using a proprietary algorithm to calculate a score (BV score) representing the likelihood of bacterial or viral infection<sup>1</sup> (figure 1).
- The BV score has superior discriminatory accuracy compared to other biomarkers of infection<sup>2,3</sup>.

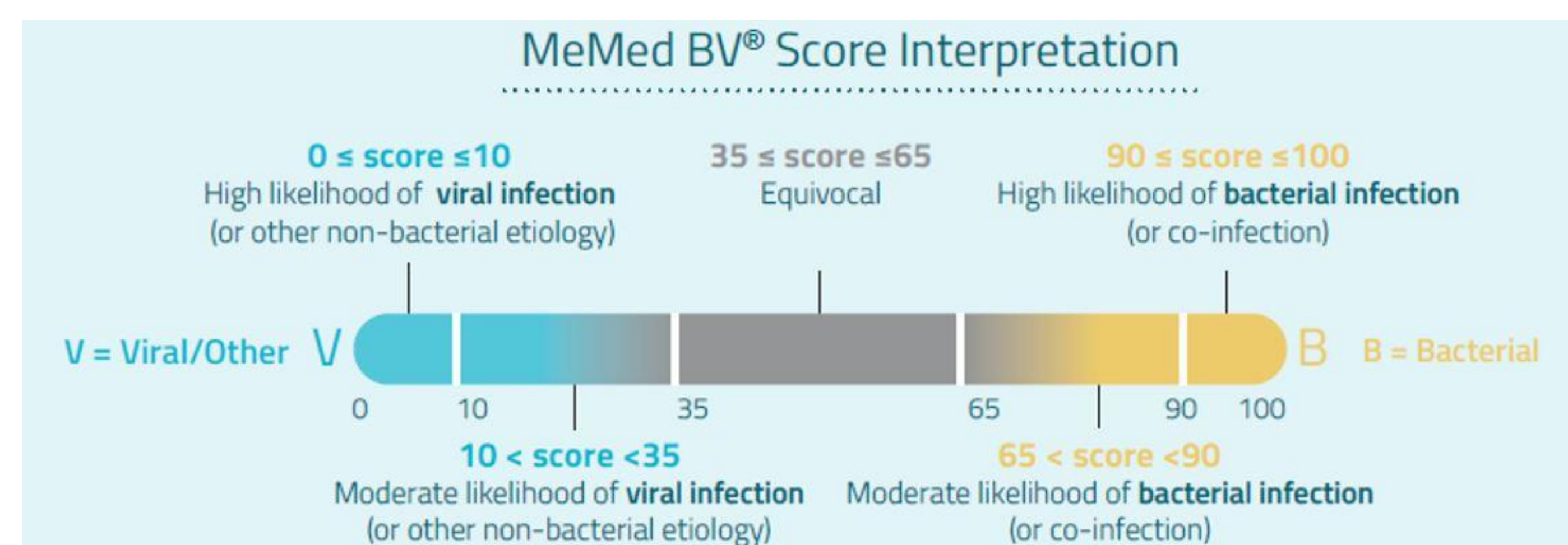


Figure 1: Interpreting the BV score: likelihood of infective aetiology.

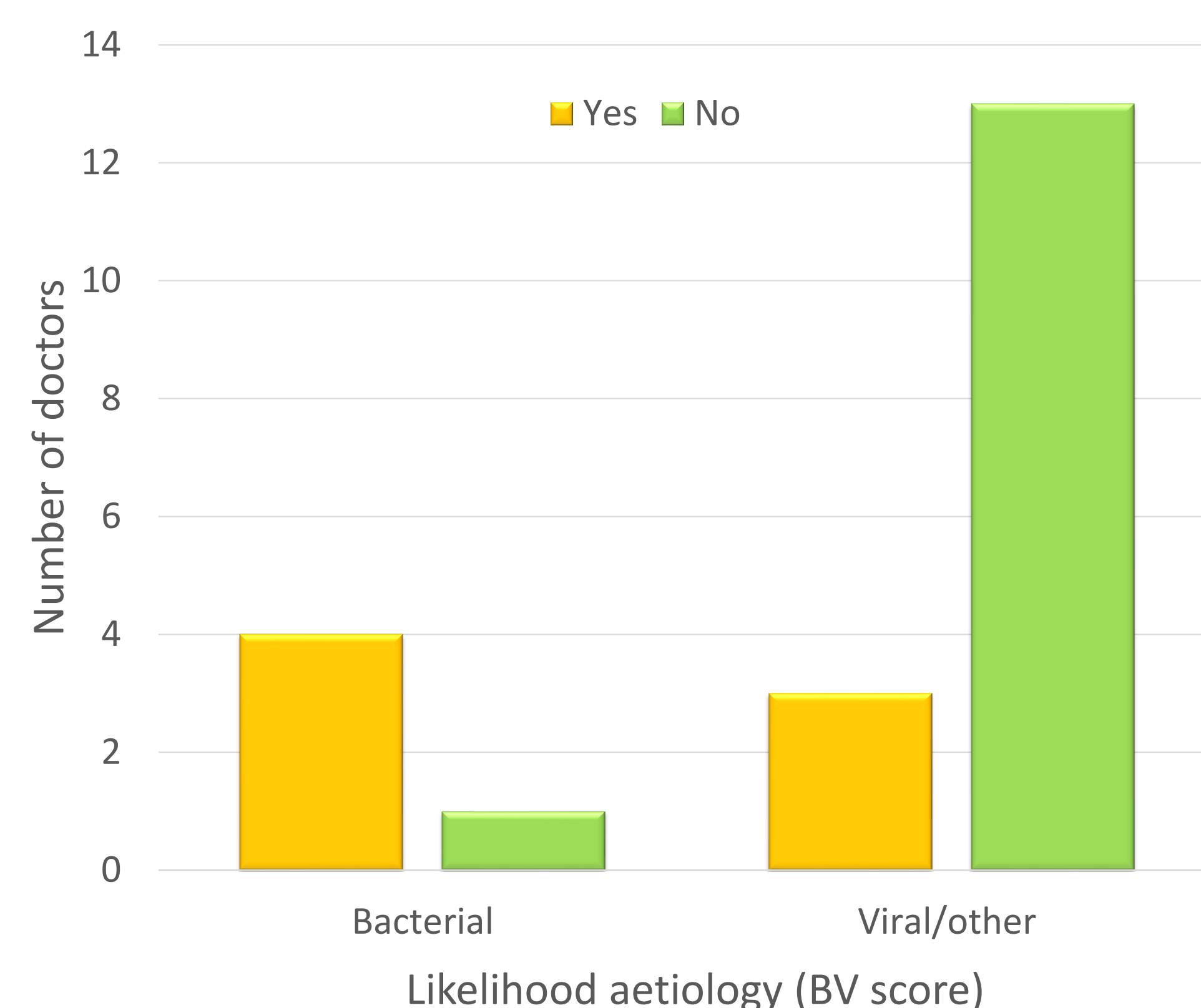


Figure 2: Antibiotic prescriptions in relation to the BV score.

## AIM

- To evaluate the impact of the BV score on clinician-perceived diagnostic certainty and antibiotic prescriptions, when treating adults with suspected lower respiratory tract infections in same day emergency care.

Inclusion Criteria	Exclusion Criteria
<ul style="list-style-type: none"> <li>Adults ≥18 presenting to AAU at the John Radcliffe Hospital in Oxford.</li> <li>Clinical suspicion of acute LRTI (e.g. new or altered cough, sputum production, shortness of breath).</li> <li>Recorded pyrexia ≥37.8°C, self-reported fever or clinical decision to obtain blood cultures.</li> <li>Illness duration ≤7 days.</li> </ul>	<ul style="list-style-type: none"> <li>Patients &lt;18 years old</li> <li>Pregnancy and up to 6 weeks post-partum</li> <li>Advanced directive to withhold or withdraw life-sustaining treatment or admission for palliative care only</li> <li>Severe immunodeficiency, e.g.:               <ul style="list-style-type: none"> <li>High-dose steroid therapy</li> <li>HIV infection</li> <li>Other immunosuppressive drugs</li> <li>Neutrophil count &lt;1000mm<sup>3</sup></li> <li>Congenital immunodeficiency</li> </ul> </li> <li>Suspicion of or confirmed colitis or gastroenteritis</li> <li>Active inflammatory disease</li> <li>Chronic fungal or parasitic infection</li> <li>HBV, HCV or TB infection</li> <li>Significant trauma, burns or major surgery in the last 7 days</li> </ul>

Table 1: Study inclusion and exclusion criteria.

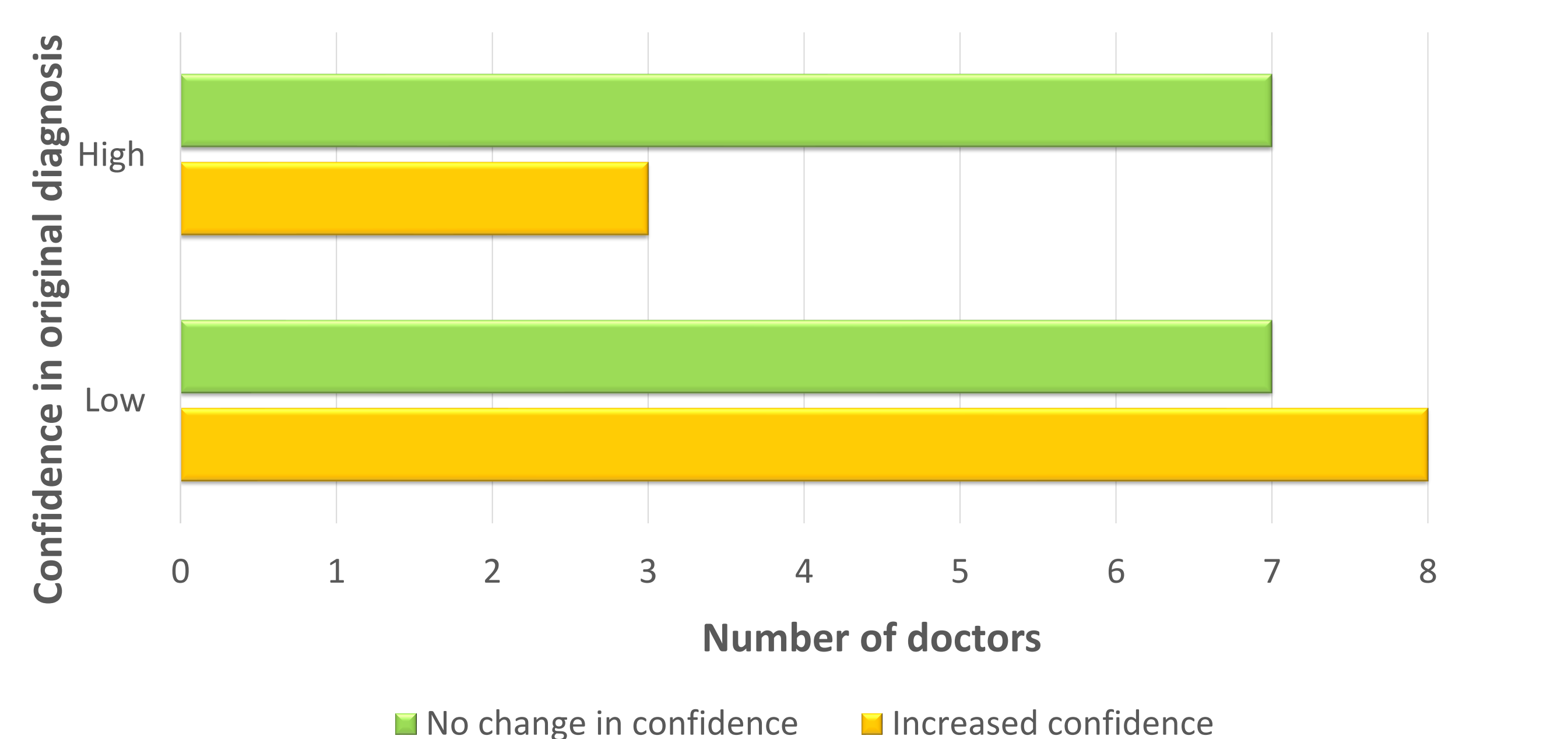


Figure 3: The effect of the BV score on diagnostic confidence.

## METHODS

- Study duration: 6<sup>th</sup> June – 22<sup>nd</sup> July 2022.
- Study site: John Radcliffe Hospital (Oxford, UK).
- Patients enrolled:
  - 51 patients had remnant serum samples from first blood draw analysed.
  - 25 patients were included in the study (21 excluded due to predefined criteria and 5 due to incomplete data) (Table 1).
- Treating physicians completed questionnaires on diagnostic confidence and antibiotic prescribing pre- and post-presentation of the BV score. Clinical care was not altered
- Approved as a service evaluation (Ulysses No. 7298).

## RESULTS

### Cohort demographics

- Mean patient age of 51 years [range: 18-86]
- Male:Female ratio 2:3
- Most common presentations: LRTI (n=9); Covid-19 (n=7); unclear or other cause of chest pain (n=5).

### Effect of the BV score on antibiotic prescriptions

- High BV score agreement with physician prescribing (Fischer's exact test p=0.03).
- In 3/16 (19%) of equivocal or viral cases antibiotics were prescribed, potentially indicating over-prescribing (Figure 2).

### Effect of the BV score on physician-perceived diagnostic confidence

- Increased confidence in 8/15 (53%) physicians with low pre-test confidence.
- Increased confidence in 3/10 (30%) with high pre-test confidence, and 11/25 (44%) physicians in total (figure 3).

## CONCLUSION

- The BV score increased physician confidence in the causative pathogen in adults with LRTI in SDEC, more so when physician pre-test confidence was low.
- Discrepancies between the BV score and clinician-determined infective aetiology, suggest potential to modify practice (e.g. antibiotic prescription).
- Larger studies are required to confirm the assay's impact on clinical care.

## REFERENCES

- Oved K. et al. *PLoS One*. 2015; **10**(3): e0120012.
- Srugo I. et al. *Pediatrics*. 2017; **140**(4).
- Van Houten CB et al. *The Lancet Infectious Diseases*. 2017; **17**(4): 431-40.