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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[®] 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 infection¹ (figure 1).
- The BV score has superior discriminatory accuracy compared to other biomarkers of infection^{2,3}.

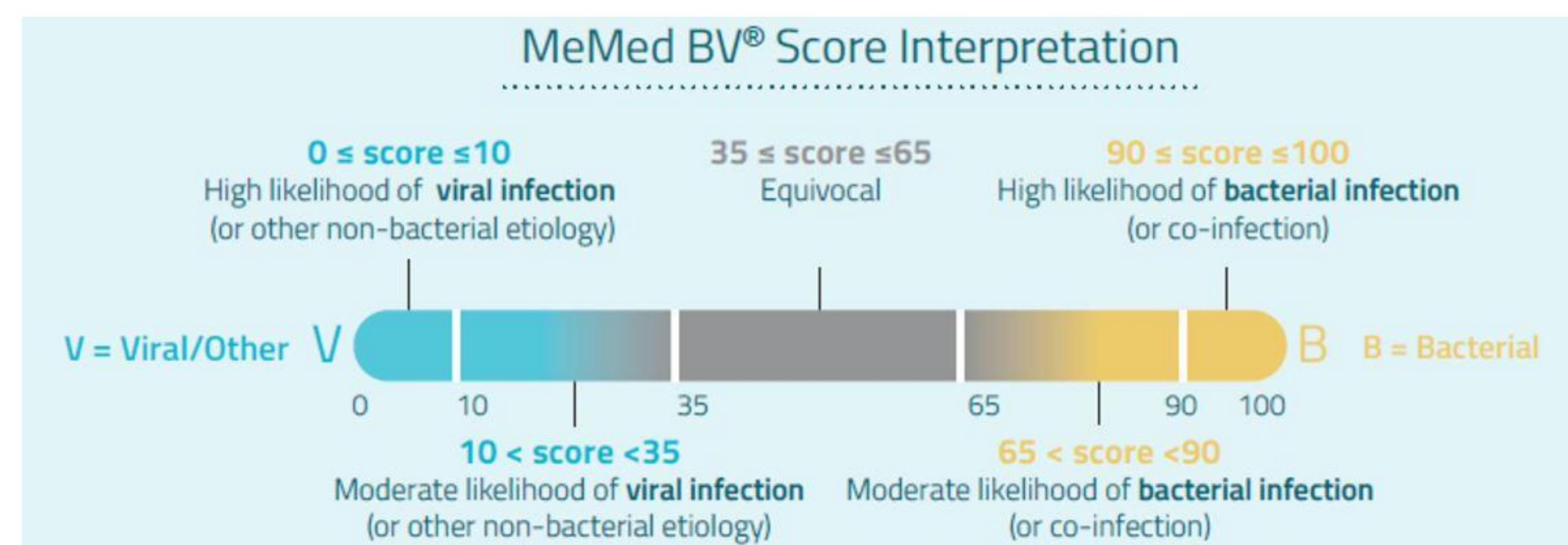


Figure 1: Interpreting the BV score: likelihood of infective aetiology.

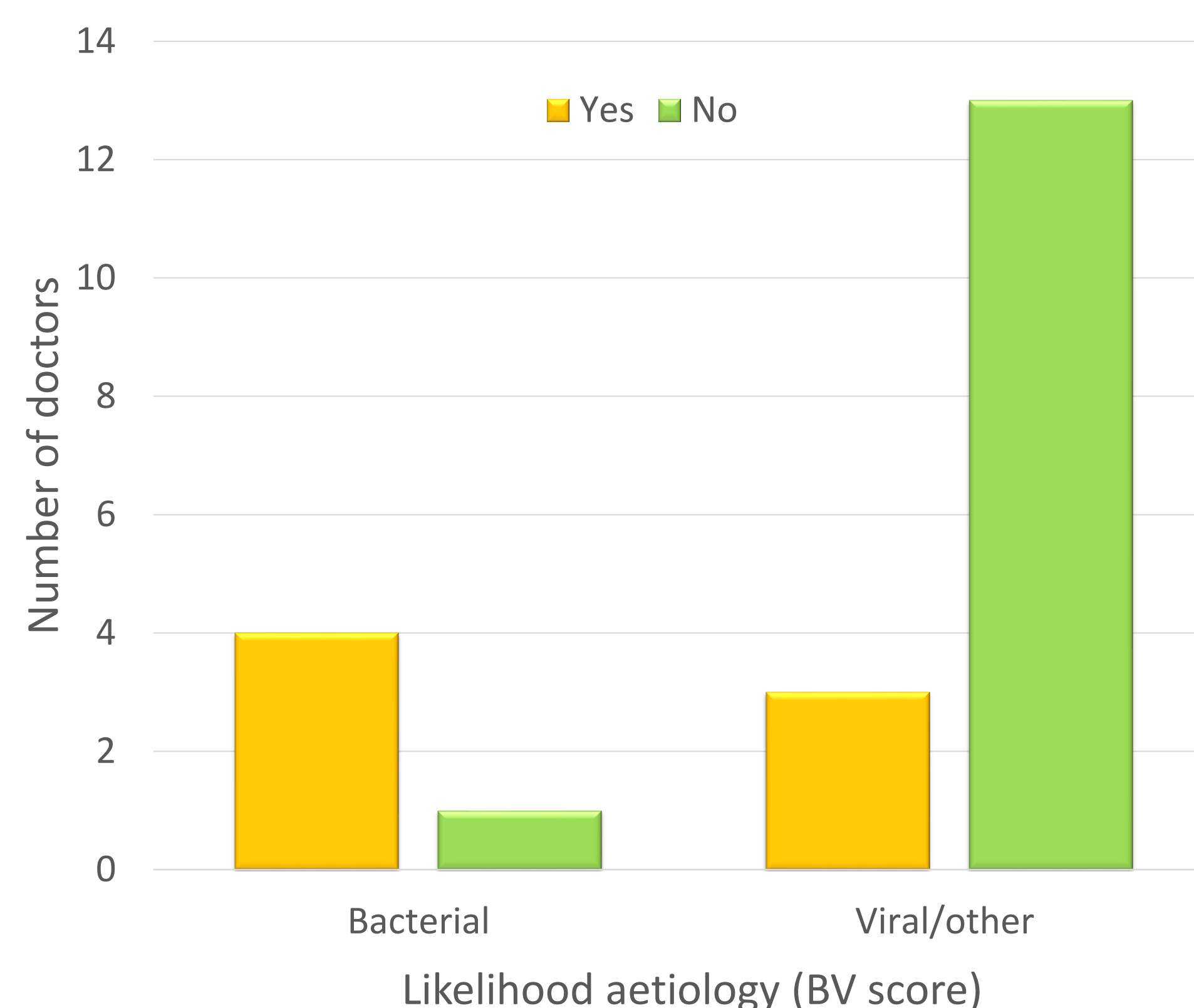


Figure 2: Antibiotic prescriptions in relation to the BV score.

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"> Adults ≥18 presenting to AAU at the John Radcliffe Hospital in Oxford. Clinical suspicion of acute LRTI (e.g. new or altered cough, sputum production, shortness of breath). Recorded pyrexia ≥37.8°C, self-reported fever or clinical decision to obtain blood cultures. Illness duration ≤7 days. 	<ul style="list-style-type: none"> Patients <18 years old Pregnancy and up to 6 weeks post-partum Advanced directive to withhold or withdraw life-sustaining treatment or admission for palliative care only Severe immunodeficiency, e.g.: <ul style="list-style-type: none"> High-dose steroid therapy HIV infection Other immunosuppressive drugs Neutrophil count <1000mm³ Congenital immunodeficiency Suspicion of or confirmed colitis or gastroenteritis Active inflammatory disease Chronic fungal or parasitic infection HBV, HCV or TB infection Significant trauma, burns or major surgery in the last 7 days

Table 1: Study inclusion and exclusion criteria.

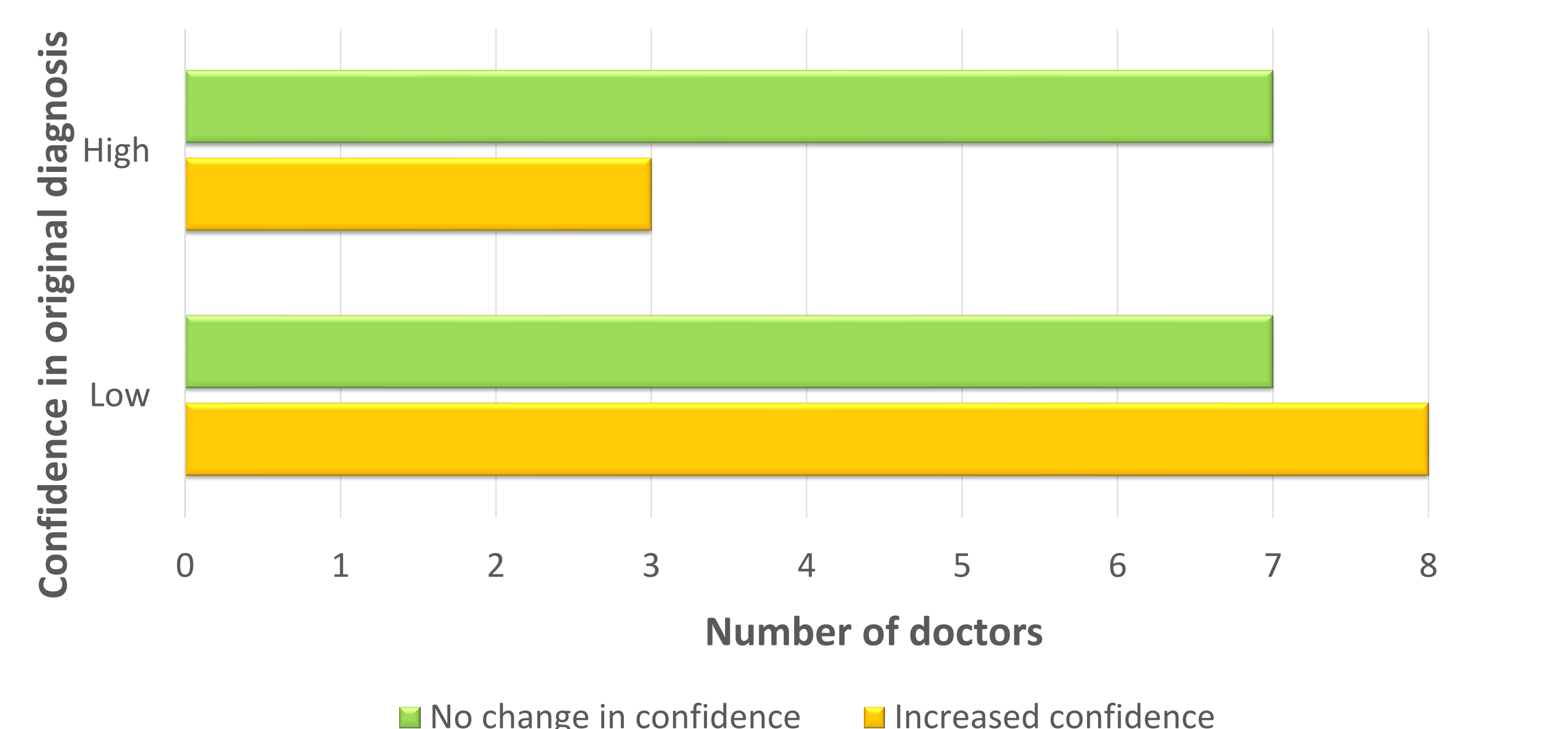


Figure 3: The effect of the BV score on diagnostic confidence.

METHODS

- Study duration: 6th June – 22nd 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.