Health and Social Care Committee

House of Commons London SW1A 0AA
Tel: 020 7219 6182 Fax 020 7219 5171 Email: hsccom@parliament.uk
Website: www.parliament.uk/hsccom Twitter: @CommonsHealth

From Rt Hon. Jeremy Hunt MP

15 June 2020

Prof Yvonne Doyle
Medical Director of PHE

By email: parliamentary@phe.gov.uk

Dear Yvonne,

I am writing in regard to Covid-19 testing.

Several correspondents have raised the issue of sensitivity in Covid-19 swab tests. This has particularly been raised in the context of false negatives. It appears that advice encourages people who have taken a single test, including self-testing, who receive a negative result to return to work: they should consider a negative swab as indicative that they do not have Covid-19.

Unfortunately, to date, the Government and Public Health England have not released data on the false negative rate of these tests – I understand that they are highly specific, but the sensitivity data is not in the public domain, either empirical or estimated. Given the potential for a false negative result to be falsely reassuring to the public, it is clearly important that this figure is released and that a level of stratification of risk be undertaken. At present, I understand that members of the public are informed of a negative result by automatic means, and are therefore not further risk stratified by a healthcare professional. This becomes more important the lower the prevalence of the disease.

I am therefore writing to ask what the sensitivity of the swab tests is (both in healthcare and home settings), and what risk stratification has been done to ensure people who may in fact have coronavirus are not falsely reassured.

Yours,

Rt hon Jeremy Hunt MP
Chair, Health and Social Care Committee

Public Health England

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23 June 2020

The Rt Hon Jeremy Hunt MP
Chair
Health and Social Care Committee
House of Commons
London SW1A 0AA

By email: hsccom@parliament.uk

Dear Mr Hunt

Thank you for your letter of 15 June 2020 regarding the sensitivity of swab tests in healthcare and home settings.

Public Health England (PHE) contributes to testing in Pillar 1 of the Government's testing strategy which covers those most vulnerable in acute care and in initial outbreak situations such as in care homes. Although my response will be limited to these settings and I would direct you to colleagues in NHS England or the Department of Health and Social Care for specific information regarding home settings (Pillar 2), the principles underlying interpretation of sensitivity will be the same.

There is a difference between sensitivity evaluated under controlled laboratory conditions (analytical sensitivity) and that obtained in real-world applications (clinical sensitivity)[1]. Multiple factors beyond the test's intrinsic performance impact the latter; disease prevalence, sample collection technique, timing in relation to illness and time taken for transport of the specimen, amongst others, can adversely impact the false negative rate.

As no test is 100% sensitive, so all results should be considered in the context of the clinical presentation, as this permits an assessment of the clinical likelihood of the disease (the pre-test probability). This allows test results to be interpreted in the clinical context and discordance in expected results to trigger consideration of alternate diagnoses or further confirmatory testing. The application of these principles and other influencing factors to COVID-19 test interpretation was discussed and explored by Watson et al[2] in a recent BMJ article.

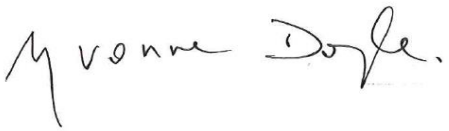
[1] Woloshin et al. False Negative Tests for SARS-CoV-2 Infection — Challenges and Implications, NEJM, https://www.nejm.org/doi/full/10.1056/NEJMp2015897

[2] Watson et al. Practice Pointer: Interpreting a covid-19 test result, BMJ, https://www.bmj.com/content/369/bmj.m1808

They also reported findings of a systematic review on the accuracy of COVID-19 tests which showed false negative rates of between 2% and 29% (equating to sensitivity of 71-98%), based on negative reverse-transcription polymerase chain reaction tests which were positive on repeat testing. PHE agrees that most tests in use in the United Kingdom will likely fall within this sensitivity range.

I hope this has answered your question and I thank you for taking the time to write to me.

Yours sincerely



Yvonne Doyle CB MD
Medical Director and Director for Health Protection

Health and Social Care Committee

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From Rt Hon. Jeremy Hunt MP

26 June 2020

Prof Yvonne Doyle
Medical Director of PHE

By email: parliamentary@phe.gov.uk

Dear Yvonne,

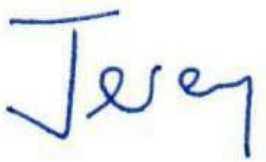
Thank you for your letter of 23rd June. I am grateful to you for addressing the issue of swab test sensitivity.

In my initial letter I asked what risk stratification had been done to ensure people who may in fact have coronavirus are not falsely reassured.

In your reply, you cited a recent BMJ article that highlighted principles that could be implemented in COVID-19 test interpretation. This forms part of a wider research and clinical practice landscape that suggests that, as you say, all results should be considered in the clinical and other context.

I am grateful to you for this. However, my question related to what work is being done and what specific measures are being put in place by Public Health England to ensure there is no false reassurance given in practice, given the relatively high false negative rate of the swab test. I would be very grateful if you could let me know what work Public Health England is doing in this area to mitigate this risk.

Yours,



Rt hon Jeremy Hunt MP
Chair, Health and Social Care Committee

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10 July 2020

Dear Mr Hunt,

Thank you for your letter of 26 June 2020 regarding measures in place to ensure that, given the possibility of false negative tests, false reassurances are not given in relation to negative COVID-19 test results.

In healthcare settings, interpretation of test results, for any disease, routinely considers an individual's risk factors and clinical likelihood of disease. In scenarios where a negative result is obtained in the presence of continuing symptoms, the individual should be further investigated through clinical assessment and risk-assessed against other possible diagnoses, the same is true for COVID-19[i]. If suspicion of COVID-19 infection remained, repeat testing would be considered whilst infection control precautions remain in place. Furthermore, individuals meeting the criteria for self-isolation in accordance with stay at home guidance would be advised of appropriate infection control measures for the duration of the required isolation period, despite any negative test result.

In hospital settings attempts can also be made to decrease the risk of a false negative results. PHE guidance recommends that if sputum is being produced or the patient is intubated, sputum should be sampled, in addition to the swab test of the nose and throat[ii]. This is because SARS-CoV-2 can be present in the lower respiratory tract despite being undetectable in the upper respiratory tract. In the event of symptomatic healthcare staff being tested due to exposure to SARS-CoV-2 at work, PHE guidance recommends that a negative result is treated with caution together with clinical assessment [i]. The need for assessment or discussion in the presence of a negative test result in these individuals has been emphasised in letters from NHS England and NHS Improvement to Trusts[iii].

PHE is carrying out research on both incidence and seroprevalence in various settings in support of the Chief Medical Officer, senior clinicians and the Scientific Advisory Committee Group for Emergencies. The challenge of both false negatives and positives has emerged in such discussions. Our advice is consistently precautionary – negative tests should not remove individuals from public health measures where the epidemiology points to settings with a higher risk of infection; or if the clinical picture indicates the test result may be inaccurate or may change subsequently.

The negative predictive value (NPV, the likelihood of negative test results being truly negative) is directly related to disease prevalence and as prevalence decreases, the NPV increases thus the number of false negatives will decrease.

Many thanks for taking the time to write back and I hope this has been helpful.

Your sincerely,

Yvonne Doyle CB MD
Medical Director and Director of Health Protection

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[i] https://www.gov.uk/government/publications/covid-19-management-of-exposed-healthcare-workers-and-patients-in-hospital-settings/covid-19-management-of-exposed-healthcare-workers-and-patients-in-hospital-settings#staff-return-to-work-criteria

[ii] https://www.gov.uk/government/publications/wuhan-novel-coronavirus-guidance-for-clinical-diagnostic-laboratories/laboratory-investigations-and-sample-requirements-for-diagnosing-and-monitoring-wn-cov-infection

[iii] https://www.england.nhs.uk/coronavirus/wp-content/uploads/sites/52/2020/06/C0586-minimising-nosocomial-infections-in-the-nhs.pdf

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From Rt Hon. Jeremy Hunt MP

16 July 2020

Dido, Baroness Harding
Executive Chair, Test & Trace

By email: Rhonna.Spindley@dhsc.gov.uk

Dear Baroness Harding

Thank you for coming before the Health and Social Care Committee on 3rd June in your role as Executive Chair of NHS Test and Trace.

During that hearing, I asked you about the problem of false negatives in coronavirus testing, which have been estimated as being up to 20% (the transcript contains this question at Q534, for your convenience). In response you stated:

> That is really a question for the medical and scientific experts, for the chief medical officer. My job is to take the scientific and medical guidance that SAGE and the CMO set, and deliver an operating system and service to meet those requirements. We all recognise that there was error in the testing system, but the current guidance is exactly as you have set out, and that is what we are building a service to deliver.

I have since written to the Medical Director of Public Health England and have included copies of this correspondence with this letter. She has written to us and has identified the mitigating steps that would be taken in healthcare settings, which includes an individual's risk factors and clinical likelihood of disease and may include repeat testing.

Given PHE's reply, I am now writing to follow up my initial question, and ask what mitigating factors against false reassurance from false negatives the Test and Trace programme has put in place in order to effectively keep the public safe, and what medical advice has been sought in that matter.

Yours,

Rt hon Jeremy Hunt MP
Chair, Health and Social Care Committee